NICNAS HANDBOOK

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1 HANDBOOK: MAIN CONTENT

The twelve chapters of the Handbook's main volume provide basic information to notifiers about fulfilling NICNAS's requirements. Further detail-along with background information is provided in the appendixes.

The appendixes also provide explanations of definitions and abbreviations and acronyms that are used in the Handbook.

Registering with NICNAS

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1.1 REGISTERING WITH NICNAS

If you are an importer and/or manufacturer (introducer) of industrial chemicals for commercial purposes you must register with the NICNAS *Register of Industrial Chemicals Introducers* in order to introduce relevant industrial chemicals into Australia.

To register you pay a yearly registration fee (regardless of the amount of industrial chemicals imported and/or manufactured in that registration year) and a charge for the value of the chemical you are introducing (this varies depending on the value).

The NICNAS registration year runs from 1 September to 31 August.

The registration **tier** is determined by the value of the industrial chemicals being imported and/or manufactured (see Deciding to register with NICNAS?).

In turn, the tier determines the registration charge to be paid (see Fees and charges - Registration).

Sections of this chapter:

- Benefits of registering with NICNAS
- Defining an industrial chemical
- How NICNAS is funded
- Deciding to register with NICNAS
- How to register with NICNAS or renew registration
- Consequences of not registering
- Transferring registration
- Penalties NICNAS can impose, relating to registration

1.1.1 BENEFITS OF REGISTERING WITH NICNAS

Registered entities are legally entitled to introduce industrial chemicals into Australia.

NICNAS registration improves industry knowledge about NICNAS and the regulation of industrial chemicals in Australia as well as enhances public confidence in our chemical industry

NICNAS registration fees and charges fund other activities designed to protect Australian workers, the public and the environment from the harmful effects of industrial chemicals, including by:

- maintaining the Australian Inventory of Chemical Substances (AICS) to distinguish between existing chemicals and chemicals needing to be notified or assessed before being introduced to Australia
- providing chemical safety information to all stakeholders through the monthly Chemical Gazette and the

NICNAS Matters quarterly newsletter

- delivering industry training on the legal obligations of introducers of industrial chemicals and the procedures for notifying a new chemical for assessment
- assessing existing chemicals on a priority basis
- maintaining a monitoring and audit program to ensure introducers comply with all legal obligations under the Act.

Once registered as a chemical introducer, you can subscribe to an electronic version of the Chemical Gazette.

You can receive additional information about chemical safety by subscribing to the *NICNAS Matters* electronic newsletter

1.1.2 DEFINING AN INDUSTRIAL CHEMICAL

Under the Act, (see Legislation and Regulations) the term **industrial chemicals** encompass many types of chemicals.

The chemical can be an element, compound or ingredient in a mixture. Chemicals can be constituents of adhesives, cosmetics (even ones containing naturally-occurring ingredients), toiletries, inks in pens/markers, laboratory chemicals, lipsticks, plastics, solvents, toners, household cleaning products, paints or coatings.

The Act specifically excludes articles such as photographic film and plastic chairs, chemicals used solely as food or food additives, medicines, pesticides and/or veterinary chemicals. Radioactive chemicals are also outside the scope of NICNAS.

See *Chemicals in Australia—Who's Who* for details of all departments and agencies which play a role in regulating chemicals in Australia.

For definitions of words and terms used in the Handbook, see Appendix A.

1.1.3 HOW NICNAS IS FUNDED

NICNAS activities are fully cost recovered through registration fees and charges as well as new chemical assessment fees and administrative charges.

1.1.4 DECIDING TO REGISTER WITH NICNAS

To help decide whether to register with NICNAS, follow the decision tree (below) and review the more detailed information on each step in the tree (see **More information on whether to register**, below).

Decision tree—NICNAS registration



STEP 1

You need to check if the chemical is an industrial chemical (see **What is an industrial chemical?** above). Specifically, decide whether you are importing it for commercial purposes.

Examples of commercial purposes include on-selling or use in your business.

Examples of a non-commercial use include personal use, teaching purposes or for charity use.

STEP 2

You need to decide the purpose for which the industrial chemical is being introduced (the definition of which is associated with a chemical's end use).

Examples of how an industrial chemical is defined by its end use are:

- glue for wood binding = an industrial chemical
- chemical for pest control = a pesticide (not an industrial chemical)
- chemical to be used both as a solvent in paint and as a carrier used in a pesticide = the proportion imported for use in paint (an industrial chemical requiring you to register your business) plus the proportion used for pesticides (not an industrial chemical).

Chemicals introduced solely for pesticide, veterinary chemical, medicine and/or food or food additive use are *not* industrial chemicals and do not require NICNAS registration.

Note: All cosmetics are industrial chemicals as they are not used for an excluded end use.

STEP 3

You need to decide how the naturally-occurring chemical is defined under the Act (see Naturally occurring chemicals). Many substances come from natural origins, but this does not mean they are naturally occurring. 11/323

You need to consider the process involved in deriving or extracting naturally-occurring chemicals and biological materials. Under the Act, only mechanical processes (such as dissolution in water and cold-pressing) are allowed if substances are to retain their naturally-occurring status.

If a chemical process (for example, fractional precipitation) was used, then the substance derived would not qualify as naturally occurring.

Examples of biological material include blood, human or animal tissue.

More information about chemicals within the scope of NICNAS registration is in NICNAS's *Relevant Industrial Chemicals* FactSheet.

STEP 4

If you need to register with NICNAS, you need to first decide which registration tier applies.

STEP 5

You need to complete Form NR-1A and return it to NICNAS.

Cost of registering

NICNAS has registration tiers based on the total value of industrial chemicals introduced each year (see Fees and charges)

A registration year runs from 1 September to 31 August in the following year.

To determine which tier you need to register for, you must first estimate the total value of the industrial chemicals you import and/or manufacture.

NICNAS registration obligations are not designed to unduly burden your accounting or record-keeping requirements. You can therefore base calculations on reasonably justifiable estimates (using commercial invoices, order or confirmation bills of lading, airway bills, insurance certificates or receipts for purchase of goods).

You have four options for estimating the value of the chemicals you will introduce, so you register at the correct tier:

Estimating the value of chemicals introduced

You have four options for estimating the value of chemicals you introduce.

Option A—import chemicals only

Annual value of all = Customs value + Insurance + Freight + Customs duty (AUD)

Option B—manufacture chemicals only

Total value of relevant industrial chemicals manufactured* = cost of labour and materials (including all ingredients) involved in manufacture + factory overhead expenses.

*manufactured refers to the making of a different chemical whereas formulate refers to the blending or mixing of chemicals to make a product.

Option C—import and manufacture chemicals (where imports are not used in manufacture)

Option A (import) + Option B (manufactured materials) 12/323

Option D—import and manufacture chemicals (but some, or all, imports are used in manufacture)

Use the methodology described in Option C. However, make sure the value of the imported chemicals (used to manufacture another chemical) is only counted *once* in the total value.

1.1.5 HOW TO REGISTER WITH NICNAS OR RENEW REGISTRATION

Initial registration

You register by completing NICNAS New Registration Form NR-1A

Your application form must:

- contain all required information
- be accompanied by the required payment
- be lodged with NICNAS before you start importing or manufacturing.

Once NICNAS processes your application, you will be given a registration number and be issued with a registration certificate. Your name (as importer and/or manufacturer) will then be placed on the Register of Industrial Chemicals Introducers

NICNAS considers each registration form as soon as practicable within 30 days of receipt.

Your registration remains in effect for the entire registration year to which it relates or for the remainder of the year (in the case of part-year registrations). There is no reduction in the registration fee if you register part way through a registration year.

Renewing registration

You must renew your registration ever year.

Every July, NICNAS will send you a renewal form and an invoice for your registration fee. You must complete the Application for Registration Renewal/Notice of Non-Renewal Form NR-2 and return it to NICNAS, with full and correct payment, by August 31.

If you renew after this deadline you will have to pay a mandatory late renewal penalty, an additional 15% of the total registration cost.

Tier levels

If you are introducing relevant industrial chemicals for commercial purposes, you must pay a registration fee and you may also need to pay a registration charge.

Use these tier descriptions to determine how much to pay:

Tier 1 is for relevant industrial chemicals with an estimated value at less than \$500,000 during the registration year. With Tier 1 you only pay the registration fee.

Note: If, in the last registration year, you imported and/or manufactured industrial chemicals valued at \$500,000 or more, you must also pay the annual registration charge and register at Tier 2 or Tier 3.

Registrants at Tier 2 and Tier 3 pay the registration fee and registration charge that applies to the value of the import or manufacture of relevant industrial chemicals.

Tier 2 is for relevant industrial chemicals valued at or above \$500,000 and below \$5,000,000 in a registration year.

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Tier 3 is for relevant industrial chemicals valued at or above \$5,000,000 in a registration year.

Depending on the value of relevant industrial chemicals you *actually* imported and/or manufactured during the registration year, you may be entitled to a refund of the registration charge at the end of the registration year. However, your registration fee is not refundable.

Notice of intent not to renew registration

If, at the end of the registration year, you do not intend to import and/or manufacture industrial chemicals, you will not be required to register in the following year. In this case, you must submit a renewal/non-renewal Form NR-2 to NICNAS by 31 August, stating you do not intend to register.

Your statement must explain why you do not intend to renew your registration.

Examples:

- you have decided to source industrial chemicals locally rather than import them
- your business has stopped trading in industrial chemicals.

Register of Industrial Chemicals Introducers

The Register of Industrial Chemicals Introducers is a list of the current details of registrants. It enables NICNAS to keep industry participants fully informed of their obligations under the Act, as well as any changes (as they occur).

1.1.6 CONSEQUENCES OF NOT REGISTERING

NICNAS is committed to maintaining the integrity of its registration programme.

NICNAS seeks to achieve compliance by disseminating information and working cooperatively with industry.

You can call the Freecall hotline—1800 638 528—to discuss any aspect of registration.

If you import and/or manufacture industrial chemicals for commercial purposes without registering with NICNAS, you are in breach of the Act.

NICNAS is empowered under the Act to prohibit introduction of industrial chemicals until you meet the Act's requirements. Penalties apply up to:

- \$33,000 for an individual
- \$165,000 for a company

Note: as a registrant, you may be subject to audits and may be required to justify the basis for determining the total value of industrial chemicals you import and/or manufacture.

1.1.7 TRANSFERRING REGISTRATION

You can only transfer your registration under these circumstances:

- if a registered person dies, the legal personal representative of the person's estate becomes the registered person
- if a registered person becomes bankrupt, the trustee of the estate of the bankrupt becomes the registered person
- if a registered body corporate is being wound up, the person appointed to be liquidator of the body corporate becomes the registered person.

When to notify changes to your circumstances

If a registered body corporate is taken over by another person (registered or not) and, as a result of the takeover, the body corporate ceases to exist, you must notify NICNAS of the takeover particulars within seven days of the takeover.

If a registered body corporate merges with another (registered or not) to form a new body corporate, you must notify NICNAS of the merger by the new corporation within seven days of the merger.

1.1.8 PENALTIES NICNAS CAN IMPOSE, RELATING TO REGISTRATION

If you do not comply with NICNAS requirements for registration you will be deemed to have committed an offence and penalties will apply.

These are summarised in the following table.

NICNAS registration offences and penalties

Section/offence	Guidance	Maximum penalty: individuals (corporation)
s80B Introducing relevant industrial chemicals without a registration in force (Strict liability offence)	Registration with NICNAS is necessary if relevant industrial chemicals are imported or manufactured in a registration year. This runs from 1 September to 31 August.	\$33,000 (\$165,000)
s80Q Failure to provide the NICNAS Director with a written statement indicating the total value of relevant industrial chemicals actually introduced in a registration year by 31 October (Strict liability offence)	If registered with NICNAS for a particular registration year, you must provide a written statement of the total value of relevant industrial chemicals actually introduced during the year, within two months of the end of that registration year.	\$3,300 (\$16,500)
s80QD Failure to retain records for five years (Strict liability offence)	If registered for a particular registration year, you must keep all records to prove the introduction value for that year. You must keep these records for five years.	\$3,300 (\$16,500)
s80W(3) Failure to comply with notice requiring information relating to the introduction of relevant industrial chemicals in a relevant registration year (Strict liability offence)	If the NICNAS Director believes you should have been registered in a particular registration year, the Director may require information from you relating to your introduction of relevant industrial chemicals for that year.	\$3,300 (\$16,500)

1.2 AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES

The Australian Inventory of Chemical Substances (AICS) lists the chemicals available for industrial use in Australia (known as **existing chemicals**).

Some are only available if certain conditions are met (such as for specified use).

The list, maintained by NICNAS, contains identity data for around 40,000 chemicals, including:

• industrial chemicals nominated as having been in use in Australia between 1 January 1977 and

28 February 1990

- chemicals assessed since 1990, and
- some amendments and corrections.

The AICS does not contain information on toxicity, manufacturers or importers.

NICNAS also uses the AICS as a legal device to distinguish between new and existing chemicals:

- an industrial chemical not included in the AICS is regarded as a **new industrial chemical***
- an industrial chemical listed on the AICS and subject to certain (specific) conditions is regarded as a **new chemical** (subject to reassessment), if it is introduced beyond the scope of such conditions.

The conditions or restrictions that may apply to chemicals you intend to import and/or manufacture or export are in Records and restrictions on introducing chemicals.

Once a chemical is listed on the AICS, you can introduce it subject to conditions of use, without prior notification and assessment.

You must notify new industrial chemicals for assessment by NICNAS, unless they qualify for an exemption, before you can manufacture or import them into Australia (new chemicals).

* However, naturally-occurring chemicals, including those extracted from natural materials using only certain allowed methods, are deemed to be on the AICS.

Sections of this chapter:

- Overview
- AICS sections
- Listing chemicals on the AICS
- · Records and restrictions on introducing chemicals
- Searching the AICS

1.2.1 OVERVIEW

The first edition of the AICS listed industrial chemicals nominated as having been in use in Australia between 1 January 1977 and 28 February 1990.

Additional chemicals (eligible chemicals) were added during a two-year amnesty period (1993 to 1995).

Since then, more than 1200 assessed chemicals have been added to the AICS through the new chemical assessment process. Today, around 40,000 chemicals are on the inventory.

Chemical details for some chemicals on the AICS have been amended where there has been a change to the Chemical Abstracts Service (CAS) number or chemical nomenclature, or where an error occurred during the compilation of the AICS.

1.2.2 AICS SECTIONS

The AICS has two sections:

- non-confidential (public), and
- confidential (non-public).

Both sections list chemicals available for industrial use in Australia.

The **non-confidential (public) section** is by far the largest section, containing about 40,000 chemicals. It makes information on a chemical's introduction into Australia as widely available as possible. For this reason, news of chemicals added to this section is published through a notice in the *Chemical Gazette*.

Anyone can search this section of the AICS through the AICS webpage of the NICNAS website (see Searching the AICS).

The confidential section is much smaller, with around 100 chemicals.

It includes chemicals for which the NICNAS Director has decided that the publication of their particulars would be likely to substantially prejudice the commercial interests of interested persons dealing in those chemicals, and that this prejudice outweighs the public interest in the publication of those particulars. Information on these chemicals is therefore not as widely available and not published through a notice in the *Chemical Gazette*.

NICNAS searches this confidential section of the AICS on behalf of those genuinely intending to introduce a chemical.

Note: the listing of a chemical in the confidential section does not mean the original notifier has exclusive introduction of the chemical into Australia. Once a chemical is listed on the AICS—in either of the two sections —it is available for all persons to introduce without notification and assessment, subject to conditions of use (if relevant). Exclusivity is only provided through Australia's intellectual property rights legislation (which includes trade secrets and patents).

Content of AICS entries

The AICS non-confidential section contains the following details:

- CAS number—a unique number assigned to a substance when it is entered into the CAS Registry database
- chemical name—chemicals are listed under their CAS-approved name
- molecular formula—this is listed on the AICS for some chemicals
- associated names (if any)—some chemicals are more commonly known by names other than their CASapproved name, and some of these more common names are included on the AICS.

The AICS confidential section generally contains the same type of information included in the non-confidential section, although—for confidentiality reasons—CAS numbers are not always included.

1.2.3 LISTING CHEMICALS ON THE AICS

All chemicals assessed as new chemicals under certificate categories are eventually included on the AICS.

Five years after an assessment certificate for a chemical is issued, the chemical is added to the AICS in one of the ways outlined in this section.

Assessed chemicals can be added to the AICS before this time, as outlined below.

Early listing

As a certificate holder, you can apply for an assessed chemical to be listed on the non-confidential section of the AICS before the five-year certificate period expires. The decision to accept this is subject to objection from other certificate holders of the chemical.

No fees apply if you apply for early listing within 28 days of an assessment certificate being issued. Fees apply when you apply after 28 days.

You cannot obtain early listing on the confidential section of AICS.

Note: The NICNAS Director must give notice in the NICNAS Chemical Gazette of all chemicals added to the

non-confidential section of the AICS.

Figure: Process of listing a chemical on the Australian Inventory of Chemical Substances



Confidential listing

At the end of five years, the company holding the assessment certificate has the opportunity to list the chemical on the confidential section of the AICS.

To list a chemical on the confidential section, you must apply to NICNAS, providing the information specified in the Guidelines for Confidential Listing.

NICNAS's Technical Advisory Group was established to review and make recommendations on applications for chemicals to be listed in the confidential section, based on both public and commercial interests. The group makes recommendations to the NICNAS Director who makes the final decision on inclusion.

If the Director decides to add the chemical to the:

- **non-confidential (public) section**, the chemical will be listed there after 28 days unless the applicant appeals to the Australian Government Administrative Appeals Tribunal (AAT)
- **confidential section**, the chemical will remain there for five years, at which point it will be transferred to the non-confidential section (unless the holder of confidence applies for confidential AICS relisting through the same process; if successful this spans an additional five years).

Five-year listing

After an assessment certificate has been in force for five years, assessed chemicals are published in the *Chemical Gazette* and added to the non-confidential section of the AICS, unless an application for confidential listing is made and approved by the NICNAS Director.

1.2.4 RECORDS AND RESTRICTIONS ON INTRODUCING CHEMICALS

Chemicals assessed by NICNAS as **new** or **existing** have secondary notification conditions. This means they may be reassessed if the circumstances under which they were originally assessed have changed significantly.

The circumstances and conditions for the chemical are included in the chemical's assessment report and/or in the AICS listing.

If a chemical has been assessed by NICNAS, its online AICS record flags it 'Assessed by NICNAS: Yes'.

Before importing or manufacturing a chemical that has been assessed by NICNAS, you should contact the Existing Chemicals team at NICNAS to find out if any secondary notification conditions apply.

The AICS may also contain conditions of use, and it is an offence under the Act to introduce a chemical outside these conditions.

Further information:

- · click secondary notifications conditions, or
- contact NICNAS directly.

1.2.5 SEARCHING THE AICS

You may need to check both the non-confidential and confidential sections of the AICS to find if a chemical is listed.

Non-confidential section

You can search the non-confidential section yourself via the NICNAS website.

The best way to optimise your search is to use the CAS Registry Number (CAS RN or CAS number).

You may also search using the CAS name or molecular formula for the chemical, although these methods may be less successful.

If you only have the common name of the chemical, you can use the 'help' function to try to locate the CAS RN or CAS names.

You can also search 'root' terms using the 'wild card' function, but if the term is too broad the search engine will not generate a list of 'candidate' chemicals.

Once you search, the AICS system will name the chemical or generate a list of chemicals to consider. The system will also indicate if the chemical has or has not been assessed by NICNAS and provide a hyperlink taking you to the appropriate AICS record.

More information: Chemical Abstracts Service registry numbers (RNs) and how to obtain them (includes examples of how to search)

Confidential section

You cannot search this section yourself; NICNAS must do so on your behalf. This service is free.

NICNAS will conduct the search if you:

- declare that you have a bona fide interest in introducing the chemical
- can prove you have searched the non-confidential section for the chemical but could not locate it (proof includes providing a printout of your search result).

More information on having NICNAS search the confidential section for you and the form (Form AICS 5C) you need to complete, are in the AICS appendix. 20/323

1.3 NOTIFYING A NEW CHEMICAL

This chapter helps you determine if you need to notify a new chemical or have it assessed.

Sections of this chapter:

- How to decide to notify a chemical
- Does NICNAS define the substance as a chemical?
- Does NICNAS define the chemical as an industrial chemical?
- Is the industrial chemical a new industrial chemical?
- Is the industrial chemical defined as a nanomaterial?
- Is the chemical exempt from notification?
- How to determine the chemical poses no unreasonable risk

1.3.1 HOW TO DECIDE TO NOTIFY A CHEMICAL

To decide whether to notify a chemical, you need to answer this series of questions:

Question 1. Is the substance a chemical as defined by NICNAS (go to: Does NICNAS define the substance as a chemical?)

- YES—go to question 2
- NO—no further action required

Question 2. Is the chemical an industrial chemical as defined by NICNAS (go to: Does NICNAS define the chemical as an industrial chemical? and Certificate categories for new chemicals)?

- YES—go to question 3
- NO-no further action required

Question 3. Is the industrial chemical a new industrial chemical (go to: Is the industrial chemical a new industrial chemical?)?

- YES—go to question 4
- NO—no further action required, however you should contact the NICNAS Existing Chemicals Program team if the chemical has been previously assessed by NICNAS

Question 4. Is the new industrial chemical exempt from notification (go to: Is the chemical exempt from notification?)?

- YES—annual reporting obligations may apply and you may need to advise NICNAS (see Is the chemical exempt from notification? and Record keeping and annual reporting)
- NO—your chemical is subject to new chemicals assessment (see: Notification categories for new chemicals)

Note: If further action is required, review what to do next.

1.3.2 DOES NICNAS DEFINE THE SUBSTANCE AS A CHEMICAL?

Yes—the substance is a chemical

Note: Use the chemical name and the CAS number to identify the chemical.

You might need to notify NICNAS if the chemical is:

- 1. A pure or technical-grade substance, which is a discrete chemical element, compound or complex of particular molecular identity. Examples:
 - a chemical element, such as lead (CAS No. 7439-92-1);
 - a chemical compound (including polymers), such as succinic acid (CAS No. 110-15-6), polyvinyl chloride (CAS No. 9002-86-2) or methacrylic acid 2-hydroxypropyl ester, polymer with ethyl acrylate, methyl methacrylate and styrene (CAS No. 29226-44-6); or
 - a chemical complex, such as ferric ammonium oxalate (CAS No. 14221-47-).
- 2. A chemical element, compound or complex, which exists as a component in a physical mixture of chemicals, either by chemical reaction or deliberate mixing of the chemicals (though the mixture itself does not need to be notified). Examples:
 - a chemical element in a mixture, such as oxygen (CAS No. 7782-44-7) in a mixture of gases;
 - a chemical compound in a mixture, such as the plasticiser dibutyl phthalate (CAS No. 84-74-2) in a poly(vinyl chloride) blend; or
 - a chemical complex in a mixture, such as ferric ammonium oxalate (CAS No. 14221-47-7) in an aqueous solution.
- 3. A chemical of unknown or variable composition, complex reaction products or biological products other than a whole plant or animal (unknown or variable composition substances). These poorly-defined substances cannot be represented by a complete chemical structure and specific molecular formula. Examples:
 - 1. an unknown or variable composition substance, such as chlorinated paraffin sodium sulfonate (CAS No. 68910-45-2), where the degree of chlorination varies;
 - 2. a complex product of a chemical reaction, such as tall oil products in reaction with diethanolamine (CAS No. 97489-16-2), where the product of a chemical reaction is in a mixture with its reactants; or
 - 3. biological material, such as geranium oil (CAS No. 8000-46-2).
- 4. A naturally-occurring chemical (see Definitions and Naturally-occurring chemicals), meaning an unprocessed chemical occurring in nature, or a chemical occurring in nature that has been extracted from the parent material through certain defined processes without chemical change. Examples:
 - 1. a naturally-occurring biological chemical;
 - 2. an inorganic chemical in soil; or
 - 3. a mineral extracted from ore by a physical process such as dissolution or flotation.

No-the substance is not a chemical

You might not need to notify NICNAS if the substance fits any of the following descriptions and is therefore not considered to be a chemical:

1. An article—an item which, due to its use, has been manufactured into a certain shape or design, and

which does not change its chemical composition during use. Examples:

- steel ball bearings
- compounded plastic pipe
- adhesive films.
- an article that does not include fluids or substances that may be manufactured or imported in particulate or aggregate form, such as a polymer in granular form which will be further processed. The addendum to the definitions has more examples.
- 2. A radioactive chemical or a chemical with a specific activity greater than 35 becquerels/g.
- A mixture—a physical combination of chemicals resulting from deliberate mixing or from chemical reactions, but not being an unknown or variable composition substance. Although you do not need to notify a mixture itself, you do need to notify new industrial chemical components in the mixture if they are not exempt.
- 4. A hydrate where the anhydrous form is listed on the AICS. A definition of a hydrate is given in Definitions.
- 5. An alloy where all the metals present in the alloy are listed on the AICS. However, intermetallic compounds with well-defined stoichiometry are considered to be chemicals, and thus must be listed separately on the AICS. Note that metals that occur in their native state, for example copper and gold, are naturally occurring and are therefore considered to be included in the AICS.

1.3.3 DOES NICNAS DEFINE THE CHEMICAL AS AN INDUSTRIAL CHEMICAL?

Yes—the chemical is an industrial chemical

You may need to notify NICNAS if the chemical has any industrial use, whether or not it has both an excluded and an industrial use.

Examples of the most common industrial uses for chemicals are those used in surface coatings, printing, fuel and oil, textile processing, photography and cosmetics.

No-the chemical is not an industrial chemical

You do not need to notify NICNAS if the chemical is used solely as an agricultural or veterinary chemical, a therapeutic good, a food or food additive. These 'excluded uses' are defined in Subsection 7(2) of the Act (see: Legislation and regulations).

See Definitions for definitions of excluded uses.

1.3.4 IS THE INDUSTRIAL CHEMICAL A NEW INDUSTRIAL CHEMICAL?

Yes—the industrial chemical is new

You may need to notify NICNAS if one or more of these points apply to the new industrial chemical:

- not listed on the AICS
- listed on the AICS with a condition of use, and its import and/or manufacture is proposed to be different
- a new synthetic polymer, defined as:
 - that which combines monomers and other reactive components, each representing at least 2% by weight of the polymer, being a combination not listed in the AICS
 - one with weight at least 2% of which is attributed to a monomer or other reactive component not listed

in the AICS as a component of a synthetic polymer.

No-the industrial chemical is not new

You do not need to notify NICNAS if the industrial chemical falls into any of these categories:

- is listed on the AICS (and where a condition of use requires compliance with proposed import/manufacture)
- reaction intermediates, due to their transient existence and/or confinement to their chemical reaction systems (see Definitions)
- incidentally-produced as an impurity or by-product from a chemical reaction (see Definitions) and that cannot have commercial value (information on these chemicals would be required if the parent chemical was subject to notification)
- naturally-occurring and regarded as being on the AICS—although they are not listed (Naturally-occurring chemicals)
- polymers that do not fulfil the criteria for a new synthetic polymer (see Definitions). Examples of such chemicals include an existing synthetic polymer:
 - where only a change in monomer ratios has occurred (for example, if the ethylene-vinyl acetate ratio in an ethylene-vinyl acetate copolymer has changed from 70/30% to 40/60%)
 - containing one or more additional monomers or reactants, each at less than 2% weight of the polymer.

1.3.5 IS THE INDUSTRIAL CHEMICAL DEFINED AS A NANOMATERIAL?

As of 1 January 2011, NICNAS put administrative arrangements in place for new industrial chemicals defined as nanomaterials (Guidance and requirements for notification of new chemicals that are industrial nanomaterials).

1.3.6 IS THE CHEMICAL EXEMPT FROM NOTIFICATION?

Once you have established through AICS that the chemical to be imported or manufactured in Australia is a new industrial chemical, the next step is to determine if it is exempt from notification.

Figure: Deciding whether you need to notify your new chemical



For most exemption categories no further action is required before you introduce the new chemical. However, in some cases you need to provide NICNAS with information before you import or manufacture. And with most exemption categories you also have to report to NICNAS every year.

Table: Summary of exemption categories and provisions

Exemption	Volume or concentratio n restriction	Other criteria	Advice required before introduction	Other reporting requirements	Reference
Research, development or analysis (manufactured)	N/A	Yes	Yes Form 6	No	see below
Research, development or analysis	Not more than 100 kg in a 12-month period	No	No	Annual	see below
Transhipment	N/A	Yes	No	Annual	see below
Non-cosmetic exemption (NCE) no unreasonable risk	Not more than 100 kg in a 12- month period	Yes	No Optional NCE- Form 1	Annual*	see below
Cosmetic no unreasonable risk	Greater than 10 kg but not more than 100 kg in a 12- month period	Yes	Yes Form 15	Annual*	see below
	Not more than 10 kg in a 12- month period	Yes	No	Annual*	see below
Cosmetic non- hazardous (≤1%)	Introduced in a product at 1% or less	Yes	No	Annual*	see below

* If you are introducing the chemical you must keep in writing, for five years after introduction, information on the occupational health and safety, public health and environmental effects of the chemical. You must also submit an annual report to NICNAS before or on 28 September each year. Detailed information on annual reporting requirements is in Record keeping and annual reporting requirements.

New chemical introduced for research, development or analysis

You introduce a new chemical for research, development or analysis purposes only, either manufactured in a fixed apparatus in a specific location, or in a quantity between 100g and 100kg in a 12-month period:

1. Manufactured in a fixed apparatus in a specific location. There is no volume restriction if the new chemical is:

- solely for research, development or analytical work
- site-limited
- in an apparatus that cannot operate effectively to produce smaller quantities.

Checklist

- advice of introduction submitted to NICNAS
- procedures in place related to the safe disposal and hazardous degradation products
- records kept and available showing type and location of the apparatus
- records kept and available showing use (research, development or analysis)
- procedures in place to monitor manufactured volume of the chemical

2. Imported and/or manufactured at a maximum of 100 kg in a 12-month period. You import or manufacture the new chemical only for research, development or analytical work in a quantity of not less than 100 g and not more than 100 kg in any 12-month period.

Checklist

- procedures in place to monitor manufactured or imported volume of the chemical
- information submitted on the research, development or analysis of the new chemical
- annual reports, using approved NICNAS format, submitted at the end of the registration year

NOTE: This exemption cannot be used to introduce new chemicals sold to an end user for research, development or analysis.

New chemical introduced under the transhipment category

You introduce the new chemical in Australia and it remains subject to the control of the Australian Customs and Border Protection Service and leaves Australia less than 30 days after the day you introduce it. There is no volume restriction on this category.

Checklist

- the chemical is stored in a bonded warehouse for not more than 30 days and is subject to Customs control during this time
- import and export records relating to the new chemical are kept and are available
- annual reports, using approved NICNAS format, submitted at the end of the registration year

New chemical intended for non-cosmetic use that does not exceed 100 kg in any 12-month period

You introduce the new chemical in quantities not exceeding 100 kg in a 12-month period for non-cosmetic use and it poses no unreasonable risk to occupational health and safety, public health or the environment.

Some chemicals are not eligible for exemption. Further details and guidance on how to determine the chemical poses no unreasonable risk are in How to determine the chemical poses no unreasonable risk.

Checklist

- evidence kept and available that the chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- advice concerning the chemical submitted to NICNAS (Form NCE-1)
- import and/o rmanufacture volumes monitored
- records kept and available relating to the use of the new chemical, demonstrating no unreasonable risk
- annual reports, using the approved NICNAS format, submitted at the end of the registration year

NOTE: Nanomaterials are not eligible for this exemption category.

New chemical intended for cosmetic use that does not exceed 100 kg in any 12-month period

The new chemical poses no unreasonable risk to occupational health and safety, public health or the environment (see: Guidance note—How to determine the chemical poses no unreasonable risk).

You must also ensure the new chemical meets all of these criteria:

- is not used in the cosmetic as a preservative, colouring agent or ultraviolet filter
- is not prohibited or restricted for use in cosmetics in the European Union under Council Directive 76/768/EEC (aas in force on 1 December 2011) or in the United States under the Food Drugs and Cosmetics Act 1938 (as in force on 1 December 2011)
- is not at a concentration of greater than 1% in the cosmetic product, unless you have information indicating that the chemical will be safe for use by potentially high-risk groups, including infants, elderly persons and atopic persons, consistent with the anticipated pattern of consumer exposure.

NOTE: Nanomaterials are not eligible for this exemption category.

1. Cosmetic of between 10 and 100 kg a year (no unreasonable risk)

The new chemical in a cosmetic is introduced in an amount greater than 10 kg but not exceeding 100 kg in a 12-month period.

Checklist

- evidence kept and available available that the chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- advice concerning the chemical submitted to NICNAS (Form 15), including copies of:
 - (Material) Safety Data Sheets ((M)SDS) relevant to the chemical or product containing the chemical
 - label to be attached to the packaging of the chemical or product containing the chemical
 - import and/or manufacture volumes monitored
 - records kept relating to the use of the new chemical
- records kept on occupational health and safety, public health and environmental effects for five years after the chemical is introduced
- if the new chemical is introduced in a cosmetic at 1% or more, information available that it will be safe for use by potentially high-risk groups (including infants, elderly persons and atopic persons)
- annual reports, using the approved NICNAS format, submitted at the end of the registration year

NOTE: Nanomaterials are not eligible for this exemption category.

2. Chemical is introduced at up to 10 kg a year for use in a cosmetic (no unreasonable risk)

The new chemical in a cosmetic is introduced in an amount not exceeding 10 kg in a 12-month period.

Checklist

- evidence kept and available that the chemical poses no unreasonable risk to occupational health and safety, public health and the environment
- import and/or manufacture volumes monitored
- records kept relating to the use of the new chemical
- records kept on occupational health and safety, public health and the environmental effects of the chemical for five years after the chemical is introduced
- if the new chemical is introduced in a cosmetic at 1% or more, information available that the chemical will be safe for use by potentially high-risk groups (including infants, elderly persons and atopic persons)
- annual reports, using the approved NICNAS format, submitted at the end of the registration year

NOTE: Nanomaterials are not eligible for this exemption category.

Non-hazardous new chemical intended for cosmetic use introduced at less than 1%

The new chemical is a non-hazardous chemical introduced in a cosmetic product at a concentration at 1% or less (no volume restriction), and meets all of these criteria:

- not a hazardous chemical (see Definitions)
- not a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail ()
- has one of these characteristics:
 - dissolves in water without dissociation or association, is not surface-active and the partition coefficient (n octanol/water) at 20°C as log Pow does not exceed 3
 - solubility in water is greater than 1 mg/litre
 - molecular weight (MW) or (number-average molecular weight (NAMW) in the case of a polymer) is greater than 1000
 - readily biodegradable
- has a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC50 or EC50 100 mg/L or greater
- introduction of the chemical is consistent with the reasonable protection of occupational health and safety, public health and the environment
- not used in the cosmetic as a preservative, colouring agent or ultraviolet filter
- not prohibited or restricted for use in cosmetics in the European Union under Council Directive 76/768/EEC (as in force on 1 December 2011) or in the United States under the Food Drugs and Cosmetics Act 1938 (as in force on 1 December 2011)

Checklist

- not a hazardous chemical, not a dangerous good and meets prescribed environmental criteria
- records kept and available relating to the use of the new chemical and its percentage in the cosmetic
- annual reports, using the approved NICNAS format, submitted at the end of the registration year

More information is in Guidance note—How to determine the chemical poses no unreasonable risk.

NOTE: Nanomaterials are not eligible for this exemption category. This category is not appropriate for chemicals introduced into Australia for formulation into cosmetic products. The chemical must be introduced in the formulated cosmetic product at 1% or less.

1.3.7 HOW TO DETERMINE THE CHEMICAL POSES NO UNREASONABLE RISK

Chemicals that cannot be considered for exemption are those:

• classified as a carcinogen, mutagen or reprotoxin under the UN's Globally Harmonised System of Classification and Labelling of Chemicals, 3rd edition (GHS), OR the Approved Criteria for Classifying Hazardous Substances, 3rd Edition (Approved Criteria) [NOHSC:1008(2004)].

Chemicals that might not be suitable for exemption—except if a strong case can be made that they do not pose unreasonable risk in use—are those:

- likely to be persistent or bioaccumulative, or have breakdown products with these characteristics (see Stockholm convention)
- containing elements other than:
 - aluminium, boron, caesium, calcium, carbon, copper, gallium, germanium, hydrogen, iron, lithium, magnesium, nitrogen, oxygen, phosphorus, potassium, rubidium, selenium, silicon, sodium, sulphur, strontium, tin, titanium, zinc, zirconium
 - bromine, chlorine and iodine, only as anions
- containing these high-concern, reactive functional groups:
 - pendant acrylates and methacrylates, aziridines, carbodiimides, halosilanes, hydrosilanes, hydrazines, isocyanates, isothiocyanates, alpha or beta lactones, vinyl sulfones or analogous compounds, partially-hydrolysed acrylamides, acid halides, acid anhydrides, aldehydes, epoxides, amines, or other reactive functional groups identified as of high concern
 - alkoxysilanes with C1 or C2 alkoxy groups
- having, or expected to have, high acute or chronic ecotoxicity to any aquatic species, including those having cationic chemicals/polymers and LC50 values of less than 1 mg/L (acute) or 0.01 mg/L (chronic) for uses where concentrated discharge is possible, more stringent ecotoxicity limits apply
- having low biodegradability
- suspected of having carcinogenic, mutagenic or repro-toxic effects.

Exemption might be justified for such chemicals if the volume is very low (substantially less than 100 kg/yr).

Assessing the risk of a chemical

In assessing risk, you need to consider:

- hazards
- potential exposure to humans and the environment
- potential risk (the maximum risk the chemical may pose)
- how to minimise potential risk (such as through specific handling techniques).

In estimating risk, concentrate on the risk associated with the chemical being introduced, rather than due to the hazards of other components in a product.

If the potential risk is high and cannot be minimised, the chemical may pose an unreasonable risk. In this case, you need to apply for an assessment permit or assessment certificate (see Notification categories for new chemicals).

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Occupational health and safety risk

To assess the occupational health and safety risk you need to first determine the hazardous nature of the chemical, using the UN's Globally Harmonised System of Classification and Labelling of Chemicals, 3rd edition (GHS).

In summary:

- If the chemical is imported as part of a formulated product, determine the hazardous nature of the product.
- If the chemical (or product) is not classified as hazardous, and does not have significant physico-chemical hazards or reactivity, then—given the maximum volume of 100 kg/year of chemical introduced—the potential risk is low.
- If the chemical (or product) is classified as hazardous, evaluate the level of exposure to workers during processes such as manufacture, formulation, end-use and disposal.

Public health risk

You need to assess the public health risk in the same way as you assess the occupational health and safety risk.

Critically assess chemicals to be used in cosmetics for deliberate application to the human body.

Form 15 lists additional criteria that cosmetic chemicals must meet for the no unreasonable risk, low-volume exemption less than or equal to 100 kg.

Environmental risk

You need to assess the environmental impact of the chemical during each release route (manufacture, use and disposal of waste) and on all environment aspects (air, soil and water).

Evaluate parameters such as volatility, solubility, mobility and the potential for biodegradation and bioaccumulation.

Consider any known ecotoxicity of the chemical and its behaviour in air, soil and water.

Minimising risk

You need to consider the potential exposure of the chemical, where appropriate, during manufacture and/or importation, formulation, end use and disposal, as well as its hazards, including toxicity.

Consider:

- measures in place to minimise or eliminate exposure of workplace personnel, to determine if unreasonable risk exists
- how risk can be minimised by using engineering controls or by wearing personal protective equipment such as gloves and safety spectacles
- ways to reduce risk in the first instance, such as through measures to prevent the chemical's release into the environment (for example, manufacture of the chemical in a closed system), or through reducing public exposure by decreasing the concentration in a formulated product
- ways to minimise risk, where environmental release occurs, such as by treating or converting the chemical to a less harmful form (for example, treating production effluent on site before discharging it into a sewer).

How to assess risks posed by a chemical—example

Although relating to a chemical used in cosmetics, this example guides you on how to consider occupational health and safety, public and environmental risks posed by a non-cosmetic.

Scenario: A new chemical is to be imported as a concentrate for formulation into a skin moisturiser. It 31/323

comprises 1% of the finished product. The annual importation volume is proposed to be 80kg. The chemical is a liquid under ambient conditions and does not satisfy the criteria for a hazard class in the GHS.

The chemical is transported in 500 ml bottles packed in impact-resistant containers. It is dispensed directly from the bottle through an open-pour method during manufacture of the cosmetic product.

OCCUPATIONAL HEALTH AND SAFETY CONSIDERATIONS

Action

Evaluate the potential for worker exposure through scenarios such as spillage or splashing, for all facets of the production process—from handling the concentrate to packaging the final product.

Extend the occupational health assessment to the end use of the cosmetic product if it is to be used in workplaces such as hairdressing and beauty salons.

Assessment

In this case the chemical is not a high occupational health and safety risk, even if some exposure should occur. It is:

- not a hazardous substance
- present at a relatively low concentration in the final product
- dispensed through a relatively safe open-pour method.

In cases where finished products only are imported, occupational health and safety considerations are usually minimal, perhaps restricted to warehousing arrangements.

PUBLIC HEALTH CONSIDERATIONS

Action

Evaluate the hazardous nature of the chemical, its concentration in the finished product and its behaviour (for example, mobility) on the surface of the skin, remembering that the potential for public exposure to the cosmetic product is high.

Assessment

In this case the chemical is not a hazardous substance and the concentration in the moisturiser is relatively low (1%). For most individuals the risk of repeated use is low.

ENVIRONMENTAL CONSIDERATIONS

Action

Examine possible routes for release of the chemical into the environment, including accidental spillage of the chemical or finished product during transport and loss during manufacture, including through disposal of waste product.

Examine the ecotoxicity and physico-chemical properties in relation to possible release volumes, to determine if the impact of any local release is unacceptable, remembering that most chemicals in consumer products are released to the environment through normal product use.

Assessment

In this case, since only a small volume of chemical is involved, the chemical is highly diluted when it enters the aquatic environment through washing or showering and the pattern of release is highly dispersed. Environmental concern is therefore extremely low in view of the amount of chemical involved (less than 100 kg/year).

Data requirements

When assessing whether no unreasonable risk applies you will need to obtain data on the hazards of the chemical or likely hazard based on structure. While no specific requirements are set out for hazard data, NICNAS expects you to make an informed determination of hazard.

1.4 NOTIFICATION CATEGORIES FOR NEW CHEMICALS

Once you establish you need to notify NICNAS of the new chemical you intend to import or manufacture (excluding a chemical introduced under exemption), you determine the most appropriate notification category.

This chapter gives an overview of all notification categories.

More information about applying to notify a new industrial chemical is in Notification processes and procedures for new chemicals.

More information about assessment certificate and permit categories is in Certificate categories for new chemicals and Permit categories for new chemicals.

Sections of this chapter:

- Permit or assessment certificate?
- Permit categories—an overview
- Assessment certificate categories—an overview

1.4.1 PERMIT OR ASSESSMENT CERTIFICATE?

Two broad categories exist for assessing a new chemical—permits and assessment certificates. To decide which to use, you need to consider:

- type of chemical
- amount you are introducing
- use of the chemical
- period of use
- your company's business needs and commitments.

TABLE: COMPARISON OF PERMITS AND CERTIFICATES

Certificate	Permit
Assessment certificate issued	Permit issued with conditions stipulated, including duration and volume
Data requirements as per category	Reduced data requirements
Eventual listing on the AICS	No eventual listing on the AICS
Publication of a risk assessment report (with recommendations) on the NICNAS website	Publication of notice in the <i>Chemical Gazette</i> with summary details
Statutory timelines: 29–90 days	Shorter statutory timelines: 14–28 days
Higher cost	Reduced cost

New chemical notification categories—a summary

The following table summarises all new chemical notification categories, providing information on outcome based on the chemical amount introduced. It also lists the duration of the certificate or permit and the assessment time frame.

TABLE: SUMMARY OF ALL NEW CHEMICAL NOTIFICATION CATEGORIES

		Outcome	Chemical amount introduced	Duration of certificate or permit	Assessment timeframe
Permits	Commercial evaluation chemical (CEC)	Permit	≤4 tonnes	Up to 2 years	Usually within 14 days
	Low volume chemical (LVC)	Permit	≤100 kg/yr	3 years	20 days
	Low volume chemical (LVC)	Permit	>100 but ≤1000 kg/yr ¹	3 years	20 days
	Controlled use permit (CUP)	Permit	Unlimited	3 years	Usually within 28 days
	Controlled use —Export only permit (EOP)	Permit	Unlimited	3 years	Usually within 20 days
	Early introduction permit (EIP)— this category accompanies Polymer of low concern (PLC), Limited (LTD) or Standard (STD)	Permit	As for PLC, LTD or STD	Until certificate issued, or permit rescinded	28 days
	Permit renewal	Permit	As for previous LVC, CEC, CUP, EOP	3 years (LVC/CUP/E OP) and up to 2 years (CEC)	20 days (LVC/EOP), and usually 28 days (CUP) and 14 days (CEC)
	Polymer of low concern (PLC) ²	Certificate	Unlimited	5 years	90 days

Certificates	Limited (LTD) ²	Certificate	≤1 tonne/yr ³ ≤10 tonne/yr3 for site limited chemicals	5 years	90 days
	Standard (STD) ²	Certificate	>1 tonne/yr	5 years	90 days
	Self assessment ⁴	Certificate	As for PLC, LTD or STD	5 years	28 days
	Extension of an Original Assessment Certificate (in short: EX)	Certificate	As for PLC, LTD or STD	5 years from granting of original certificate	45 days

¹ Low hazardous criteria apply

 2 For STD, LTD and PLC, there are modular notification categories available, with reduced fees, where:

- Similar chemical: the notified chemical or polymer is similar to a chemical or polymer previously assessed by NICNAS, or
- Group Assessment: the notified chemical or polymer is being notified at the same time as a similar chemical or polymer , and for a similar use, or
- Approved Foreign Scheme: an assessment of the notified chemical in Canada (under a comparable schedule) is available, or
- Comparable Agency: an assessment of the notified chemical by:
 - the Therapeutic Goods Administration (TGA), the Australian Pesticides and Veterinary Medicines Authority (APVMA) or Food Standards Australia New Zealand (FSANZ) is available, or
 - a chemicals notification and assessment scheme from the USA, EU (pre-REACH), Canada (where the criteria for the Approved Foreign Scheme category are met) or OECD member country is available.

See Modular notification categories and Use of overseas assessments in the notification of new chemicals for more details.

³ Volume restriction does not apply to synthetic polymers with NAMW >1000 Da.

⁴Nanomaterials are not eligible for this certificate category.

Permit application

You will need to apply for a permit for new chemicals which meet certain criteria. Having a permit essentially means:

• you are allowed to introduce fixed quantities of the chemical for the permit duration
- a notice of the permit will be published in the Chemical Gazette
- the chemical will not be added to the AICS
- a shorter assessment time and lower fees than for assessment certificates (see table, above)
- you can renew your existing permit in certain circumstances (see Renewal of permits)
- for CUP and LVC permits, you will need to submit annual reports, using the approved NICNAS format, at the end of the registration year.

Assessment certificate

You will need to apply for an assessment certificate for chemicals that do not meet the permit criteria or where you prefer a certificate notification resulting in listing the chemical on the AICS.

There are two types: self-assessment and non self-assessment.

HAVING AN ASSESSMENT CERTIFICATE ESSENTIALLY MEANS:

- you are allowed to introduce the chemical
- brief facts about the identity of the notifier, and chemical's identity and key hazard, volume and use information on the chemical will be published in the Chemical Gazette and a public report will be made available on the NICNAS website
- the chemical will eventually be added to the AICS.

1.4.2 PERMIT CATEGORIES-AN OVERVIEW

This part details the permit categories, the intention of each and the criteria that applies to each.

Information on notification procedures and the information required to demonstrate that the criteria are met is in Permit categories for new chemicals.

Commercial evaluation chemical (CEC) permits

CEC permits are issued for new industrial chemicals introduced solely for commercial evaluation where the maximum quantity to be introduced is 4000 kg in a maximum period of two years.

A CEC permit can only be renewed once, provided certain criteria are met.

Examples of possible uses are to:

- test a new polymer in a surface coating when a large quantity is required to fill paint lines; or
- evaluate a new process requiring a new industrial chemical.

Low volume chemical (LVC) permits

LVC permits are issued for new industrial chemicals to be introduced at a maximum volume of 100 kg/year (1000 kg/year where the low hazardous criteria are met) for a period of three years.

Controlled use permits (CUP)

CUPs are issued for the introduction of low-risk new chemicals used in highly controlled circumstances for a maximum of three years (note: certain prescribed criteria apply). There is no volume restriction.

A CUP can be renewed any number of times, provided certain criteria are met.

Controlled use (export only) (EOP) permit

EOPs are issued for the controlled introduction of a new chemical for export. The entire quantity of the new 37/323

chemical must be exported within a maximum of three years.

This permit can be renewed any number of times, provided certain criteria are met.

Early introduction permit (EIP)

An EIP is issued in conjunction with an LTD, STD or PLC notification for chemicals meeting prescribed criteria. As the holder of an EIP, you can start introducing the chemical before the NICNAS assessment is completed.

Under strict circumstances special EIPs (section 30 of the Act) may be issued for new chemicals where you can show that their immediate introduction is in the public interest.

This permit is issued only for the period until a certificate is issued; it cannot be renewed.

1.4.3 ASSESSMENT CERTIFICATE CATEGORIES-AN OVERVIEW

This part details the assessment certificate categories (non self-assessment and self assessment), the intention of each and the criteria that applies to each. Details on the notification procedures and information required are in Certificate categories for new chemicals.

Non self-assessment certificate categories

The major categories of certificate are non self-assessment.

1. POLYMER OF LOW CONCERN (PLC) NOTIFICATIONS

PLC notifications are for polymers that meet the PLC criteria (see Polymers of low concern):

• Number-average molecular weight

Except for certain polyesters (see: last dot point below), a PLC must have a NAMW greater than 1000.

For polymers with NAMW between 1000 and 10,000, the allowable low MW species (below 1000 and 500) for these polymers is 25% and 10% respectively provided that the polymer has a limited content of reactive functional groups.

For polymers with NAMW greater than 10,000, the allowable low MW (below 1000 and 500) for these polymers remains at 5% and 2% respectively. There is no restriction on the number of reactive functional groups in the polymer.

• Low-charge density

A polymer has a low-charge density if it is not a cationic polymer or is not reasonably anticipated to become a cationic polymer in a natural aquatic environment (4 < pH < 9). Certain solid materials and polymers with a low content of cationic groups are allowable as PLCs.

Hazard classification

A PLC must not be classified as a hazardous chemical.

Stability

A polymer is stable under the conditions in which it is used if it does not readily break down by hydrolysis, thermal degradation, photodegradation, depolymerisation or any other means.

Chemical composition

A PLC must contain as an integral part of its composition at least two atomic elements—carbon, hydrogen, nitrogen, oxygen, silicon and sulfur. There are restrictions on the content of other elements.

• Water-absorbing polymers

A water-absorbing polymer with NAMW 10,000 and greater cannot be a PLC.

• Polyesters

A polyester with a NAMW less than 1000, manufactured solely from one or more allowable reactants, may be a PLC provided that the polymer meets the other criteria.

2. LTD NOTIFICATIONS

LTDs are for chemicals fitting one of these categories:

- small-volume chemicals, biopolymers, and low MW synthetic polymers (NAMW <1000 Da)—that is, chemicals to be imported or manufactured at a rate of up to 1 tonne/12-month period
- site-limited chemicals, biopolymers, and low MW synthetic polymers (NAMW <1000 Da)—that is, chemicals restricted to their manufacturing site and manufactured at a rate of not more than 10 tonnes/12month period
- synthetic polymers with NAMW >1000 Da that do not meet the PLC criteria.

3. STD NOTIFICATIONS

STDs are for chemicals, biopolymers and low MW synthetic polymers (NAMW<1000 Da) imported or manufactured at greater than 1 tonne/year that do not fulfill the requirements of any other category.

4. EXTENSION OF A CURRENT ASSESSMENT CERTIFICATE

Extension of a current assessment certificate may cover other companies intending to import or manufacture a notified chemical, where the holder of the original certificate agrees and as long as certain criteria are met.

Self-assessment certificate categories

Self-assessment certificate categories allow industry to self-assess low regulatory concern chemicals against specified criteria and provide an assessment report which is screened and amended by NICNAS in consultation with the notifier if necessary before publication.

The assessment time frame is shorter than for non self-assessment categories (28 days as opposed to 90 days) and the fees you pay are lower.

Self-assessment certificates cannot be extended.

Self-assessment applications can be made for these categories of chemicals:

1. PLC

PLC notifications are for polymers meeting the PLC criteria (Polymers of low concern)

2. NON-HAZARDOUS CHEMICALS OR POLYMERS

The onus is on you to demonstrate the non-hazardous nature of the chemical or polymer. You must gather data to demonstrate the non-hazardous nature, as outlined under the Act (see Legislation and regulations).

Note: Some chemicals are not eligible for self-assessment. These are: 39/323

- 1. persistent and bioaccumulative chemicals and polymers (see Stockholm Convention).
- 2. nanomaterials (see Guidance and requirements for notification of new chemicals that are industrial nanomaterials).

Obligations

To ensure the robustness and integrity of the self-assessment process, you—as holder of a self-assessed assessment certificate—may be subject to NICNAS audits, since you are responsible for the content of the self-assessment report.

Under the Act, you must keep records to support statements made in, or in connection with, the certificate application, for five years from the date the certificate is issued. You must also submit a report to the NICNAS Director at the end of each registration year, stating:

- name of the chemical or polymer for which the certificate is issued
- volume of the chemical or polymer introduced during the year
- any adverse effect of the chemical or polymer on occupational health and safety, public health or the environment of which you became aware during the year.

1.5 NOTIFICATION PROCESSES AND PROCEDURES FOR NEW CHEMICALS

This chapter outlines processes you need to follow when submitting a notification to NICNAS for new chemicals.

See also:

- forms and guidance that you require, in order to apply
- a listing of notification and assessment fees.

Sections of this chapter:

- Who can make an application for notification and assessment of a new chemical?
- Statement and certification
- Submitting information
- Withdrawing notification
- · Applications, notification statements and other documents
- Exempt information (information claimed as confidential from publication)
- Method of paying assessment fees
- Screening applications to notify a new chemical
- Requests for more information
- Providing new information during assessment
- Assessment process and reports
- Issuing an assessment certificate
- Transferring an assessment certificate
- Record keeping and annual reporting
- New Chemicals offences and penalties under the Act—a summary

1.5.1 WHO CAN MAKE AN APPLICATION FOR NOTIFICATION AND ASSESSMENT OF A NEW CHEMICAL?

If you are a manufacturer or importer of a new industrial chemical, you can apply for a permit or assessment certificate for the chemical.

Do not apply for an assessment permit or certificate if you do not intend to manufacture or import a new chemical.

Two or more manufacturers or importers may make a joint application (with a single fee). NICNAS issues a permit or certificate to each successful applicant.

If the application is for a joint notification, each applicant needs to be an introducer of the chemical.

Joint applications are *not allowed* for self assessments.

To seek an extension for the certificate, each certificate holder must sign a form agreeing to the extension.

1.5.2 STATEMENT AND CERTIFICATION

On your application form, you need to provide a declaration for each notification, specifying that:

- you are entitled to use all data provided, including that which has not been produced in laboratories owned or otherwise affiliated with you
- all information notified is true and correct.

You must also indicate if the:

- test data were generated in accordance with the Organisation for Economic Co-operation and Development's (OECD) Guidelines for the Testing of Chemicals or other standard test methods recognised by NICNAS, such as the European Commission Directive
- laboratory used to generate the test data operated under standards equivalent to those in the OECD's Principles of Good Laboratory Practice.

1.5.3 SUBMITTING INFORMATION

You can send all applications and information relating to notifications:

By post

Director, National Industrial Chemicals Notification and Assessment Scheme (NICNAS) GPO Box 58 SYDNEY NSW 2001 AUSTRALIA

By courier

Director, National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Level 7, 260 Elizabeth Street SURRY HILLS NSW 2010 AUSTRALIA

1.5.4 WITHDRAWING NOTIFICATION

You can withdraw your application at any time before the assessment report is published or certificate or permit issued.

As the applicant, you:

- can write to NICNAS and ask them to return all documents you submitted, including your application
- may also be eligible for a partial application fee refund (see Refund policy table in Screening applications to notify a new chemical).

1.5.5 APPLICATIONS, NOTIFICATION STATEMENTS AND OTHER DOCUMENTS

Your application:

- must be legible and submitted in English
- be accompanied by a translation for any data not in English, and a signed statement certifying the translation was carried out by a competent translator (person or organisation)
- (M)SDSs must be legible and suitable for publication.

You should use the specific form and checklist associated with each notification category to submit required data and information. Some forms, such as an application to keep certain information confidential from publication, may also be required. However, for most notification categories, you can submit some data, such as toxicity studies, (M)SDSs and occupational data, using your own format.

You must provide schedule data requirements in your application according to each notification category and all information on health and environmental effects of the chemical available to you so NICNAS can assess the chemical. You must also declare you are entitled to use the data provided and authorised to give it to NICNAS.

You can use professional help to prepare your application.

You should submit your application in loose-leaf form, not bound.

Number of copies

For certificate notifications you must submit:

- Two copies of the complete notification statement
- Two copies of the supporting physico-chemical and environmental effects data
- One copy of the supporting health effects data

For permits you must submit one copy of all information.

Data requirements

For most notification categories, the data requirements reflect the Schedule to the Act (see Data requirements for new chemicals applications).

For STD and LTD notifications, different data are required, depending on whether the chemical is a polymer or a non-polymer.

Scheduled data requirements represent the minimum data required. If you have access to additional information, you must provide it to NICNAS with your application.

SUBMITTING TEST RESULTS

It is best to obtain data in support of your application in accordance with currently accepted principles of good laboratory practice (such as the OECD Principles of Good Laboratory Practice). This includes test results.

When applying it is recommended that you:

- indicate the test method and the testing organisation used for each data item
- indicate whether testing carried out in Australia was in accordance with the National Association of Testing Authorities' standards
- ensure you carry out your responsibilities for observing good laboratory practice during testing
- consider the need for good laboratory practice requirements when engaging a testing laboratory
- provide a quality assurance statement for each test (usually part of the study report).

Other testing techniques are acceptable if they are a valid method for determining the required information. NICNAS determines this case-by-case.

NOTE: Tests conducted before 1981 may not have been carried out in accordance with good laboratory practice.

VARIATION OF DATA REQUIREMENTS

If you cannot provide all of the data required for the notification NICNAS does allow for variations to the scheduled data requirements. However, you must seek NICNAS approval if you want to vary the schedule data requirements (omitting or substituting) by completing the relevant section of the notification form.

You may be able to omit certain data items if you satisfy NICNAS that:

- the introduction of the chemical is not against the public interest
- the omissions or substitutions are justified (when the substitution is for data from an analogue chemical this includes justification for why the proposed analogue chemical is suitable)
- an adequate assessment of the occupational health and safety, public health and environmental hazards of the chemical can be made without submitting the data items.

You must include the required fee with your application. The only time the fee may be waived is when it is physically impossible to conduct a particular test or study. NICNAS will consider this case-by-case.

More information is available in:

Data requirements for new chemicals applications

Guidance and requirements for notification of new chemicals that are industrial nanomateriials.

1.5.6 EXEMPT INFORMATION (INFORMATION CLAIMED AS CONFIDENTIAL FROM PUBLICATION)

You may want to exempt confidential items of information required because of the commercial harm caused by disclosing them. Exemption means the items will not be included in publicly-available versions of the assessment report or in the *Chemical Gazette*.

When applying for exemption, clearly indicate in your notification statement what information you want to exclude from publication and explain your rationale, including why any prejudice to your commercial interests resulting from publication outweighs public interest.

For further guidelines, see Confidentiality.

NICNAS cannot exempt certain items of 'basic information' described in the Act since publishing these items is deemed to be in the public interest. Basic information is available in Definitions and in Subsection 75(2) of the Act (see Legislation and regulations).

NICNAS will notify you in writing if your application for exemption is rejected.

You can appeal to the Administrative Appeals Tribunal for the decision to be reviewed. Once again, you will hear from NICNAS in writing.

Submission of information by persons other than the applicant (third-party data)

At times you may need a third party to provide NICNAS with information in support of your notification or application, including an:

- overseas manufacturer who will not release confidential information to you on a chemical, even though you need it
- Australian or subsidiary company that has a policy not to release confidential information to import agents.

The third party can supply the information direct to NICNAS on your behalf. To protect confidentiality, however, it is the third party's responsibility to specify on the Third Party Information Lodgement form what information is not to be disclosed.

Third parties must clearly identify their documents as such so NICNAS can unequivocally identify their status when assessing. Information on the Third Party Information Lodgement form must be eligible for exemption (that is, it must not be 'basic information').

1.5.7 METHOD OF PAYING ASSESSMENT FEES

You can pay your assessment fees by cheque, electronic funds transfer or credit card.

Details for each payment method can be found on the notification forms.

1.5.8 SCREENING APPLICATIONS TO NOTIFY A NEW CHEMICAL

NICNAS conducts an initial screening of an application to determine if it is complete and that all fees are paid (see figure below).

When doing so, NICNAS:

- 1. conducts administrative screening
- 2. conducts technical screening (in conjunction with assessment staff in the Department of the Environment) to determine if the application is:
 - 1. complete—which means assessment can start (from date of submission)
 - 2. incomplete, but requires outstanding data that can be easily rectified—which means assessment *may* start
 - 3. substantially deficient—which means assessment cannot start
- 3. specifies the timeframe for addressing any gaps in data required, which is 14 days (permits) / 28 days (certificates) or the option of submitting your own timetable for resolving data gaps if you cannot do so in 14 (permits) or 28 (certificates) days.

After screening is complete (usually within 14 days) NICNAS will inform you of the outcome and details of the

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information required to resolve any data gaps. This letter will also include the details of the assessment clock dates (if the clock has started) or the dates by which additional data needs to be provided to NICNAS (if the clock has not started).

NICNAS also screens any additional information you are asked to provide, until your application is complete. The assessment clock will start on the date NICNAS received the complete submission.

NOTE: NICNAS can return deficient submissions that are not rectified within the specified timeframes.

SCREENING PROCESS FOR NEW CHEMICALS ASSESSMENT



REFUND POLICY

Scenario		Status of application	Refund estimation
1	Application received and processed—no technical screening conducted OR preliminary screening shows it is an existing chemical	Withdrawn or returned	Refund 90% of assessment fees
2	Application received and technical screening completed	Withdrawn or returned	Refund 85% of assessment fees
3	Assessment already started	Withdrawn or returned	Depending on stage of assessment (e.g., STD withdrawn at day 45 (clock on) = refund 65% of assessment fees)
4	Assessment completed and Day-90 report completed	Withdrawn	No refund
5	EIP submitted	EIP rejected	No refund

1.5.9 REQUESTS FOR MORE INFORMATION

In some cases, the NICNAS assessor may need to clarify information or ask you for additional information (for example, to resolve ambiguities or inconsistencies in data, interpret unqualified test data or to properly assess a chemical).

In these cases, NICNAS will write to you with the details and timeline for the required information.

Examples of specific test data or information you may be asked for:

- chronic toxicity test results where long-term exposure to the chemical is likely and short-term toxicity tests indicate possible longer-term effects
- information to satisfy the requirements of the Stockholm Convention on Persistent Organic Pollutants (for chemicals that may be persistent in the environment and/or bioaccumulative
- extra details for chemicals that are industrial nanomaterials.

1.5.10 PROVIDING NEW INFORMATION DURING ASSESSMENT

If new, relevant information on the chemical becomes available to you during assessment you must submit it to 46/323

NICNAS.

This includes information such as:

- references to the chemical in scientific literature
- results of further testing carried out in Australia or in a foreign country
- new information on occupational, public or environmental exposure
- new uses of the chemical
- information available from within the company or from the parent company or supplier
- information presented at conferences
- information from patent specifications.

This requirement means you are responsible for regularly monitoring scientific literature and other known information sources for additional details on the notified chemical.

Failure to provide such information during chemical assessment may lead NICNAS to suspend the assessment process until the new information is received.

1.5.11 ASSESSMENT PROCESS AND REPORTS

In normal circumstances, NICNAS completes a certificate assessment for a new industrial chemical within 90 calendar days from the date the complete notification package (application) is received.

Once you have received the assessment report from NICNAS, you have two weeks to apply for a variation.

You receive an assessment certificate for a new chemical within seven days of consent to publish, after 28 calendar days if no consent is provided, or after 90 calendar days when:

- the NICNAS Director has asked for additional information, in which case the 90 calendar days will begin from the date the additional information is received
- an unusually detailed or complex assessment is necessary, in which case an additional 90 calendar days may be granted—you will be advised as soon as practicable.

Following the assessment of a notified chemical under the STD, LTD and PLC categories, NICNAS will send to you:

- exempt information
- public report (not including exempt information).

NICNAS will delete justifiable third party information provided on your behalf before sending exempt information to you.

For further infromation / guidelines, see: Confidentiality.

NICNAS will also send advice on publication of a report and possible variation before publication (see sections below.

Requests to vary assessment reports before publication

Within 14 days of receiving an assessment report (non self-assessed), you can ask the NICNAS Director to change it if, for example, you disagree with the conclusions and/or recommendations on scientific grounds.

You need to complete Form 4, attach the appropriate fee and send the completed form to NICNAS. Always provide reasons for your request and supporting documentation (if you have it or if NICNAS requires it).

The NICNAS Director may agree or refuse to change the report, depending on your rationale and the extra 47/323

information you provide. The Director will provide the decision in writing.

You can then:

- give written consent for the report to be published
- appeal the decision (see Appeals)
- withdraw your notification.

You can also apply to vary an assessment report after it has been published (see below).

Publication of assessment reports

If the NICNAS Director has not received a request to change the assessment report within 28 days from when you forwarded it, the report can be published.

Under the Act, NICNAS does this by:

- publishing summary details of the assessment in the Chemical Gazette
- giving a copy of the assessment report to the Department of the Environment
- giving a copy of the public report to any person the Minister directs
- publishing the public report on the NICNAS website.

Variation of assessment reports after publication

You can apply to the NICNAS Director to vary the public report within 28 days after the summary details of the assessment have been published in the *Chemical Gazette*.

To apply for a variation before publication (see above).

Before varying the report, the NICNAS Director must first publish a notice in the *Chemical Gazette* setting out the proposed variation.

Under the Act, third parties (such as members of the public) can also apply to the Director to vary a report after it is published.

1.5.12 ISSUING AN ASSESSMENT CERTIFICATE

NICNAS will issue you with the assessment certificate for a new chemical within seven days of consent to publish, or after 28 days if no consent is provided.

The chemical will be added to the AICS five years after the assessment certificate is given, unless you apply for it to be listed on the non-confidential AICS earlier.

1.5.13 TRANSFERRING AN ASSESSMENT CERTIFICATE

Under Section 73 of the Act (see Legislation and regulations), in certain circumstances a business may arrange to transfer an assessment certificate it holds if:

- the holder dies, in which case the legal personal representing the estate becomes the certificate holder
- the holder becomes bankrupt, in which case the person who becomes the trustee of the estate becomes the certificate holder
- a corporate body is being wound up, in which case the liquidator of the body corporate becomes the certificate holder
- the business is disposed of and it is a term of the agreement for disposal that the person who acquires the

business becomes the certificate holder.

NOTE: Permits are issued for limited periods and are not eligible for transfer.

When to notify NICNAS of changes to circumstances

Under Section 73 of the Act, the new holder must give notice to the NICNAS Director of the transfer as soon as practicable. The Director may revoke a certificate if a person fails to provide notice of a transfer.

If a registered body corporate is taken over by another person (whether registered or not) and if, as a result, the body corporate ceases, you must notify the NICNAS Director of the takeover particulars within seven days after the takeover takes effect.

If a registered body corporate merges with another body corporate (whether registered or not), you must notify the NICNAS Director of the new corporate body within seven days of the merger taking effect.

In all of these cases, use Form 73—Agreement to Transfer an assessment certificate.

1.5.14 RECORD KEEPING AND ANNUAL REPORTING General requirements

Under Regulation 7A of the Industrial Chemicals (Notification and Assessment) Regulations 1990 (see: Legislation and regulations), the importer/manufacturer of a chemical must keep:

- A written statement detailing if:
 - the chemical is, or contains, an industrial chemical
 - $\circ~$ in the case of an industrial chemical, a submission is being prepared for including the chemical in the AICS
 - the chemical is a new industrial chemical
 - an assessment certificate is in force for the chemical
 - a permit is in force for the chemical.

All relevant commercial documents (within the meaning of Section 240 of the *Customs Act 1901*) relating to an industrial chemical for at least five years after it is imported into Australia (including commercial documents that came into your possession or control before, on and after the entry of the industrial chemical into Australia).

Relevant commercial documents could include a commercial invoice describing the goods, orders or confirmations, bills of lading or airway bills, insurance certificates, receipts for purchase of goods, illustrated descriptive material and other records provided to Australian Customs and Border Protection Service.

Annual reporting and record-keeping obligations for exemption categories

Under exemption categories, you have 28 days from the end of the registration year (31 August) to submit an annual report to NICNAS on the chemical you have introduced. This means an annual report will be required if you have introduced chemicals under the following exemption categories:

- chemicals are introduced solely for research, development or analysis in quantities of not more than 100 kg/year
- chemicals introduced at a port or airport that remain subject to Customs and Border Protection Service control are at a port or airport at all times, and leave Australia less than 30 days after the day they are introduced

- chemicals are used for non-cosmetic purposes, introduced in quantities of less than 100 kg/year and pose no unreasonable risk to human health and the environment
- chemicals in quantities of less than 100 kg for cosmetic purposes which meet prescribed requirements, such as packaging and labelling, and pose no unreasonable risk to human health and the environment
- non-hazardous chemicals introduced in a cosmetic are in a concentration of less than 1%.

The annual report must state the name and volume of chemical introduced during the year.

Annual reporting and record-keeping obligations for Low volume permits, Controlled use permits and Self-assessment certificates

If you are the holder of a LVC, CUP and/or Self-assessment certificate, you must keep records for five years for audit purposes.

The NICNAS Director can require you to provide information in, or in connection with, the application for, or application for renewal of, such a permit or certificate.

You must forward an annual report to the NICNAS Director stating the name and volume of the chemical and any adverse effect the chemical may have on occupational health and safety, public health or the environment. You must provide the report within 28 days from the end of the registration year (31 August).

1.5.15 NEW CHEMICALS OFFENCES AND PENALTIES UNDER THE ACT-A SUMMARY

If you do not comply with NICNAS requirements for new chemicals you will be deemed to have committed an offence and penalties will apply.

TABLE: SUMMARY OF NEW CHEMICALS OFFENCES AND PENALTIES

Section/offence	Guidance	Maximum penalty: individual (corporation)
s15A Failing to comply with conditions of use of an AICS-listed chemical (Fault based offence)	The NICNAS Director may include in the AICS certain conditions associated with the chemical's mode of use or introduction. If you are importing or manufacturing the chemical you must comply with these conditions.	\$13,200 (\$66,000)
s21 Introducing a new industrial chemical (without an assessment certificate or permit and not exempt) (Fault based offence)	A new industrial chemical is either not listed on the AICS, or is listed but with certain conditions attached to its importation and/or manufacture. NICNAS must be notified of all new industrial chemicals and you must obtain an assessment certificate or permit before you can import or manufacture the chemical in Australia. This does not apply if the new industrial chemical is exempt from notification to NICNAS.	\$33,000 (\$165,000)
s21AA(4) Failing to provide an annual report (Fault based offence)	If you are introducing a new industrial chemical under an exemption you must provide an annual report to the NICNAS Director before or on 28 September of the following registration year.	\$1,100 a day to a maximum of \$13,200 (\$5,500 a day to a maximum of \$66,000)
S21L(4) Contravening any conditions imposed on the Commercial evaluation permit (Fault based offence)	CEC permits are subject to stipulations relating to safeguarding occupational health and safety, public health and the environment. You, and agreed users, must adhere to all permit conditions.	\$33,000 (\$165,000) For both individual and corporation the NICNAS Director can also cancel the permit (s21N)
s21W(5) Contravening any condition imposed on the Low volume	LVC permits are subject to stipulations relating to safeguarding occupational health and safety, public health	\$33,000 (\$165,000)

permit (Fault based offence)	and the environment. You must follow all permit conditions.	For both individual and corporation the NICNAS Director can also cancel the permit (s21N)
s22I Contravening any condition imposed on the Controlled use permit (Fault based offence)	CUPs are granted subject to conditions that the chemical is imported or manufactured only for the use stated on the permit. Conditions designed to safeguard occupational health and safety, public health and the environment also apply. You must follow all permit conditions.	\$33,000 (\$165,000)
s30C Using a chemical after receiving a revocation notice from the NICNAS Director (regarding an EIP) (Fault based offence)	In certain circumstances, the NICNAS Director can revoke an EIP. You must stop importing and/or manufacturing the chemical as soon as you receive the revocation notice.	\$33,000 (\$165,000)
s40K(3) Failing to keep supporting records for permits or certificates (Fault based offence)	If you are issued with a LVP, CUP, or a self-assessed assessment certificate you must keep records in support of information associated with your application for five years.	\$13,200 (\$66,000)
s40L(3) Failing to supply requested information on permits or certificates to the NICNAS Director (Fault based offence)	You must provide information to the NICNAS Director, if asked, on a LVP, a CUP, or a self- assessed assessment certificate.	\$6,600 (\$33,000)
s40N(4) Failing to provide an annual report for permits or certificates (Fault based offence)	If you are introducing a new industrial chemical under a CEP, LVP, CUP, or a self-assessed assessment certificate, you must provide a report to the NICNAS Director before or on 28 September of the following registration year.	\$1,100 a day to a maximum of \$13,200 (\$5,500 a day to a maximum of \$66,000)

s64(1)(2) Failing to notify the NICNAS Director within 28 days of certain specified circumstances occurring giving rise to the obligation of secondary notification (Fault based offence)	 If you have introduced an industrial chemical that was assessed by NICNAS and become aware of certain changes you must notify the NICNAS Director of the changes within 28 days. This includes when: the function or use of the chemical has or is likely to change the amount of chemical introduced has or is likely to increase an imported chemical has begun to be manufactured the method of manufacture has or is likely to change additional information is available on the adverse occupational health and safety, public health or environmental effects of the chemical other circumstances recommended on the assessment report for the chemical have occurred. 	\$13,200 (\$66,000)
s67 Failing to comply with secondary notification requirements (Fault based offence)	The NICNAS Director may, by notice in the <i>Chemical Gazette</i> , require you to submit a Secondary Notification of a chemical by persons to whom the notice applies, within 28 days. You must provide this information within 28 days.	New industrial chemical \$13,200 (\$66,000) For both individuals and corporations, the Minister can also suspend any assessment certificate or introduction permit you hold for the chemical <i>in any other case</i> \$13,200 (\$66,000) For both individuals and corporations, the Minister can also prohibit you from importing or manufacturing the chemical
	The NICNAS Director may require, to assess a new or	

s69 Contravening a notice by the NICNAS Director in the <i>Chemical</i> <i>Gazette</i> requiring information to assess chemicals (existing or new) requiring secondary notification (Fault based offence)	 existing industrial chemical requiring secondary notification, a notice in the <i>Chemical Gazette</i> for all persons who introduce the chemical specified persons who introduce the chemical specified persons who may have relevant information on the chemical but who are not required to 	\$6,600 (\$33,000)
	give secondary notification, to provide the NICNAS Director the information specified on the notice.	

1.6 SUBMISSION TIPS FOR NEW CHEMICAL NOTIFICATIONS

This chapter provides tips to help with your NICNAS assessment application, so that you include all necessary information in your application. This will mean it can be completed without delay.

If you are unsure you have sufficient information to support your application, contact NICNAS before submitting it.

Sections of this chapter:

- Confirm chemical identity
- Provide complete payment
- Provide complete information on exposure and release
- Identify all uses
- Determine notification category
- Justify commercial evaluation for a CEC permit
- Ensure you have the data for a self-assessed Polymer of low concern category

1.6.1 CONFIRM CHEMICAL IDENTITY

NICNAS cannot begin an assessment without a chemical identity-this is critical.

Identifying chemicals can be challenging, particularly for polymers. To ensure NICNAS can verify chemical identity, provide:

- a copy of the Chemical Abstracts Service (CAS) report from the CAS Inventory Expert Service if only a CAS name is available (that is, CAS has not yet assigned a CAS number)
- accurate structural and molecular formulae.

1.6.2 PROVIDE COMPLETE PAYMENT

The assessment will not begin until all required fees have been paid.

See Fees and charges for details and information.

If you are paying from a foreign bank you are responsible for covering all bank charges and fees required for getting the exact \$AUD to NICNAS.

1.6.3 PROVIDE COMPLETE INFORMATION ON EXPOSURE AND RELEASE

Based on use scenarios and import volume, describe the occupational health and safety, public health and environmental effects in as much detail as possible for each notification category, including all potential exposure and release scenarios from 'cradle to grave'.

Before you submit your notification, also check you have:

- described the personal protective equipment used and controls in place for each stage of occupational use
- clarified the chemical concentration during each stage of use
- demonstrated you have considered all categories of workers and end users
- ensured the sum of all the environmental releases equals the volume introduced (quantity in = quantity out).

1.6.4 IDENTIFY ALL USES

No matter which assessment category you apply for, the information you provide should cover all potential uses of the chemical. Therefore, the introduction volume—as well as occupational, public and environmental exposure—should cover all foreseeable uses of the chemical. This will avoid you having to apply for a secondary notification for a new use, introduction volume or exposure scenario.

1.6.5 DETERMINE NOTIFICATION CATEGORY

Ensure you determine the correct assessment category. Notification under the wrong category is a common cause for delay in processing applications. Two problematic categories are the CEC and the SAPLC.

1.6.6 JUSTIFY COMMERCIAL EVALUATION FOR A CEC PERMIT

As the notifier, you need to reasonably justify why the chemical is needed for evaluating its commercial viability. The Act (see Legislation and regulations) states that you need to provide:

... a written explanation why the quantity of the chemical that the applicant seeks to introduce under is the permit is reasonably needed for effective commercial evaluation of the chemical.

It is not enough to state on your application that the chemical is needed to increase production volumes. An example of a valid justification for a CEC could be a new ingredient in ink for industrial printing processes.

You need to provide a signed Form 8 from end users to NICNAS, which is an agreement that the end users will abide by any relevant permit conditions. Additional users can submit a Form 8 after the permit iss issued.

Note: A CEC is never issued for a chemical in a consumer product—this would require every end-user to sign a CEC agreement before using the product, which is not possible.

1.6.7 ENSURE YOU HAVE THE DATA FOR A SELF-ASSESSED POLYMER OF LOW CONCERN CATEGORY

You must ensure a polymer meets the PLC criteria and have on hand test reports for data such as MW, physico-chemical properties and available toxicity studies. You do not need to provide test reports with your self-assessment application.

For the self-assessment PLC category, you must hold all relevant data.

If a third party holds the data you will not be able to use the self-assessment option, and will need to submit under the PLC category instead.

If you are unsure what should be included in the risk assessment sections of the SAPLC-1 form, review examples of published NICNAS PLC assessment reports.

CONTACT US

You can talk to a NICNAS New Chemicals Assessor by phone (+61 (0)2 8577 8800) or by email to discuss issues before you submit your application.

1.7 ASSESSING EXISTING CHEMICALS

Around 40,000 industrial chemicals are listed on the Australian Inventory of Chemical Substances (AICS). These are termed 'existing chemicals'.

Due to the large number, NICNAS assesses existing chemicals as a priority in response to concerns about occupational health and safety, public health or environment effects. These may be assessed as single chemicals or groups of chemicals.

NICNAS will conduct different types of assessments depending on the circumstance. The Priority Existing Chemical (PEC) assessment is the most detailed. Recommendations on the safe use of these chemicals are made in PEC assessment reports.

NICNAS also undertakes other assessments on existing chemicals to fulfil specific data needs or if new data becomes available on a chemical that has already been assessed by NICNAS. In the past these included lower-scale (non-PEC) assessments—such as reviews that result in the production of FactSheets or Alerts.

As part of the reform regarding assessment of existing chemicals, NICNAS has implemented a new framework known as the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework (see Assessment methodologies) for the accelerated assessment of industrial chemicals in Australia.

From July 2012, NICNAS began assessing around 3,000 existing chemicals which had been identified as 'Stage One' chemicals, using the IMAP framework.

Sections of this chapter:

- Types of assessments
- Priority Existing Chemical assessments

1.7.1 TYPES OF ASSESSMENTS

NICNAS has two types of assessments-non PEC and PEC.

NON-PRIORITY EXISTING CHEMICAL

NICNAS may ask for information on existing chemicals of concern although they may not require assessment as a PEC. A less extensive assessment may meet requirements.

Non-PEC assessments and other information products produced under the Existing Chemicals Program include:

- Summaries of available data on one or more aspects of a chemical that has not been declared a PEC.
- Safety information sheets—summarise, in plain English, the major findings of a PEC assessment, designed to be displayed in the workplace.
- NICNAS Alerts—highlight information on topical activities.
- Chemical information sheets—provide information on general chemical subjects.

IMAP Assessments—the IMAP framework delivers assessment outcomes at each of the assessment tiers. The level of detail in the assessment output each tier reflects the required relative assessment effort. More information on IMAP assessment outputs is provided in Factsheet 3: IMAP—Better chemical safety information.

PRIORITY EXISTING CHEMICAL

The PEC is the most in-depth assessment conducted by NICNAS. These industrial chemicals must be investigated in detail because—by their very nature—there are always reasonable grounds to believe they give rise, or may give rise to, adverse occupational health and safety, public health and/or environmental effects—either through manufacturing, handling, storing, using or disposing it.

There are two categories of PEC assessment-'preliminary' and 'full'.

Preliminary assessment: assesses exposure and/or hazard; undertaken to determine the significance of chemical properties, intended use, adverse occupational health and safety, public health or environmental effects and/or extent of exposure. For example, a chemical may be a known carcinogen, but the extent of human exposure in Australia may be unknown.

Full assessment: uses international standards and guidelines to determine the risk of adverse health or environmental effects that could be caused by the import, manufacture, use, storage or disposal of the chemical.

1.7.2 PRIORITY EXISTING CHEMICAL ASSESSMENTS

The PEC is the most in-depth assessment conducted by NICNAS.

What is a Priority Existing Chemical?

A PEC is an industrial chemical for which NICNAS requires investigation in detail because there are reasonable grounds to believe it gives rise, or may give rise to, adverse occupational health and safety, public health and/or environmental effects—either through manufacturing, handling, storing, using or disposing it. For example, formaldehyde was declared a PEC in March 2002 because of concerns about its wide occupational and public exposure and potential adverse health effects.

A PEC can be:

- any chemical listed on the AICS
- any naturally-occurring chemical deemed to be listed in the AICS
- a new industrial chemical that is any of the following:
 - manufactured in a fixed apparatus, solely for research, development or analytical work
 - introduced under a <100 kg exemption for cosmetic and non-cosmetic chemicals which poses no unreasonable risk to occupational health and safety, public health or the environment
 - introduced solely for research, development or analysis, and in a quantity of not more than 100 kg in any 12-month period
 - introduced by a person at a port or airport in Australia and which remains subject to the control of Australian Customs and Border Protection Service at the port or airport at all times and leaves Australia less than 30 days after the day of introduction
 - covered by a CEC.

Selection of a Priority Existing Chemical

Nominations may come from a company, union, industry body, individual, government department or nongovernment organisation. NICNAS may nominate a chemical listed on the AICS for assessment as a PEC at any time.

In addition, NICNAS has called for nominations of chemicals as potential PECs from the public and wider community. For example, sodium ethyl xanthate, N-vinyl-2-pyrrolidone, glycolic acid and glutaraldehyde, were nominated by the public in response to a call from NICNAS.

Nominated chemicals are screened against set criteria including volume of use, potential exposure and severity of occupational health and safety, public health and environmental effects.

Following consultation with other government departments, industry, unions and the public, NICNAS has drawn up a candidate list of chemicals to consider declaring as PECs. This list is updated as necessary.

The NICNAS Director may also consider declaring a chemical as a PEC based on an immediate threat to the environment or to the health of workers and/or the public—for example (previously), 1,3,5-triglycidyl isocyanurate and Savinase (proteinases).

When a chemical or group of chemicals is being considered for declaration as a PEC, the Director may publish a notice in the *Chemical Gazette* calling for information on it or providing detail on where copies of the call for information can be obtained.

Once the NICNAS Director has considered all information available and consulted with interested parties, the Director decides if there are reasonable grounds for believing the manufacturing, handling, storing, using or disposing of the chemicals might give rise to adverse health or environmental effects. If so, the Director recommends to the Minister that the chemical should be declared a PEC.

Declaring and assessing Priority Existing Chemicals

If you are importing or manufacturing chemicals declared as PECs, you must apply, under the Act (see Legislation and regulations) for NICNAS to assess the chemicals. If no application is lodged after a chemical is declared a PEC, the NICNAS Director can request an assessment report be started at any time within 12 months.

The Director may require relevant persons to supply information required for the PEC assessment. Supplying such information is compulsory.

NICNAS depends on information provided directly by importers/manufacturers of the chemical in Australia (as a result of calls for information), overseas organisations and in the published literature to assess chemicals. Wherever possible, NICNAS refers to international chemical reviews and reports, to improve efficiency and minimise duplication.

Detailed information and data is collected on occupational health and safety, public health and environmental effects.

NICNAS will complete a draft assessment report within six months of the Director receiving all required information, unless there are good reasons for extending the timeframe. For example, there may be important matters to resolve between NICNAS and importers and/or manufacturers which require more than the usual amount of consultation, or new critical data may become available.

The overall assessment involves ongoing interaction between NICNAS, PEC applicants, other suppliers of information and other interested or relevant persons.

In most cases, NICNAS officers conduct informal site visits to obtain additional information and to ensure assessment report recommendations are practical and relevant.

NICNAS conducts consultative progress meetings with relevant parties, such as applicants and other suppliers of information, at specific points in the assessment and provides opportunities for comment and appeal on draft and final reports.

If a chemical has been listed as a PEC for 12 months and no applications for its assessment have been received, or the Director has not requested for the assessment to be started, the Director must remove the chemical from the AICS.

The overall procedures NICNAS follows from the point a chemical is declared a PEC to the publication of the final assessment report are summarised in the figure below.

Figure: Procedures following declaration of a chemical to the publication of final assessment report

DECLARATION

A chemical is declared a PEC under s51 of the Act by notice in the *Chemical Gazette*. The notice specifies whether the declaration applies to the chemical generally or only when it is used for particular purposes or in particular circumstances. If more than one chemical is declared, the notice will specify if the chemicals are to be assessed together.

INFORMATION GATHERING

Within 28 days after declaration, introducers of the chemical lodge applications for assessment. Information specified in the declaration notice must accompany an application.

The NICNAS Director may require persons to provide information for assessment by publishing a Section 58 notice in the *Chemical Gazette*. This notice specifies a period of not less than 28 days for compliance.

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ASSESSMENT

All information required for the assessment is collected and assessment begins. Preparing the draft assessment report may take up to six months after all required information is received (this timeframe may be extended by the Minister).

NICNAS may also publish a Section 58 notice during this stage if additional information is required.

If no applications were lodged after the declaration phase, the NICNAS Director may direct that the assessment report be started within 12 months, or the Director removes the chemical from the AICS after 12 months.

CONSULTATION

Corrections—NICNAS sends the draft report to applicants, who are given 28 days to check for errors. The applicants notify the NICNAS Director of errors. The NICNAS Director has 28 days to correct any errors.

Variation and/or public comment—NICNAS sends the draft report to applicants and notifiers (that is, responders to Section 58) who are given 28 days to comment.

A notice is published in the *Chemical Gazette* indicating that the draft report is publicly available for comment. Relevant persons are given 28 days to consider the draft report.

VARIATION OF DRAFT REPORT

The NICNAS Director considers submitted requests for variation within 28 days.

Decisions made by the Director are sent to each applicant and the person who made the request.

NICNAS publishes a notice that a copy of all decisions is available in the Chemical Gazette.

PUBLICATION OF FINAL REPORT

Persons are given 28 days from date of the notice on the draft report in the *Chemical Gazette* to consider the NICNAS Director's decision in their request for variation and can apply to the AAT to review this decision. The final report cannot be prepared or published until the AAT review is finalised.

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The final report is published once there are (a) no requests for variation, (b) no applications made to the AAT for review of the Director's decision or (c) following finalisation of any appeal to the AAT.

Section 48 Call for information notice

With a Section 48 Call for information notice, the NICNAS Director—when deciding whether to make a recommendation to declare a chemical as a PEC—can require you (and possibly others) to submit additional

information:

- about a chemical, such as its use and health and/or environmental effects
- the quantities of the chemical used for a specified purpose in a specified period (for example, its use in cosmetics over the past three years)
- the quantities of the chemical manufactured or imported in a specified period.

The notice will list those required to provide information and the period in which they must provide the information (at least 28 days). The list may include specific companies or associations, or it can be more general and ask all introducers or users to comply.

You must comply with the notice request within the time specified unless you provide a reason that satisfies the NICNAS Director. You can be penalised for non-compliance.

You must send the information required to the NICNAS Director, in English and as complete as possible to help the Director decide whether to recommend declaration.

When providing information, you can claim certain content as confidential and therefore exempt from publication, as long as you justify your request (see Confidential Information).

More guidance on exempt information is available in Confidentiality.

Section 51 Declaration notice

The Section 51 Declaration notice is published in the *Chemical Gazette* and sent by mail to relevant people stating what information should accompany an application.

The declaration may:

- apply to all aspects of the chemical or only to specific uses (for example, the assessment of 2butoxyethanol was for its use in cleaning products only)
- apply only when the chemical is manufactured, handled, stored or used at specific sites or in specific circumstances (for example, when stored in large quantities at specific locations)
- mention whether the chemical is to be assessed with another chemical or as a class of chemicals (chemicals can be declared and assessed as a group to increase assessment efficiencies—for example, the persulfates of ammonia, potassium and sodium were declared in April 1998 for assessment together).

The Declaration notice generally has four main components:

- 1. declaration statement, listing the chemical with its name and CAS number, whether the assessment is preliminary or full, and whether the declaration is to apply to the chemical generally or to a specific use, geographical area or circumstance
- 2. details on the requirement to apply for assessment, specifying who must apply, how and when
- 3. list of matters to be taken into account when assessing (for example, likely uses and risk to human health and the environment)
- 4. list of information that should accompany an application for assessment and how to provide it.

Information about responding to a Section 51 Notice is below.

Responding to a Section 51 Declaration notice

Once a chemical has been declared a PEC, anyone who wants to import or manufacture it—while it is a PEC —must first apply to have NICNAS assess the chemical.

The same applies to industry associations, unions or members of the public with health and/or environmental concerns about the chemical.

In all but exceptional circumstances, those who have applied for chemical assessment can continue to import or manufacture it during the assessment period. Certain activities (for example, the method of manufacture, or a particular use) may be prohibited while the chemical is a PEC on the grounds that the activity may be an unacceptable public health or environmental risk. In such cases, the Minister publishes a prohibition notice in the *Chemical Gazette*. A copy of this notice is sent to importers and manufacturers of the chemical.

To apply to have a PEC assessed, you must fill in the relevant form. There are no application fees, but there are financial penalties for failing to supply required information.

The information you need to supply with your application, and contact details for NICNAS assessment officer, will be included in the declaration notice published in the *Chemical Gazette*. The information you need to supply may include:

- the physical and chemical properties of the chemical, as listed in paragraph 9, Part B of the Schedule
- the occupational health and safety, public health and environmental effects of the chemical, including known effects and the items listed in Part C of the Schedule
- the quantity, or proposed quantity, of the chemical imported or manufactured, as listed in paragraph 5, Part B of the Schedule
- the uses or potential uses of the chemical, as listed in paragraph 3, Part B of the Schedule
- names of customers to whom you have supplied or intend to supply the chemical
- information on procedures relating to manufacturing procedures, handling (including transportation) and storing the chemical
- information about occupational health and safety, public health and environmental matters, particularly exposure matters, as outlined in paragraphs 6 to 8, Part B of the Schedule
- copies of labels and (M)SDSs of the chemical and products containing the chemical
- a description of procedures in place to deal with emergencies involving the chemical.

The information you need to supply will generally vary from chemical to chemical. For example, more information is usually required for a full assessment than for a preliminary assessment. Also, if no environmental assessment is required, then information on this will not be needed. Specific data on specific aspects of toxicology and ecotoxicity, other than those mentioned in a schedule may be required, depending on the chemical and its hazards.

With your application you also need to describe test methodology and test data and findings. NICNAS prefers that test data be gathered in accordance with currently accepted principles of good laboratory practice, such as OECD's Principles of Good Laboratory Practice.

NOTE: Tests conducted before 1981 may not have been carried out in accordance with good laboratory practice.

If you are a potential notifier, you are encouraged to discuss data requirements with the nominated NICNAS contact officer.

Section 58 Call for information notice

With a Section 58 notice NICNAS may ask past manufacturers, those expecting to introduce a chemical in the near future, formulators and industry associations to supply information.

The information requested is usually the same as with a Section 51 Notice, but sometimes additional information is required from a particular notifier.

You must comply with the request within the time specified unless you provide a reason that satisfies the NICNAS Director. You can be penalised for non-compliance.

You must send the information to the NICNAS Director, in English and as complete as possible to help the Director decide whether to recommend declaration.

When providing information, you can claim certain content as confidential.

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Joint applications

Joint applications for assessment are allowed under the Act (two or more manufacturers or importers). This may involve sharing information and compiling it so it is only supplied once (for example, common toxicity data). You may also need to appoint one coordinator to liaise with NICNAS.

Information on use, worker exposure and handling procedures of the chemical should be submitted individually by each applicant so NICNAS has a cross-section of information to assess.

Confidential information

When providing information, you can claim certain content as confidential and therefore exempt from publication, as long as you justify your request. Send the main body of information with Form 3, detailing what you need to be kept confidential. At the same time, send your nominated fee payment.

More guidance on exempt information is available in Confidentiality.

Assessment report contents

While the contents of all PEC assessment reports differ—depending on scope and matters that need to be taken into account—most contain the common elements outlined in the table below.

Table: Common elements of Priority Existing Chemical assessment reports

Element	Description
Introduction	Background, scope, purpose
About the chemical Chemical identity General information about the chemical	Identity, physical and chemical properties Methods of detection and analysis
Uses of chemical and products containing the chemical	Details on import, manufacture and formulation (concentrating on uses in Australia) etc.
Occupational exposure assessment	Exposure during manufacture and/or formulation and during various end uses Usually includes monitoring results and details of surveys conducted
Environmental exposure assessment	Sources of environmental exposure and fate and transformation processes Measures and estimates of environmental exposure
Public exposure assessment	Sources and routes of public exposure Measures and estimates of public exposure
Health hazards of the chemical	Based on an assessment of toxico-kinetics and metabolism, effects in animals and <i>in vitro</i> test systems, and human health effects, including an assessment of toxicological studies submitted by applicants and studies and reports in the literature Where possible, results from international reports
Health hazard classification	Based on an assessment of health effects against the Approved Criteria for Classifying Hazardous Substances and GHS.
Environmental hazard	Assessment of effects on plants and organisms
	Results from examination of potential exposure to the chemical, bringing together results of the human

Human health risk characterisation	health hazard assessment and the occupational, health and safety and public exposure assessments—to give a measure of risk to workers and the public (for example, this might be a margin of exposure estimated for each exposure scenario)	
Environmental risk characterisation	Identification of critical effects and estimation of environmental risks	
Risk management strategies for controlling human exposure, particularly occupational health and safety exposure	Assessment of current labels and (M)SDSs of the chemical and of products containing the chemical Includes details of current regulatory controls such as exposure standards and health surveillance	
Environmental risk management practices	Assessment of control measures and monitoring practices and options for improved risk management	
Recommendations	 May be on such matters as: uses of the chemical and, for example, whether any restriction on use is warranted control measures, including regulatory controls that need to be implemented during manufacturing, importing, handling, storing, using and disposing of the chemical to ensure the health of anyone exposed to it is not negatively affected control measures, including regulatory controls[1] that need to be implemented to protect the environment packaging and labeling requirements for the chemical and products containing the chemical content of the (M)SDSs of the chemical and products containing the chemical means of disposing the chemical procedures to protect people and the environment in an emergency associated with the chemical further assessment if required 	
Circumstances in which Secondary Notification may be required	Includes a summary of the occupational health and safety and environmental matters assessed Lists recommendations about certain matters specified in the Act	

[1] Regulatory controls may include hazard classification, exposure standard, poisons scheduling, health surveillance and other matters such as substitution, ventilation, safe work practices and emission control systems.

PEC assessment reports do not contain exempt information.

More information on assessment methodologies for NICNAS assessments is in Assessment methodologies.

Consultation on a draft assessment report

NICNAS is committed to accuracy in its reports and is rigorous in its assessments. To this end, NICNAS invites scrutiny of reports (with drafts reviewed by applicants and other interested parties) as they are produced and welcomes corrections, comments and suggestions for variations throughout the period in which the draft report is available for public comment.

Correcting errors in a draft assessment report

The steps for correcting errors in draft assessment reports and how applicants may be involved are listed here:

After a draft assessment report is completed:

1. NICNAS sends a copy to each applicant asking them to correct any apparent errors. These may include factual (for example, volumes of chemical imported), calculation and/or editorial errors.

2. If you find errors in the draft assessment report, you must:

3. NICNAS verifies your notice and amends the draft report if required. Under the Act NICNAS must do so within 56 days of the notice being sent to you.

- notify the Director within 28 days of the notice being sent to you;
- do so in writing, clearly state where the error is located in the report, the suggested correction to be made and, if necessary, a reference to support the suggested correction.

This phase of the assessment process is not intended to address formal amendments to the report based on matters such as scientific methodology and expert judgment.

These types of changes are handled later in the formal variation period. You may, however, take the opportunity when commenting on the draft assessment report to foreshadow that you will be submitting applications detailing these type of changes.

Variation of corrected draft assessment report

You can request changes or variations to the corrected draft assessment report. There are no fees for doing so.

After corrections are made, a copy of the next version of the draft report is sent to you and anyone else who provided information for the assessment in response to a notice under Section 58 of the Act. This must be done within 56 days of the initial uncorrected draft report and notice being sent to applicants.

NOTICE IN CHEMICAL GAZETTE

Within these 56 days, NICNAS will place a notice in the *Chemical Gazette* describing how a person may obtain a copy of the corrected draft report and how to make a request to vary it. Copies of the corrected draft report are available from NICNAS.

REQUEST TO VARY THE DRAFT ASSESSMENT REPORT

Within 28 days of this notice being published in the *Chemical Gazette*, you may ask the NICNAS Director to vary the draft assessment report.

For example, you may disagree with the conclusions or recommendations in the report on scientific grounds and make a request that the report be altered.

You must make variation requests on Form 4a, and send it to the NICNAS Director. You must identify the exact words, sentences or paragraphs in the report you want varied and state replacement words, sentences or paragraphs. You must also clearly explain the rationale behind your request for variation and provide references so the Director can decide whether to alter the report.

VARIATION OF THE DRAFT ASSESSMENT REPORT

The Director may accept or refuse any request to vary the report. In all cases, the decision will be based on sound scientific judgment and advice, and the reasons will be clearly stated in the response. It must also be made within 56 days of the notice in the *Chemical Gazette* inviting applications for variation. NICNAS will send a copy of each decision to each applicant and make it publicly available.

If you disagree with the Director's decision relating to an assessment report you can submit your concerns to the AAT. NICNAS will hold back on publishing the document until this process is finished and any of the AAT's directions incorporated. If no appeals are made, the Director changes the report and proceeds to publish. In doing so, the Director:

- publishes a notice in the *Chemical Gazette* stating the decision made on the request, the rationale behind it and specifying how a copy of the decision can be obtained
- gives a copy of the decision and the notice to each applicant.

Once the draft assessment report is changed in accordance with the variation process, it becomes the final assessment report for the PEC.

Finalising assessment reports

FINAL ASSESSMENT REPORT

A notice is published in the *Chemical Gazette* stating that the report is available on the NICNAS website.

NICNAS issues the final assessment report to each applicant and each respondent to the Section 58 Notice as well as to Australian Government departments responsible for public health and the environment.

In addition, NICNAS usually gives copies to the relevant authorities in each state and territory, which may adopt some recommendations.

Once the final assessment report is published, the chemical is no longer a PEC.

Post-assessment reporting obligations

The Secondary Notification of a chemical previously assessed as a PEC may be required where NICNAS or a person introducing, or has introduced, the chemical becomes aware of circumstances that may warrant reassessing its hazards and risks.

The NICNAS assessment report lays out circumstances under which you must advise the NICNAS Director of post-assessment obligations. It is the importer's and/or manufacturer's responsibility to inform the NICNAS Director of a change of circumstances and this must be done within 28 days of the changed circumstance. Obligations are detailed under Section 64, Division 6, of the Act.

Chapter 9 provides guidance on the types of circumstances that may require a Secondary Notification as well as the Secondary Notification procedure.

Removing a chemical from the Australian Inventory of Chemical Substances

The NICNAS Director must remove a chemical declared a PEC from the AICS when:

- no application for its assessment as a PEC has been received within 12 months after declaration
- the chemical has not been assessed under the NICNAS Director's instruction.

1.7.3 PRIORITY EXISTING CHEMICAL OFFENCES AND PENALTIES-A SUMMARY

If you do not comply with NICNAS requirements for PECs you will be deemed to have committed an offence and penalties will apply. These are summarised in the table below.

TABLE: SUMMARY OF PRIORITY EXISTING CHEMICALS OFFENCES AND PENALTIES

Section/offence	Guidance	Maximum penalty: individual (corporation)
s48(7) Contravening a notice requesting information about potential PECs (Fault based offence)	The NICNAS Director may place a notice in the Chemical Gazette calling for information about an existing chemical being considered for declaration as a PEC. The notice will include details of the persons required to provide the information and the period in which it is to be provided (at least 28 days).	\$6,600 (\$33,000)
s56 Introducing a PEC (without applying for assessment under s55) (Fault based offence)	Importing and/or manufacturing a PEC is prohibited without submitting an application for the assessment of the chemical.	\$33,000 (\$165,000)
s58(8) Contravention of a call for information about a PEC (Fault based offence)	To assess a PEC, the NICNAS Director may, by notice in the Chemical Gazette, require a person to provide information about the chemical. All persons specified in the notice must provide the required information to the Director within the time specified.	\$6,600 (\$33,000)
s61(4) Failure of an importer or manufacturer to comply with a notice prohibiting an activity while the chemical remains a PEC (Fault based offence)	If the Minister believes an activity involving a PEC gives rise to an unacceptable risk of adverse public health or environmental effects, the Minister may prohibit that activity by a notice in the Chemical Gazette. You must comply with the notice.	\$33,000 (\$165,000)
s61(5) Failure of a person other than an importer or manufacturer to comply with a notice prohibiting an activity while the chemical remains a PEC (Fault based offence)	If the Minister believes an activity involving a PEC gives rise to an unacceptable risk of adverse health or environmental effects, the Minister may prohibit that activity by a notice in the Chemical Gazette. A person, other than an importer or manufacturer of the chemical,	\$26,400 (\$132,000)

1.8 SECONDARY NOTIFICATIONS

The Secondary Notification of a chemical previously assessed by NICNAS may be required if a person who introduces the chemical, or NICNAS, becomes aware of circumstances that may warrant reassessment of its hazards and risks.

This requirement is detailed under Section 64, Division 6, of the Act - see: Legislation and regulations.

Sections of this chapter:

- Providing secondary notification information
- Making a secondary notification to NICNAS
- Assessment process and reports
- Penalties for failing to notify

1.8.1 PROVIDING SECONDARY NOTIFICATION INFORMATION

Even after NICNAS has formally assessed a new or existing chemical there may be a significant change in circumstances requiring a reassessment of particular aspects of the chemical. This is called a Secondary Notification and assessment.

NICNAS will assess the information you provide on the changed circumstances and determine if they impact significantly on the original report's findings. If so, NICNAS will call for Secondary Notification of the notified chemical through the *Chemical Gazette*.

1.8.2 MAKING A SECONDARY NOTIFICATION TO NICNAS

You must notify NICNAS when you become aware of a significant change in circumstances relating to an assessed new or existing chemical.

You are responsible for informing NICNAS of any significant changes from those outlined in the original assessment report of the chemical. You must do so within 28 days of becoming aware of such a change.

These obligations apply regardless of the AICS status of a chemical. Even after a chemical is listed on the AICS you must still advise the NICNAS Director of significant changes.

Relevant changes requiring a Secondary Notification are those that may increase occupational health and safety, public health or environmental risks, including but not limited to:

- A significant new use of the chemical which may:
 - increase the potential for human exposure (for example, increased concentrations in consumer products)
 - increase environmental exposure
 - change the type of exposure (for example, from dermal exposure to inhalation or a chemical initially used as a catalyst in a chemical reaction may later be used as a metal cleaning agent).

- A significant increase in the quantity of chemical imported or manufactured (for example, a tonnage increase from 1 to 10 tonnes/year or from 50 to 500 tonnes/year). Apart from potentially increased exposure, a significant increase in quantity may lead to a change in the type of exposure (for example, the method of disposing large quantities may be different from the method of disposing small quantities).
- Production in Australia may have begun for a chemical initially assessed as an imported chemical.
- A change from less than 1 tonne to more than 1 tonne for a chemical originally notified as a LTD (<1 tonne).
- A polymer originally notified as a PLC that no longer meets the PLC criteria.
- A change in manufacturing method, which may lead to increased risk by:
 - changing from a closed process to an open system
 - using different raw materials
 - using different processing conditions
 - increasing the number of workers required to deal with the chemical
 - changing the type of exposure
 - changing the method of waste disposal
 - increasing the environmental exposure.
- New information on the chemical's potential hazardous properties that have been identified since initial assessment (for example, it may become known that the chemical is carcinogenic).

If in doubt on whether a Secondary Notification is required, contact NICNAS for advice.

Determining and calling for secondary notification

NICNAS will assess the information you provide on a significant change and any other information of which NICNAS becomes aware, to determine if reassessment and a secondary notification is required.

If the NICNAS Director decides Secondary Notification is required, a notice will be placed in the Chemical Gazette, addressed to a specific notifier (usually selected importers and manufacturers) or to everyone who imports or manufactures the chemical.

The Director may also contact persons who may have information that can help with the secondary assessment. In these cases, the Director will give notice in the Chemical Gazette to other selected importers and manufacturers of the chemical, asking them to submit information on the changed circumstances that prompted the Secondary Notification.

By taking into account the change in circumstances and the impact they will have on occupational health and safety, public health and the environment, the notice will specify the data items in the schedule where information must be provided. For example, a significant new use of the chemical may lead to a revised occupational health and safety assessment or additional toxicity data being required.

Applying for secondary notification

You need to apply for a Secondary Notification of a new chemical on the relevant form (Form SN-1) and an existing chemical on this form (Form 1A-SN). You must include all available information specified in the notice placed by the NICNAS Director in the Chemical Gazette.

You must provide all documents supporting the Secondary Notification in English. You can request certain content confidential (meaning it will not be published), as long as you justify your request.

More information is available in Confidentiality.

There is no fee for applying for Secondary Notification of an existing chemical on the AICS. In all other circumstances a fee applies and the types and amounts are listed at Fees and Charges.

1.8.3 ASSESSMENT PROCESS AND REPORTS

The process, including assessment time frames, differs depending on whether it is a secondary notification of an existing chemical or a new chemical.

Secondary notifications of chemicals listed on the AICS are assessed as existing chemicals.

Secondary notification of chemicals not yet listed on AICS, but which have been assessed by NICNAS (i.e. those still in the 5-year certificate period) are assessed under the new chemicals process.

NICNAS completes a new chemical Secondary Notification assessment within 90 days from the date a complete secondary notification application package is received.

Following the assessment of a new chemical under a Secondary Notification, NICNAS revises the original assessment report within 90 days.

NICNAS then prepares a revised report and sends to the applicant the:

- assessment report (version containing exempt information)
- public report (assessment report without exempt information)

Comparison of secondary notification procedures for new and existing chemicals

The secondary notification procedures differs for new chemicals and existing chemicals, as outlined in the following table.

TABLE: COMPARISON OF SECONDARY NOTIFICATION PROCEDURES FOR NEW AND EXISTING CHEMICALS
Phase	New chemicals procedures	Existing chemicals procedures
Receipt of additional information	Review of information to determine if Secondary Notification is required.	Review of information to determine if Secondary Notification is required. Publication of an information product (for example a Chemical Gazette notice) if Secondary Notification is not required.
Calling for Secondary Notification	Secondary Notification is required from you as the provider of additional information and possibly other introducers of the notified chemical.	Secondary Notification is required from you or from all parties holding information.
Fee	Fee applies	No fee applies
Assessment time frame	Within 90 days from receipt of last information (may be extended)	Six months from receipt of last information (may be extended)
Correction of draft report	Forwarded to you (applicant) for correction and/or variation. Applicant has 14 days to respond.	Report provided to all applicants asking that any factual errors must be notified to NICNAS within 28 days. NICNAS then has 28 days to correct the errors.
Variation of draft report	Only you (applicant) can ask for a draft report to be varied. No separate variation phase. It is	Following the correction phase, the draft assessment report is provided to you and other applicants and persons who provided information for the assessment. A Chemical Gazette notice is published, inviting others to obtain a copy of the report and request variations. NICNAS must receive variation
	combined with the correction phase.	requests within 28 days and respond to them within 56 days. NICNAS must provide variation decisions to all applicants and

		persons requesting variations. Other parties may also request this information. Anyone can lodge appeal within 28 days.
Public comment	The public can comment after the final report is published, but must request variations within 28 days of the publication date. You may also request further variation at this time.	Public comment on draft reports (discussed under 'Variation of draft report' immediately above).
Publication of final report	Published 28 days after the final report is first provided to the applicant, unless other variation requests are outstanding.	Report may be published after the last date for submitting variation requests if none are received. Otherwise, unless an appeal against a variation decision is made, publication occurs 56 days after the last date for submitting variation requests.
Appeal	Variation decisions can be appealed to the AAT.	Variation decisions can be appealed to the AAT.

1.8.4 PENALTIES FOR FAILING TO NOTIFY

You can be penalised for failing to notify the NICNAS Director of a change in circumstances relating to a chemical, if you had—or should have had—relevant knowledge or information.

When deciding whether you should have been aware of a change in circumstances, the Director will take into account your knowledge, skills and experience, as well as the nature of the changed circumstances. This could include, for example, the impact of the change on the occupational health and safety of workers, the public at large and/or the environment.

If you are in doubt about whether a secondary notification is required contact NICNAS for advice.

If you fail to make a Secondary Notification for new chemicals the Minister can suspend any assessment certificate or permit you hold for that chemical.

If you are importing or manufacturing the chemical in Australia as an existing chemical, non-compliance can lead to the importation or manufacture being prohibited.

If you do not comply with NICNAS requirements for Secondary Notification you will be deemed to have committed an offence and penalties will apply. These are summarised in the following table.

TABLE: SUMMARY OF SECONDARY NOTIFICATION OFFENCES AND PENALTIES

Section/offence	Guidance	Maximum penalty: individual (corporation)
s64(1)(2) Failure to notify the NICNAS Director within 28 days of certain specified circumstances occurring giving rise to the obligation of Secondary Notification (Fault based offence)	 If you have introduced an industrial chemical that was assessed by NICNAS and become aware of certain changes you must notify the NICNAS Director of the changes within 28 days. This includes when: the function or use of the chemical has or is likely to change significantly the amount of chemical introduced has or is likely to increase significantly an imported chemical has begun to be manufactured the method of manufacture has or is likely to change in a way that increases the risk additional information is available on the adverse occupational health and safety, public health or environmental effects of the chemical other circumstances recommended on the assessment report for the chemical have occurred. 	\$13,200 (\$66,000)
s67 Failure to comply with secondary notification requirements (Fault based offence)	The NICNAS Director may, by notice in the Chemical Gazette, require the Secondary Notification of a chemical by persons to whom the notice applies within a period of not less than 28 days. Persons to whom the notice applies must provide information about the chemical that is to be given by way of Secondary Notification within not less than 28 days.	In the case of a new industrial chemical: the Minister may suspend any assessment certificate or introduction permit held by the person for that chemical AND impose a penalty of \$13,200 (\$66,000) In any other case: the Minister may prohibit the importation and manufacture of the chemical by that person AND impose a penalty of \$13,200 (\$66,000)
	The NICNAS Director may	

s69 Contravention of a notice by the NICNAS Director in the Chemical Gazette requiring information for the purposes of assessment of chemicals (existing/new) requiring Secondary Notification (Fault based offence)	 (through a notice in the Chemical Gazette) for the purpose of assessing a new or existing industrial chemical requiring Secondary Notification, require any of the following to provide the information specified on the notice: all persons who introduce the chemical specified persons who introduce the chemical specified persons who may have relevant information on the chemical but who are not required to give Secondary Notification. 	\$6,600 (\$33,000)
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1.9 CHEMICAL GAZETTE

NICNAS's Chemical Gazette is a special edition of the Commonwealth Government Gazette.

It covers important matters, regulatory issues and requirements for chemical introduction and publishes operational information relating to NICNAS by way of notices or declarations by the Minister for the Department of Health and Ageing or by the Director of NICNAS. Occasionally it includes information on other industrial chemical matters, such as exposure standards.

The Chemical Gazette is published by NICNAS electronically on the first Tuesday of each month.

For the most recent and archived editions, see: Chemical Gazette webpage.

Additional editions are occasionally published.

Companies, organisations, government departments and individuals may subscribe to receive emails alerting them to new editions of the *Chemical Gazette*.

Printed copies are available by contacting NICNAS on 02 8577 8800 / +61 2 8577 8800 or freecall 1800 638 528.

You can read the *Chemical Gazette* during business hours, free of charge, at: NICNAS Level 7, 260 Elizabeth Street SURRY HILLS NSW 2010

You will need to call 02 8577 8800 to make an appointment to visit the NICNAS office.

You can also read the *Chemical Gazette* at a number of state and territory libraries, or other libraries that subscribe.

Important notices and/or declarations relating to NICNAS, which must be published in the *Chemical Gazette*, are detailed in this chapter.

Sections of this chapter:

- Summary of new chemicals assessments
- Notice calling for information about an existing chemical 76/323

- Declaration of a Priority Existing Chemical
- Publication of final assessment report for an existing chemical
- Other notices and/or declarations which must be published in the Chemical Gazette

1.9.1 SUMMARY OF NEW CHEMICALS ASSESSMENTS

Once a permit or certificate has been issued for a new chemical, a notice is published in the Chemical Gazette consisting of:

- name of the chemical
- name of each applicant or notifier
- whether or not the chemical has been determined to be a hazardous chemical
- introduction volume
- use of the chemical
- a link to the public report on the NICNAS website (for certificate assessments only).

1.9.2 NOTICE CALLING FOR INFORMATION ABOUT AN EXISTING CHEMICAL

A notice calling for information about an existing chemical will be issued in the *Chemical Gazette* when the NICNAS Director is considering whether to recommend declaring it a PEC. The notice will request you, as applicant, to provide the following information:

- specific information about the chemical (for example, its health and environmental effects)
- the names and quantities of those chemicals used for a specified purpose in a specified period
- the names of those chemicals introduced in specified quantities in a specified period (for example, volumes manufactured over the previous five years).

1.9.3 DECLARATION OF A PRIORITY EXISTING CHEMICAL

When the Minister for the Department of Health and Ageing (the Minister) declares a chemical or group of chemicals as PECs, this is announced through the *Chemical Gazette*. The notice specifies, for each chemical:

- whether the declaration applies to the chemical generally or specifically (for example, only to specific uses)
- · whether the assessment is to be a preliminary assessment or a full assessment
- matters to be taken into account in the assessment
- information to accompany applications for assessments
- whether the declared chemicals are to be assessed together (when more than one chemical is involved).

1.9.4 PUBLICATION OF FINAL ASSESSMENT REPORT FOR AN EXISTING CHEMICAL

A notice stating that the report is available on the NICNAS website will be issued in the Chemical Gazette.

1.9.5 OTHER NOTICES AND/OR DECLARATIONS WHICH MUST BE PUBLISHED IN THE CHEMICAL GAZETTE

In addition to the notices outlined above NICNAS is obliged to publish a range of other notices and/or declarations in the *Chemical Gazette*, as outlined in the following table.

TABLE: OTHER NOTICES OR DECLARATIONS THAT MUST BE PUBLISHED IN CHEMICAL GAZETTE

Section in the Act	Notice or declaration
14(1)	Inclusion of a new chemical in the AAICS five years after the giving of an assessment certificate (other than an extension of an original certificate).
20(a)	Addition of information concerning chemicals added to the AICS before 17 July 1990, or between 1 March 1993 and 17 July 1993.
20(aa)	Addition of extra information about industrial chemicals already in the AICS, obtained under Section 20AB (details of trade name products).
20(b)	Correction of an error in the AICS (except for the wrong inclusion of a chemical in the inventory).
20AA(1)	Removal of a chemical that has been wrongly included in the AICS.
20AB	Request for identity of chemicals making up (comprising) trade name products.
21AB(2)	List of chemicals introduced under an exemption.
21J	Issue of Commercial evaluation permit.
21Y	Issue of Low volume permit.
21ZA(2)	List of chemicals for which a Low volume permit has been issued.
30(2)	Issue of a permit to import a chemical before assessment is completed.
30A	Grant of a permit for early introduction of a non- hazardous chemical.
40(2)	Application for variation of a full public report.

40(7)	Decision on an application for variation of a full public report.
40G	Publication of a summary assessment report, incorporating modifications.
41(2)	Equivalence of a state or territory government scheme.
41(4)	Revocation of a state or territory government scheme equivalence.
43(2)	Notice of approval of a foreign scheme.
43(6)	Notice of a foreign scheme no longer approved.
50A(4)	Notice stating where a summary of information given under Section 48 of the Act can be obtained.
54(3)	Lists of chemicals that are PECs and chemicals that have been PECs.
58(1)	Notice to seek information for assessment of a PEC.
60E(1)	Notice for variation of draft PEC assessment report.
60E(6)	Notice of a decision concerning a request for variation of draft PEC assessment report.
61(2)	Prohibition of an activity involving a PEC until assessment is completed.
65(1)	Notice to require secondary notification.
68(4)	Notice stating the availability of the public assessment report after secondary notification, by

	reference toSection 38.
69(1)	Notice requiring information for a secondary notification to be provided.
71(3)	Lists of chemicals that require secondary notification or that have required, but no longer require, secondary notification.
72	Declaration that a chemical is no longer subject to secondary notification.
74(2)	List of chemicals for which assessment certificates are in force.
105(1)	Amendment of the schedule to the Act.
106(2)	Notice requiring persons importing or exporting a particular chemical named under a specified international agreement to give information in the approved form about movements of the chemical into or out of Australia.

1.10 COMPLIANCE AND ENFORCEMENT

NICNAS works with all importers and manufacturers to help them meet their compliance requirements when introducing industrial chemicals.

Communication takes place by phone and email, information sessions, site visits and occasional auditing visits—through which NICNAS compliance staff help you better understand processes and compliance requirements.

This chapter outlines NICNAS's approach to compliance and enforcement.

Sections of this chapter:

- NICNAS's compliance style
- The NICNAS Compliance and Enforcement Program
- Detecting and managing non-compliance
- Enforcement provisions, offences and penalties
- Role of NICNAS's compliance inspectors

• Can a foreign company make an application under the ICNA Act?

Note: Further information on compliance requirements is available from the Regulation and Compliance webpage.

1.10.1 NICNAS'S COMPLIANCE STYLE

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (see Legislation and regulations), NICNAS scientifically assesses industrial chemicals for their health and environmental effects and makes recommendations for safe use. The Act also details the regulatory obligations of importers, manufacturers and exporters of industrial chemicals. These regulatory obligations provide the focus of the NICNAS Compliance and Enforcement Program.

The program aims to ensure that manufacturers, importers and exporters of industrial chemicals are aware of, and exercise, their responsibilities under the Act.

As an industrial chemical manufacturer, importer or exporter, you need to be aware that NICNAS conducts audits, inspections and investigations to ensure compliance with legislation.

NICNAS values a cooperative approach in ensuring compliance, through partnerships with the Australian chemical industry and the public, and by maintaining a strong focus on education and awareness-raising activities such as training seminars.

NICNAS protects the business interests of compliant importers, manufacturers and exporters by ensuring high levels of transparency, competence and professionalism in its approach to compliance.

HIERARCHICAL ENFORCEMENT

The enforcement of the NICNAS Compliance and Enforcement Program is hierarchical. It starts with a persuasive approach—employing no sanctions—and gradually moves, as necessary, to formal sanctions. The program's hierarchy is illustrated in the figure.

FIGURE: NICNAS COMPLIANCE AND ENFORCEMENT PROGRAM HIERARCHY



1.10.2 THE NICNAS COMPLIANCE AND ENFORCEMENT PROGRAMME

The NICNAS Compliance and Enforcement Programme maximises voluntary compliance by:

- identifying, assessing and resolving non-compliance
- raising awareness of NICNAS obligations
- acquiring and encouraging feedback from industry and the public to help NICNAS develop and evaluate its
 education and compliance strategies
- assessing industry compliance and awareness of regulatory requirements
- developing and nurturing relationships with industry and community interest groups
- maintaining a visible presence in the chemical industry
- demonstrating NICNAS' proactive approach to compliance.

1.10.3 DETECTING AND MANAGING NON-COMPLIANCE

NICNAS's non-compliance casework is generated through self-reporting, third party allegations, audits and internal checks.

Self-reporting of non-compliance

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Sometimes importers or manufacturers (introducers) or exporters formally advise NICNAS that they are inadvertently not complying with the legislation.

Self-reporting is an important early step in taking action to rectify non-compliance. NICNAS has the discretion to apply or not apply sanctions to a non-compliant party that self-reports. In deciding NICNAS takes into account a range of factors such as:

- the explanation/reason for the non-compliance and whether it was inadvertent
- whether non-compliance was due, or partially due, to a systemic flaw and the offender initiated or expressed willingness to remedy the flaw and check for other instances of non-compliance that may have resulted from that flaw
- the offender is committed to remedying the breach within agreed time frames.

When NICNAS is informed of an inadvertent non-compliance, the approach taken is to meet with the offender to negotiate a timetable of actions to remedy the issue.

Third-party allegations

NICNAS encourages third parties to provide information on breaches of industrial chemicals legislation.

NICNAS investigates all formal third-party allegations, ensuring complete confidentiality in all cases.

Third parties should bring potential non-compliance issues to the attention of the NICNAS compliance and enforcement team by:

- emailing NICNAS
- telephoning 1800 638 528
- faxing 02 8577 8888 / +61 2 8577 8888
- writing to the Compliance and Enforcement Program at NICNAS, GPO Box 58, SYDNEY, NSW 2001
- arranging to meet with a NICNAS officer.

Third parties need to use the NICNAS form for reporting non-compliance.

1.10.4 ENFORCEMENT PROVISIONS, OFFENCES AND PENALTIES

If you commit an offence under the *Industrial Chemicals (Notification and Assessment) Act 1989* you can be punished.

Offences and specific penalties are detailed under the Act and throughout this Handbook. This information in this Handbook should only be used as a guide and not relied on as legal advice.

Those prosecuted and found to be in breach of the Act are liable for fines of up to \$33,000 for an individual and \$165,000 for a company.

More information on your obligations, possible offences and penalties is in the *Industrial Chemicals (Notification and Assessment) Act 1989* and the Industrial Chemicals (Notification and Assessment) Regulations 1990, both of which can be accessed at Legislation and regulations.

Other offences—a summary

If you do not comply with NICNAS requirements for miscellaneous requirements you will be deemed to have committed an offence and penalties will apply. These are summarised in the following table.

Table: Summary of miscellaneous offences and penalties under the Act

Section /offence	Guidance	Maximum penalty: individual (corporation)
s81A A person commits an offence if they import or manufacture a cosmetic which is subject to a standard set under Section 81 and the cosmetic does not meet that standard	Importers or manufacturers of cosmetics must ensure that the requirements of the Cosmetic Standard 2007 are met.	\$13,200 (\$66,000)
s88(3) Refusal to answer questions or produce documents requested during an inspection	A person must produce documents and requested information to NICNAS so an inspector can determine compliance with the Act or regulations.	\$3,300 (\$16,500)

1.10.5 ROLE OF NICNAS'S COMPLIANCE INSPECTORS

NICNAS compliance inspectors are appointed by the NICNAS Director. They are usually NICNAS staff, but the Director has the authority under the Act to arrange for state and territory public servants to exercise inspectorate powers on behalf of NICNAS.

NICNAS inspectors conduct:

- site visits to monitor compliance with the Act
- investigations into suspected and/or reported breaches of the Act.

Inspectors are empowered to conduct searches to monitor compliance with the Act where there are reasonable grounds for suspecting that:

- an industrial chemical is being manufactured
- an industrial chemical—whether imported into Australia or manufactured in Australia—is being stored, processed or used
- records relating to importing, manufacturing, handling, storing, using or disposing of an industrial chemical are kept.

An inspector may enter any premises to ascertain compliance with the Act if the inspector has the consent of the occupier of the premises. If consent is not given, the inspector may apply to a Court for a warrant to enter the premises.

Conducting an inspection

During an inspection, the inspector (or inspectors) may, to the extent it is reasonably necessary for determining compliance or non-compliance with the Act:

• search the premises

- take photographs (or make sketches) of the premises or any substance or thing at the premises
- take and keep samples of any substance at the premises
- inspect any record or document kept at the premises
- remove or make copies of any such record or statement.

Search and seizure provisions

Where the inspector has reasonable grounds for suspecting there may be evidence on the premises of a breach of the Act, the inspector may:

- with the consent of the occupier of the premises, search the premises and seize the evidence
- without the consent of the occupier, obtain a warrant and then search the premises and seize the evidence.

Where the inspector seizes any 'thing' under the search and seizure provisions of the Act (including samples, records and other documents), the inspector may keep the 'thing' until proceedings are concluded.

Prosecutions

Where NICNAS has determined an offence has been committed under the Act, the relevant inspectors will prepare evidence briefs. These briefs of evidence are referred to the Commonwealth Director of Public Prosecutions for consideration. The decision to prosecute an offender resides with the Director.

1.10.6 CAN A FOREIGN COMPANY MAKE AN APPLICATION UNDER THE ICNA ACT?

For example an application for a chemical assessment or for confidential listing on the Inventory?

Yes, a foreign company can make an application under the ICNA Act, provided that the foreign company has complied with requirements of the Corporations Act 2001 (Cth), such as obtaining an Australian Registered Body Number (ARBN). The Corporations Act 2001 (Cth) is administered by the Australian Securities and Investments Commission (ASIC). Information for foreign companies that wish to carry on business in Australia is available from the ASIC website: http://www.asic.gov.au/asic/asic.nsf/byheadline/Foreign+Companies

1.11 INTERNATIONAL OBLIGATIONS

On behalf of the Australian Government, NICNAS administers two international conventions that promote the safe management of hazardous chemicals:

- Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (known as Rotterdam Convention)
- Stockholm Convention on Persistent Organic Pollutants (known as Stockholm Convention).

Sections of this chapter:

- Rotterdam Convention
- Stockholm Convention on Persistent Organic Pollutants
- Other international treaties
- Offences and penalties relating to Australia's obligations under international agreements—a summary

Note: Further information about NICNAS's international activities is available on the International Engagement webpage.

1.11.1 ROTTERDAM CONVENTION ORIGINS

Increased production, trade and use of chemicals internationally during the 1960s and 1970s coincided with a growing awareness of, and concern about, the risks that the use of hazardous chemicals could pose to human health and the environment. Further concerns arose that regulatory action in some countries to ban or restrict the use of certain chemicals could result in these chemicals being exported to other countries where regulatory systems, infrastructure and resources were sometimes not adequate to assess and control the risks.

The Rotterdam Convention, a multilateral environment agreement, provides obligations on the import and export of certain hazardous chemicals. Signatory countries (including Australia) are empowered through virtue of membership, to make informed decisions about the chemicals they want to receive, and to exclude those they believe they cannot manage safely.

The Rotterdam Convention entered into force on 24 February 2004. On entry into force it became legally binding for its parties.

Objectives and scope

The Rotterdam Convention's overall objective is to promote shared responsibility and cooperative efforts among parties in the international trade of certain hazardous chemicals to protect human health and the environment from potential harm, and contribute to their environmentally sound use.

The chemicals eligible for inclusion are industrial chemicals and pesticides that have been banned or severely restricted nationally for public health and environmental concerns. A group of pesticides called 'severely hazardous pesticide formulations' are also included.

Prior informed consent procedure

The PIC procedure applies to the chemicals listed in Annex III of the Convention. For each chemical a Decision Guidance Document is prepared and sent to all parties, with a request that they decide whether to allow it to be imported. These decisions, known as import responses, are sent to the Convention's Secretariat.

The Secretariat compiles the decisions and circulates them to all parties every six months through the PIC Circular.

The PIC Circular contains information on national final regulatory actions to ban or severely restrict chemicals, as well as proposals for hazardous pesticide formulations submitted by parties. It also includes an up-to-date list of the chemicals subject to the PIC procedure, a compilation of all party's import decisions and a list of parties that have not provided import decisions.

All parties are required to ensure that chemicals subject to the PIC procedure are not exported contrary to the decision of an importing party. This means that a chemical will not be exported to a party that has indicated it does not wish to receive imports of the chemical. If the importing party has indicated it will allow import subject to certain condition(s), then the exporting party must ensure these condition(s) are met. The key to PIC, in other words, is to ensure that chemicals are not shipped by an exporting party without the PIC of the importing party.

Information exchange and the Rotterdam Convention

Information exchange is imperative to upholding the spirit of the Rotterdam Convention. Opportunities for information exchange cover a broad range of chemicals, including those listed in Annex III of the Convention and those that have been banned or severely restricted by any party. In addition, Article 14 mandates a general exchange of scientific or regulatory information 'relevant to the objectives of the Convention' and of potential interest to regulators around the world.

Convention provisions provide opportunities to obtain information on potentially hazardous chemicals and to share information and experience with countries facing similar concerns. The most important tools for information exchange include the PIC Circular, export notifications, decision guidance documents, the network 87/323

of Designated National Authorities and the Rotterdam Convention website.

Designated National Authorities are expected to disseminate information to all relevant agencies that may be involved in regulating, producing and trading chemicals in their country (for example, government departments, manufacturers and export industries). This is to enable agencies to take appropriate action to ensure exports do not occur contrary to importing party decisions.

Article 13 of the Rotterdam Convention outlines the information that is to accompany exported chemicals, both those included in Annex III and those banned or severely restricted for export. The purpose of Article 13 is to ensure information on chemicals is provided to importing parties to help them minimise risks to human health and the environment.

Specific requirements include:

- Specific Harmonized System customs codes for chemicals in Annex III assigned by the World Customs Organization
- labelling that provides adequate information on the hazards and risks posed by the chemical to human health and the environment
- a copy of an up-to-date safety data sheet, in an internationally recognised format, to be sent to the importer (the information on the safety data sheet and labelling should be in the official language of the importing country as far as is practicable).

A shared responsibility

The Rotterdam Convention is a multilateral environmental agreement. Its primary purpose is to share responsibility for protecting human health and the environment. It does this by facilitating information exchange on chemicals that have been banned or severely restricted by one or more national governments, as well as on severely hazardous pesticide formulations.

One source of information exchanged is the list of chemicals in Annex III of the Convention, which enables countries to assess the risks associated with use and to decide whether to allow imports. Annex III also lists the decisions of countries regarding future imports of these chemicals. Exporting parties are obliged to ensure exports do not occur contrary to these decisions.

The decision to include a chemical in the annex is triggered by the final regulatory actions to ban or severely restrict a chemical by at least two parties from two PIC regions.

Pesticide formulations causing problems under the conditions of use in a party that is a developing country or country with an economy in transition may also be included.

Parties to the Convention are expected to make their own informed decisions regarding import and use of chemicals listed in Annex III and subject to the PIC procedure. It is not intended that these chemicals be automatically subject to national regulatory actions to ban or severely restrict their use.

Australian Government's role in Prior informed consent administration

The Department of Sustainability, Environment, Water, Population and Communities is the lead Australian Government agency administering the Rotterdam Convention domestically. It is also the Designated National Authority responsible for international liaison and communication with the PIC Secretariat of the United Nations Environment Programme, and the Food and Agriculture Organization of the United Nations.

NICNAS, as the Australian Government regulator of industrial chemicals, is responsible for implementing the Rotterdam Convention domestically for those chemicals for an industrial use.

The Department of Agriculture, Fisheries and Forestry is the Designated National Authority responsible for pesticides and is responsible for implementing Australia's obligations under the Rotterdam Convention for chemicals with an agricultural or veterinary application.

Banned and severely restricted chemicals

A chemical, as defined in Article 2 of the Rotterdam Convention, includes substances that are pure and/or mixtures with other substances; and can be listed in use categories as 'industrial' or 'pesticide' or both. Further, some chemicals are banned or severely restricted.

Banned chemicals: the use of banned chemicals, in either industrial or pesticide categories, has been prohibited by final regulatory action, to protect human health or the environment. It includes chemicals that have been not been approved for first-time use or have been withdrawn by industry from domestic market or from further consideration in the domestic approval process, based on evidence that withdrawal is required to protect human health or the environment.

Severely restricted chemicals: the use of these chemicals is virtually prohibited in either or both industrial or pesticide categories, based on final regulatory action to protect human health or the environment, except for certain specific uses. It includes chemicals that have, for virtually all use, not been approved or been withdrawn by industry, either from the domestic market or from further consideration in the domestic approval process; based on evidence that this is required to protect human health or the environment.

Chemicals covered by the Rotterdam Convention

The Rotterdam Convention applies to 43 banned and/or severely restricted chemicals and severely hazardous pesticide formulations. These Annex III listed chemicals are subject to the PIC procedure, and include 28 pesticides, four severely hazardous pesticide formulations and 11 industrial chemicals (see table below).

Under Article 5 of the Rotterdam Convention, a party notifies the Rotterdam Convention of an explicit decision to ban or severely restrict a chemical within its jurisdiction to protect human health or the environment. The party does so based on a national hazard or other risk-based decision. The decisions by parties that have signed on to the Convention affect what chemicals can be imported into Australia, as well as the conditions for import and legislative or administrative measures conditions pertain therein. Australia's import decisions can be found at: www.pic.int/Procedures/ImportResponses/Database/tabid/1370/language/en-US/Default.aspx.

TABLE: INDUSTRIAL CHEMICALS LISTED IN ANNEX III OF THE ROTTERDAM CONVENTION AND SUBJECT TO THE PRIOR INFORMED CONSENT PROCEDURE

Chemical	CAS numbers
Crocidolite asbestos	12001-28-4
Actinolite asbestos	77536-66-4
Anthophyllite asbestos	77536-67-5
Amosite asbestos	12172-73-5
Tremolite asbestos	77536-68-6
Polybrominated biphenyls	
- Hexabromobiphenyl	36355-01-8
- Octabromobiphenyl	27858-07-7
- Decabromobiphenyl	13654-09-6
Polychlorinated biphenyls	1336-36-3
Polychlorinated terphenyls	61788-33-8
Tetraethyl lead	78-00-2
Tetramethyl lead	75-74-1
Tris (2,3-dibromopropyl) phosphate	126-72-7

Regulatory obligations for importers and/or exporters

Australia's import decision for industrial chemicals listed in Annex III reflects the current regulatory status of that chemical in Australia. Exporters are responsible for remaining informed on the status of Annex III-listed chemicals and import decisions published in the PIC Circular, to ensure exports do not occur without appropriate authorisation or notification. Initial inquiries for industrial chemicals should be directed to:

Director, Chemicals Policy Australian Government Department of Sustainability, Environment, Water, Population and Communities Environment Protection Branch GPO Box 787 Canberra ACT Australia 2601

Tel: +61 2 6274 1841 Fax: +61 2 6274 2060

Compliance and enforcement

The obligations of the Rotterdam Convention are implemented under the Industrial Chemicals (Notification and Assessment) Act 1989 and the Industrial Chemicals (Notification and Assessment) Regulations 1990; administered by NICNAS.

Regulations have been developed for the purposes of Section 106(1) of the Act, to prohibit the export of certain industrial chemicals without the prior written permission of the NICNAS Director. This means that a breach of the Act has occurred if a chemical is exported that:

- has been banned, severely restricted or Annex III PIC-listed chemical
- has no valid export permit, export notification or express written permission from the NICNAS Director for subject export, as detailed in the Act.

NICNAS authorisation also applies to PIC-listed chemicals even if the exporting or importing destination country is not a party to the Rotterdam Convention.

NICNAS views any breach of the Rotterdam Convention and/or the Act as a serious matter and may enforce a range of options, including legal proceedings.

Pursuant to paragraph 5, Section 106 of the Act, it is an offence to import, manufacture or export industrial chemicals in contravention of an international agreement to which Australia is a party. The associated penalty is up to \$33,000 for an individual and \$165,000 for a company.

Officers of NICNAS's Compliance and Enforcement Program are responsible for processing export authorisation applications and conducting audits of importers, manufacturers and exporters of industrial chemicals.

Importers, manufacturers and exporters are responsible for keeping relevant commercial documents relating to industrial chemicals for at least five years. These could include:

- a commercial invoice providing a description of the goods
- orders/confirmations
- bills of lading/airway bills
- insurance certificates
- receipt of purchase of goods
- illustrated descriptive material and other records provided to the Australian Customs and Border Protection Service.

Subsection 100G(1) of the Act allows the NICNAS Director to obtain any information or document from a person if, on reasonable grounds, that information or document is believed to be necessary to allow Australia to comply with the Rotterdam Convention's obligations.

The Director's request will specify the information required and how it is to be provided. It will also specify the final date the information must be provided by, giving at least 14 days' notice of this.

Failure to provide the requested information to the Director is an offence. The associated penalty is up to \$6,600 for an individual and \$33,000 for a company.

Exporting or importing an Annex III listed chemical?

Export – annual authorisation

The following two scenarios will incur a fee of \$750 for the processing of an annual authorisation for the **export** of certain industrial chemicals under the PIC procedure of the Rotterdam Convention:

(1) NICNAS clients seeking an **annual authorisation** to export Annex III listed industrial chemicals to a country that is a Party to the Convention and have provided an import response that gives consent for the import to occur, or gives consent for the import to occur subject to specified conditions; or

(2) A NICNAS client that seeks an **annual authorisation** to export an Annex III listed industrial chemical to a country that is not a Party to the Convention.

Export – export notification

The processing of **export notifications** for the **export** of certain industrial chemicals under the PIC procedure of the Rotterdam Convention will incur a fee of \$1700 which will apply to the following two scenarios:

(1) A NICNAS client that seeks an **export notification** to be processed by NICNAS to export an Annex III listed industrial chemical to a country that is a Party to the Convention but have not provided an import response to the Rotterdam Convention Secretariat for subject chemical; or

(2) A NICNAS client that seeks an **export notification** to be processed by NICNAS to export an Annex III listed industrial chemical to a country that is a Party to the Convention but have provided an import response to the Rotterdam Convention Secretariat for subject chemical of 'no consent'.

The industrial chemicals pertinent to the aforementioned **export** scenarios are:

- (a) polybrominated biphenyls: (hexa; octa; and deca);
- (b) tris (2,3 dibromopropyl) phosphate;
- (c) polychlorinated biphenyls;
- (d) polychlorinated terphenyls;
- (e) tetraethyl lead; and
- (f) tetramethyl lead.

Import - annual authorisation

The processing of an **annual authorisation** for the introduction of certain industrial chemicals under the PIC procedure of the Rotterdam Convention will incur a fee of \$1700 – currently this applies to the import or manufacture of:

- (a) polybrominated biphenyls: (hexa; octa; and deca); and
- (b) tetramethyl lead;

NB: Legislation is beingfinalised regarding a fee for the processing of an annual authorisation for the introduction of tetraethyl lead; however an annual authorisation and fee are not applicable for the introduction of tetraethyl lead if:

- (1) The tetraethyl lead is introduced in aviation gasoline (avgas), or for use in the production of avgas; or
- (2) The tetraethyl lead is introduced:
- 1. in a leaded fuel or fuel additive; and
- 2. by a person in respect of whom an approval granted under subsection 13 (1) of the Fuel Quality Standards Act 2000 is in force at the time of introduction; and
- 3. for the purpose of a supply that is specified in the approval.

If you intend to import tetraethyl lead in circumstances other than the above-mentioned scenario please contact NICNAS.

Payment instructions

Submission of either an annual authorisation or export notification application will not be processed by NICNAS until accompanied by both the appropriate payment and *Payment Options Form.*

Once an application has been submitted to NICNAS and has been determined to meet the appropriate criteria for vetting, your payment will be processed and will be non-refundable.

Further information about the Rotterdam Convention

The following websites contain additional information on the Rotterdam Convention:

Rotterdam Convention / PIC homepage

Department of Agriculture, forests and fisheries information page

If you have any further inquiries regarding Australia's industrial chemical obligations under the Rotterdam Convention, please contact the NICNAS Compliance Team on (02) 8577 8800 or 1800 638 528; via email – info@nicnas.gov.au or fax: (02) 8577 8888.

1.11.2 STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS

The Stockholm Convention is an international treaty targeting chemicals that threaten humans and the environment by their persistence in ecosystems around the world and accumulation in the fatty tissue of humans and wildlife.

The Convention entered into force in 2004 and requires parties to take measures to eliminate or reduce the release of persistent organic pollutants into the environment. During assessment of industrial chemicals, new and existing, NICNAS assessors are required to consider the pollutants' criteria in Annex D of the Convention. These criteria are listed in Stockholm Convention, for ease of reference.

The United Nations describes persistent organic pollutants as:

... chemical substances that persist in the environment, bio-accumulate through the food web, and pose a risk of causing adverse effects to human health and the environment. With the evidence of long-range transport of these substances to regions where they have never been used or produced and the consequent threats they pose to the environment of the whole globe, the international community has now, at several occasions called for urgent global actions to reduce and eliminate releases of these chemicals.

More information:

United Nations Environment Programme

Stockholm Convention

Stockholm Convention (1) international persistent organic pollutants criteria (2) national environmental persistent bioaccumulative and toxic criteria

1.11.3 OTHER INTERNATIONAL TREATIES

Australia participates in two other international treaties promoting the safe management of hazardous chemicals, known as the Basel Convention and the Montreal Protocol. Both are administered by the Department of Sustainability, Environment, Water, Population and Communities and are described here.

Basel Convention on Control of Transboundary Movements of Hazardous Wastes and their Disposal

The Basel Convention is the most comprehensive global environmental agreement on hazardous and other wastes.

In response to pressure from new environmental regulations in Western countries, the trade in toxic chemicals to developing countries rose rapidly. When uncovered, this activity led to international indignation, followed by the drafting and adoption of the Basel Convention.

From 1989 to 1999 a framework was set up for controlling the transboundary movements of hazardous wastes (that is, the movement of hazardous wastes across international frontiers).

From 2000 to 2010 the Basil Convention focused on implementing and regulating treaty obligations as well as promoting a reduction in generating hazardous wastes. Future activities include promoting cleaner technologies—in the West and in developing countries—monitoring the activities of and prosecuting, where required, those involved in hazardous waste movement and developing regional training centres for technology transfer.

More information: Basel convention.

Montreal Protocol on Substances that Deplete the Ozone Layer

The Montreal Protocol is an international treaty designed to protect the ozone layer by phasing out the production of a number of substances believed to be responsible for ozone depletion.

The treaty's obligations are implemented in Australia by the Australian Government Department of Sustainability, Environment, Water, Population and Communities.

More information about Ozone Depleting Substances and Synthetic Greenhouse Gases, Department of Sustainability, Environment, Water, Population and Communities

1.11.4 OFFENCES AND PENALTIES RELATING TO AUSTRALIA'S OBLIGATIONS UNDER INTERNATIONAL AGREEMENTS-A SUMMARY

If you do not comply with Australia's obligations under international agreements you will be deemed to have committed an offence and penalties will apply. These are summarised in the following table.

TABLE: SUMMARY OF OFFENCES AND PENALTIES RELATING TO AUSTRALIA'S OBLIGATIONS UNDER INTERNATIONAL AGREEMENTS

Section/offence	Guidance	Maximum penalty: individual (corporation)
s100G A person commits an offence if the person fails to comply with the NICNAS Director's request to provide information in relation to Australia's obligations under the Rotterdam Convention	The NICNAS Director's request will specify the information required and how it is to be provided. It will also specify the final date the information must be provided by, giving at least 14 days' notice of this.	\$6,600 (\$33,000)
s106(5) Introduction or export of chemical in contravention of a regulation made under s106 (that is, a regulation that bans or restricts a chemical that is the subject of an international agreement) (Strict liability offence)	An industrial chemical that has been prohibited through an international agreement cannot be introduced (imported or manufactured) or exported.	\$33,000 (\$165,000)

2 HANDBOOK: APPENDIXES

The nineteen Appendixes provide detail and background information to support the information in the chapters of the Handbook's main volume.

Definitions, abbreviations and acronyms that are used in the Handbook are detailed at the start of the Appendixes.

Appendix A: Definitions

• Addendum: description of an article

Appendix B: Abbreviations and acronyms

Appendix C: Certificate categories for new chemicals

- Polymer of low concern notification
- Standard or Limited notifications
- Extension of an original assessment certificate notification
- Self-assessment applications
- Modular notification categories reduced fee options
- Use of overseas assessments in the notification of New Chemicals

Appendix D: Polymers of low concern: additional information

Reactive functional groups

• Functional group equivalent weight 95/323

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- Molecular weight
- Cationic polymers
- Hazard classification
- Elemental criteria
- Degradable or unstable polymers
- Water absorbing polymers
- Polyesters

Appendix E: Permit categories for new chemicals

- Commercial evaluation chemical permit
- Low volume chemical permit
- Controlled use (export only) permit
- Controlled use permit
- Early introduction permit
- Renewal of permits

Appendix F: Data requirements for new chemicals applications

• Schedule Part A

the set of information (identification of data requirements, health and environmental effects, how the chemical meets hazardous substance definition, overseas notification of the chemical) you must submit as part of Standard or Limited notification application

• Schedule Part B

the core set of information (chemical identity, use and exposure details, physico-chemical properties) you must submit as part of Standard or Limited notification application

• Schedule Part C

the health and environmental effects data you must submuit as part of Standard notification application

• Schedule Part D

the information you must provide to characterise a polymer, polymer mixture, its additives and adjuvants, as closely as possible

• Schedule Part E

details of additional data required for new industrial chemicals that are to be used as an untraviolet filter in a cosmetic (additional to toxicological endpoints in Schedule C)

Variation to data requirements

test or data items that can be omitted if irrelevant, unnecessary or scientifically inapporpriate to an evaluation

Appendix G: Data requirements for notification of new chemical substances containing a perfluorinated carbon chain

- Background
- Regulatory actions
- What perfluorinated chemicals are covered?
- What does this mean for a notification?
- Refinement of NICNAS defaults
- What are the notification options for notifiers?
- Existing chemicals assessments

Appendix H: Guidance and requirements for notification of new chemicals that are industrial nanomaterials

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- NICNAS working definition of industrial nanomaterial
- Exemption categories
- Permit categories
- Certificate categories
- Specified conditions for requesting additional data requirements
- Guidance on providing additional data requirements
- Guidance on testing health effects of nanomaterials
- Guidance on testing the environmental fate and effects of nanomaterials

Appendix I: Exposure criteria and scenarios for Controlled use permit: additional information

- Controlled use exposure criteria
- Controlled use exposure scenarios

Appendix J: Structural alerts for permit categories

- Table J1 C Structure contains only C, H, (O)
- Table J2 CHal Structure contains only C, H, (O) and Halogen atoms
- Table J3 CN Structure contains only C, H, (O) and N atoms
- Table J4 CNHal Structure contains only C, H, (O), N and Halogen atoms
- Table J5 CNS/CNSHal Structure contains only C, H, (O), N and S atoms or Structure contains only C, H, (O), N, S and Hal atoms
- Table J6 CS/CSHal Structure contains only C, H, (O) and S atoms or Structure contains only C, H, (O), S and Hal atoms
- Table J7 CSi and CSiHal Structure contains only C, H, (O), and Si atoms or Structure contains only C, H, (O), Si and Halogen atoms
- Table J8 Other Structure contains atoms other than C, H, N, O, S, Si and Halogen atoms

Appendix K: Assessment methodologies

- Risk assessment of chemicals: assessment of exposure from all sources
- Human health hazard assessment
- Occupational health and safety assessment
- Public health assessment
- Environmental assessment
- References

Appendix L: Forms and paperwork notifiers must complete to support an application; fees and charges payable

Appendix M: Confidentiality

- Initial notification (first five years)
- Initial confidential Australian Inventory of Chemical Substances listing
- Re-listing a chemical on the Australian Inventory of Chemical Substances confidential section

Appendix N: Australian Inventory of Chemical Substances online searching advice

• Searching public section online

Confidential AICS search

Appendix O: Chemical Abstracts Service registry numbers

Appendix P: Naturally-occurring chemicals

- Definition of a naturally-occurring chemical
- Application of the definition
- Steam distillation
- Extraction of essential oils

Appendix Q: Stockholm Convention: (1) international persistent organic pollutants criteria (2) national environmental persistent bioaccumulative and toxic criteria

Appendix R:Summary of applications under the Act

See also Legislation and regulations.

Appendix S: Appeals

Appendix T: Weblinks used in this Handbook

- NICNAS
- Other Australian Government regulators, Departments and agencies
- Relevant international bodies

2.1 APPENDIX A: DEFINITIONS

Definitions provided in this appendix are consistent with the in the *Industrial Chemicals* (Notification and Assessment) Act 1989 (Cwlth) (the Act) and relevant Safe Work Australia documents.

For details and a link to the Act, see Legislation and Regulations.

Notes:

- Although the National Occupational Health and Safety Commission (NOHSC) has been through name changes and is now Safe Work Australia (an independent statutory agency responsible for improving occupational health and safety and worker compensation arrangements across Australia), titles for some of its codes remain unchanged as they are yet to be updated. These codes are referred to throughout the appendices as NOHSC documents, reflecting the former name. All specific references have direct links to the relevant NOHSC document. All NOHSC and Safe Work Australia documents can be found on the Safe Work Australia website.
- 2. The addendum to this appendix provides the description of an article.

THE ACT

Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth)

ADMINISTRATIVE APPEALS TRIBUNAL (AAT)

The AAT created by the Actprovides independent review of a wide range of administrative decisions made by the Australian Government and some non-government organisations.

Agricultural chemical

A substance or mixture of substances that is a means of directly or indirectly:

- destroying, stupefying, inhibiting, attracting or repelling a pest in relation to a plant, a place or a thing, or
- destroying a plant, or
- modifying the physiology of a plant so as to alter its natural development, productivity or reproductive capacity, or
- modifying the effect of another agricultural chemical product

but does not include a:

- veterinary chemical product, or
- substance or mixture of substances of a kind that is declared by the Regulations not to be an agricultural chemical product for the purposes of the Agricultural and Veterinary Chemicals Code Act 1994 (Cwlth).

ALLOY

Alloys are mixtures composed of two or more elements, usually metals or metalloids, for example brass or stainless steel. Note that intermetallic alloys with well-defined stoichiometry are considered to be chemicals and should be notified if they are not listed on the AICS.

APPROVED FOREIGN SCHEME

A foreign chemical assessment scheme, assessment products from which can be used by a notifier when submitting notification of a new chemical (or polymer) to NICNAS (under Sections 43 and 44 of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Specified foreign schemes (currently the Canadian scheme) must be approved by the Minister. If access to the overseas health and environmental hazard assessment is provided to NICNAS, the hazard assessment can be considered and, where appropriate, used in the NICNAS assessment report.

ARTICLE

An object that:

- is manufactured for use for a particular purpose, being a purpose that requires that the object have a particular shape, surface or design, and
- is formed to that shape, surface or design during manufacture, and
- undergoes no change of chemical composition when used for that purpose except as an intrinsic aspect of that use

but does not include a particle or a fluid.

See Appendix A Addendum for more information.

AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS)

A list of the chemicals available for use in Australia. Some chemicals may only be available for specified and/or conditional use. The AICS is available online.

BASIC INFORMATION

In relation to a chemical, means all of the following:

- name or names by which the chemical is known to the public or is intended by its importer or manufacturer to be so known
- general(common) uses of the chemical
- precautions and restrictions to be observed in manufacturing, handling, storing, using and disposing of the

chemical

- recommendations arising from the assessment of the chemical under the Act relating to disposing of the chemical and rendering it harmless
- procedures to be followed in the event of an emergency involving the chemical
- prescribed physical and chemical data about the chemical, not being data that would reveal the chemical's composition (Regulation 3)
- prescribed data relating to the health effects or environmental effects of the chemical (Regulation 4).

BIOPOLYMER

- a polymer directly produced by living or once-living cells or cellular components, or
- synthetic equivalent of such a polymer, or
- derivative or modification of such a polymer in which the original polymer remains substantially intact.

CHEMICAL ABSTRACTS SERVICE REGISTRY NUMBER (CAS RN)

A unique numeric identifier which usually designates only one substance (Appendix O).

CHARGEABLE PERSON (TIER 2 AND TIER 3 REGISTRANTS)

One who proposes to introduce relevant industrial chemicals in the National Industrial Chemicals Notification and Assessment Scheme's (NICNAS) registration year of September 1 to August 31:

- of a value that equals or exceeds the threshold value if that person:
 - did not introduce relevant industrial chemicals in the previous financial year, or
 - introduced relevant industrial chemicals in the previous financial year of a value less than the threshold value
- of any value if that person introduced relevant industrial chemicals in the previous financial year of a value that equalled or exceeded the threshold value.

CHEMICAL

Describes a:

- chemical element, including a chemical element contained in a mixture, or
- compound or complex of a chemical element, including such a compound or complex contained in a mixture, or
- substance of unknown or variable composition, complex reaction products or biological materials (UVCB), or
- naturally-occurring chemical

but does not include:

- an article, or
- a radioactive chemical, or
- a mixture.

CHEMICAL NAME

In the case of a pure chemical, chemical name refers to the Chemical Abstracts preferred Index Name or, if such a name is not available, the name used – or to be used – by the International Union for Pure and Applied

Chemistry. Alternatively (in any other case) it refers to a complete description of the chemical. In the case of a biopolymer, the includes the biological source of the biopolymer.

COMMERCIAL EVALUATION

In relation to an industrial chemical, means testing the chemical with a view to ascertaining its potential for commercial application.

COMMERCIAL EVALUATION PERMIT (CEP)

Allows the importing and/or manufacturing of a limited, specified amount of a chemical for a specific time for commercial evaluation.

COSMETIC

A substance or preparation:

- intended for placement in contact with any external part of the human body, including the mucous membranes of the oral cavity and teeth with a view to:
 - altering the odours of the body, or
 - changing its appearance, or
 - cleansing it, or
 - maintaining it in good condition, or
 - perfuming it, or
 - protecting it, or
- prescribed by regulations made for the purposes of this paragraph

but does not include a:

- therapeutic good within the meaning of the Therapeutic Goods Act 1989 (Cwlth), or
- substance or preparation prescribed by regulations made for the purposes of this paragraph.

More details can be found at NICNAS Cosmetics Guidelines, to be found elsewhere on the NICNAS website.

DANGEROUS GOODS

Substances or articles that—because of their physical, chemical (physicochemical) or acute toxicity properties —present immediate hazard to people, property or the environment.

Types of substances classified as dangerous goods include explosives, flammable liquids and gases, corrosives, chemically reactive or acutely (highly) toxic substances.

Dangerous goods are also defined as substances that fall within the Australian Dangerous Goods Code.

DAY

Under the Act, refers to a calendar day.

DIRECTOR

The Director of NICNAS, as appointed under Section 90 of the Act.

DISPOSAL

In relation to a chemical, includes disposal of waste resulting from the manufacture or use of the chemical.

ELIGIBLE CHEMICAL

An industrial chemical eligible to be submitted for inclusion on the AICS at a time during the period that began on 1 January 1977 and ended on 16 July 1990.

ENVIRONMENT

Includes all aspects of the surroundings of humans, whether affecting them as individuals or in social groupings.

ENVIRONMENTAL EFFECT

In relation to an industrial chemical, the effect on the environment of importing, manufacturing, handling, storing, using or disposing of the chemical.

EXCLUDED USE

In relation to a chemical, means:

- use as an agricultural chemical or a constituent of an agricultural chemical, or
- use as a veterinary chemical or a constituent of a veterinary chemical, or
- therapeutic use or use as an ingredient or component in the preparation or manufacture of goods for therapeutic use, or
- use as food intended for consumption by humans or animals or a constituent of such food, or
- use as a food additive in food referred to in Subsection 7(2) of the Act.

EXEMPT INFORMATION AND CONFIDENTIAL INFORMATION

Information about which the NICNAS Director has given a notification under Section 75 of the Act, and includes information for which an application for treatment as exempt information has been made under the Act, but not finalised.

Exempt information is not included in the public reports published by NICNAS.

See also Appendix M - Confidentiality

EXISTING CHEMICAL

An industrial chemical not defined as a new chemical. This includes naturally occurring chemicals. Existing chemicals are those listed on the AICS.

FACTORY COST

In relation to the industrial chemicals manufactured, means the total of the:

- cost of labour involved in the manufacture, and
- cost of materials involved in the manufacture other than the cost of any relevant industrial chemical:
 - that is used as an ingredient in the manufacturing, and
 - in respect of which an amount of registration charge has been paid, and
- factory overhead expenses

incurred by a person in respect of the manufacture of the industrial chemicals manufactured by that person.

FOOD ADDITIVE

A chemical permitted in food as a food additive by the Food Standards Code as defined under the *Australia New Zealand Food Authority Act 1991* (Cwlth).

FOREIGN SCHEME

A chemicals notification and assessment scheme operating in a foreign country.

FULL ASSESSMENT

Under the Act the assessment of a Priority Existing Chemical (PEC) that requires that at least one of the matters in paragraphs 51(3) to 51(3)(h) of the Act be taken into account in preparing a summary assessment report on the chemical.

This term is specific to the PEC process as defined in the Act.

HANDLING

Includes transporting a chemical.

HAZARDOUS CHEMICAL

Those that, following worker exposure, can have an adverse effect on health. Examples of hazardous chemicals include poisons, substances that cause burns or skin and eye irritation, and substances that may cause cancer. Many hazardous chemicals are also classed as dangerous goods.

A substance is deemed to be hazardous if it satisfies the criteria for a hazard class in the UN's Globally Harmonised System of Classification and Labeling of Chemicals, 3rd edition (GHS), but does not include a chemical that satisfies the criteria solely for one of the following hazard classes:

- a) flammable gases, category 2
- b) acute toxicity—oral, category 5
- c) acute toxicity—dermal, category 5
- d) acute toxicity—inhalation, category 5
- e) skin corrosion/irritation, category 3
- f) serious eye damage/eye irritation, category 2B
- g) aspiration hazard, category 2
- h) hazardous to the aquatic environment, category acute 1, 2 or 3
- i) hazardous to the aquatic environment, category chronic 1, 2, 3 or 4
- j) hazardous to the ozone layer.

Note: The GHS has been adopted in the Work Health and Safety legislation of many jurisdictions, with more to follow. A five year transition period (up until 31 December 2016) will apply in which classifications under the Approved Criteria will be acceptable if classification under the GHS is not available to the notifier.

To assist in classification, Safe Work Australia maintains the Hazardous Substances Information System, an online database containing classification information for hazardous substances that have been classified in accordance with the approved criteria. However, the database is not a comprehensive source of classification information for workplace substances.

HEALTH EFFECT

In relation to an industrial chemical, the effect on occupational health and safety or on public health of importing, manufacturing, handling, storing, using or disposing of the chemical.

HOLDER

In relation to a permit or an assessment certificate, means a person to whom the permit or certificate is issued.

HYDRATES

Hydrates are chemicals containing water of crystallisation, where the water does not react with the parent compound. Examples of so-called hydrates where the water has reacted with the parent compound are chloral hydrate ($CI_3C-CH(OH)_2$) and ninhydrin, sometimes misleadingly called indane-1,2,3-trione monohydrate. Examples of true hydrates are hydrated copper sulfate ($CuSO_{4.5}H_2O$), cobalt chloride hexahydrate ($CoCI_{2.6}H_2O$) and asparagine monohydrate ($C_4H_8N_2O_3H_2O$).

HOLDER OF A CONFIDENCE

In relation to an industrial chemical, a person who under Section 17 of the Act is to be treated as the holder of a confidence about the chemical.

IMPORT

In relation to an industrial chemical, means to do an act which constitutes importation of the chemical for the purposes of the *Customs Act 1901* (Cwlth), or would constitute such importation (if that Act also extended to the external territories).

IMPORTER

In relation to an industrial chemical, a person who imports or proposes to import the chemical.

INCIDENTALLY-PRODUCED CHEMICAL

A chemical that is produced as a result of the:

- exposure of another chemical to light, heat or other environmental conditions in the course of handling or storing, or
- occurrence of a chemical reaction during the manufacture or use of another chemical (e.g. a by-product)

but not a chemical for which production has commercial value for a person manufacturing, handling, storing or using that *other* chemical.

INDUSTRIAL CHEMICAL

A chemical that has an industrial use, regardless of whether it also has an excluded use.

INDUSTRIAL NANOMATERIAL

Working definition as at 1 January 2011:

• Industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (that is, that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (that is, having an internal or surface structure at the nanoscale).

Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- unique properties refers to chemicals and/or physical properties that are different because of their nanoscale features as compared to the same material without nanoscale features, and result in unique 104/323

phenomena (for example, increased strength, chemical reactivity or conductivity) that enable novel applications

- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.

See also Appendix H for more details.

INDUSTRIAL USE

In relation to a chemical, means a use other than an excluded use.

INTRODUCE

The general term used for the import and/or manufacture of industrial chemicals in Australia. An 'introducer' is therefore someone who is an 'importer' and/or 'manufacturer' of industrial chemicals—referred to often throughout this guide as 'you'.

INTRODUCTION

In relation to an industrial chemical, the importation or manufacture in Australia of the chemical.

INTRODUCTION PERMIT

Allows the introduction of a new industrial chemical under Section 30 of the Act before the summary assessment report is completed.

LABEL

A set of information on a container that identifies a substance together with sufficient information so it can be used safely. A label must contain the minimum information described in the Safe Work Australia National Model Code of Practice for the Labeling of Workplace Hazardous Chemicals. More details can be found on the Safe Work Australia website.

Listed industrial chemical

An industrial chemical for which particulars are included in the AICS.

LOW VOLUME CHEMICAL PERMIT

A permit that allows, under specified conditions, the importation and/or manufacture of an industrial chemical in volumes not exceeding 100 kg a year nationwide or 1000 kg a year where certain criteria are met.

MANUFACTURE

Synthesis/creation of a chemical entity. Does not include formulation and/or blending activities.

MANUFACTURER

A person who manufactures or proposes to manufacture an industrial chemical in Australia.

(MATERIAL) SAFETY DATA SHEET ((M)SDS)

In relation to a chemical or to a product or substance containing a chemical, a (Material) Safety Data Sheet is a document prepared in accordance with the Safe Work National Model Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals.

MATTERS TO BE TAKEN INTO ACCOUNT

Matters that may be taken into account when assessing a PEC (Subsection 51(3) of the Act) are:

- the properties of the chemical
- any use to which the chemical is intended to be, or is reasonably likely to be, put
- any adverse effects on the environment or persons which the chemical has the intrinsic capacity to cause
- the extent to which the environment, persons in a particular occupation or the public will be exposed to the chemical
- any risk to the health or safety of persons who, because of their occupation, are engaged, or likely to be engaged, in manufacturing, handling, storing, using or disposing of the chemical
- any risk to the health or safety of likely consumers handling or using the chemical or any product containing the chemical
- any risk to the environment arising from the use of the chemical or from the discharge of waste products resulting from the manufacture or use of the chemical
- the extent to which any risk referred to is capable of being reduced by compliance with:
 - appropriate procedures relating to manufacturing, handling, storing, using or disposing of the chemical, or
 - special requirements in the packaging or labelling of the chemical, or
 - procedures relating to the control of, or the discharge into the environment of, the chemical or waste products resulting from the manufacture or use of the chemical, and
- any other relevant information available to the NICNAS Director.

MINISTER

The Australian Government Minister for the Department of Health.

MIXTURE

A physical combination of chemicals resulting from deliberate mixing of those chemicals or from a chemical reaction, but not including a UVCB substance.

MONOMER

A chemical, the molecules of which are capable of forming covalent bonds with two or more like or unlike molecules under the conditions of relevant polymer-forming reactions used for a particular process of polymer formation.

NANOMATERIAL (INDUSTRIAL)

See industrial nanomaterial definition.

NATURALLY-OCCURRING CHEMICAL

Includes:

- an unprocessed chemical occurring in a natural environment
- a chemical occurring in a natural environment, being a substance that is extracted by:
 - manual, mechanical or gravitational means, or
 - dissolution in water, or
 - flotation, or
 - a process of heating for the sole purpose of removing uncombined water, but not including by steam distillation

without chemical change in the substance.

See Appendix P for more information.

NEW INDUSTRIAL CHEMICAL

- either:
 - a chemical that is an AICS-listed industrial chemical for which its introduction is subject to a condition of use under Section 13 of the Act—but only to the extent that the manufacturer or importer of the chemical introduces, or proposes to introduce, the chemical for any other use, or
 - an industrial chemical not listed as an industrial chemical on the AICS, and
- in the case of a synthetic polymer: a chemical that is a new synthetic polymer
- but does not include:
 - a reaction intermediate, or
 - an incidentally-produced chemical.

NEW SYNTHETIC POLYMER

A polymer:

- including a combination of monomers and other reactive components, each representing at least 2% by weight of the polymer, being a combination not listed in the AICS, or
- of weight at least 2% is attributable to a monomer or other reactive component that is not listed in the AICS as a component of a synthetic polymer.

NON-HAZARDOUS CHEMICAL

A chemical for which these conditions are met:

- not a hazardous chemical
- not a dangerous good
- prescribed criteria relating to the environmental effect of the chemical have been met (Regulation 4J)
- any other prescribed conditions have been met
- introduction consistent with the reasonable protection of occupational health and safety, public health and the environment.

The NICNAS Director must take account of the following in deciding whether to be satisfied that occupational health and safety, public health and the environment are reasonably protected:

- proposed nature of the use of the chemical
- extent of the proposed use of the chemical
- effect of the chemical on the environment
- effect of the chemical on occupational health and safety and public health
- structure and activity of the chemical
- whether, in Australia or overseas, the chemical is the subject of
 - investigations initiated by a person because of concerns about a possible adverse effect on occupational health and safety, public health or the environment
 - action taken by a person to control the use of, or access to, the chemical
- any other prescribed matter.

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See hazardous chemical definition.

PERFLUORINATED CARBON CHAIN

A carbon chain for which all of the hydrogen atoms attached to carbon atoms have been replaced by fluorine atoms (see Appendix G).

PESTICIDE

See agricultural chemical definition.

POISONS SCHEDULING

Chemicals likely to be hazardous to the public may be referred for poisons scheduling by NICNAS to the scheduling delgate for consideration. If a chemical is listed in a schedule of the Standard for the Uniform Scheduling of Medicines and Poisons, certain signal headings, warning statements and/or safety directions must be placed on the product label.

POLYMER

A chemical consisting of:

- molecules that are:
 - characterised by the sequence of one or more types of monomer units, and
 - distributed over a range of molecular weights for which differences in molecular weight can be primarily attributed to differences in the number of monomer units, and
- comprising a simple weight majority of molecules containing at least three monomer units covalently bound to at least one other monomer unit or other reactant, and
- comprising less than a simple weight majority of molecules of the same molecular weight.

POLYMER OF LOW CONCERN (PLC)

A polymer that:

- either has a number average molecular weight, as defined by Industrial Chemicals (Notification and Assessment) Regulations 1990, Regulation 4A, that is:
 - >1000, or
 - $\circ \leq$ 1000, and is a polyester manufactured from approved monomers / reactants, and
- has a low cationic charge density
- is not a hazardous chemical
- does not dissociate readily
- is stable under the conditions in which it is used, and
- has such other characteristics as are prescribed by the regulations.

PRELIMINARY ASSESSMENT

The preliminary assessment of a PEC requiring at least one of the matters in paragraphs 51(3) (a) to (d) of the Act to be taken into account when preparing a summary assessment report on the chemical.

PRIORITY EXISTING CHEMICAL (PEC)

An industrial chemical in respect of which a declaration under Section 51 of the Act is in force.
A chemical is declared a PEC when there are concerns about its potential effects on health and/or environment.

RADIOACTIVE CHEMICAL

A chemical having a specific activity >35 becquerels/g.

REACTION INTERMEDIATE

A substance that:

- is produced in the course of a chemical reaction, and
- has a transient existence, and
- does not become a major component of the reaction mixture, and
- is not removed from the reaction system.

REGISTER OF INDUSTRIAL CHEMICALS INTRODUCERS

List of registered importers and manufacturers of relevant industrial chemicals.

REGISTRATION (NICNAS)

The registration by importers or manufacturers in Australia to import or manufacture relevant industrial chemicals for commercial purposes.

REGISTRATION CHARGE

A charge for the registration of a chargeable person (that is for more than \$500,000 total value of relevant industrial chemicals introduced) so far as it is:

- a duty of customs by the Industrial Chemicals (Registration Charge-Customs) Act 1997 (Cwlth), and
- a duty of excise by the Industrial Chemicals (Registration Charge—Excise) Act 1997 (Cwlth), and
- neither a duty of customs nor a duty of excise by the *Industrial Chemicals* (*Registration Charge—General*) Act 1997 (Cwlth).

REGISTRATION YEAR

NICNAS's registration year begins 1 September and finishes on 31 August the following year.

RELEVANT INDUSTRIAL CHEMICAL

For the purposes of NICNAS registration, an industrial chemical that is not intended for an excluded use and is not one of the following:

- a naturally-occurring chemical
- biological material
- an incidentally-produced chemical
- a reaction intermediate.

SEQUENCE

In relation to a polymer molecule, a continuous string of monomer units within the molecule, which are covalently bound to one another and uninterrupted by units other than monomer units.

SITE LIMITED CHEMICAL

A chemical confined to its site of manufacture solely for the purpose of further manufacture.

SUPPLEMENTARY INFORMATION STATEMENT

Relates to an application to extend an original assessment certificate to cover other importers or manufacturers:

- if there has been a significant variation in matters affecting occupational health and safety, public health or environmental exposure as set out in the notification statement that accompanied the application for the original certificate, or as set out in any additional information given under Section 27 or Section 28 of the Act in respect of the application for the original certificate, details of the variation, and
- new information available to the applicant or notifier about the health and environmental effects of the chemical, and
- confirmation that the applicant has access to a copy of the full public assessment report about the chemical.

SYNTHETIC POLYMER

Any polymer other than a biopolymer.

THERAPEUTIC USE

Use in, or in connection with:

- preventing, diagnosing, curing or alleviating diseases, ailments, defects or injuries in humans, or
- influencing, inhibiting or modifying physiological processes in humans, or
- testing the susceptibility of humans to diseases or ailments and

without limiting this, includes use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics.

THRESHOLD VALUE (NICNAS REGISTRATION)

The bottom or top dollar value of each of the three NICNAS registration tiers (levels). Represents the dollar value for industrial chemicals introduced by a person in a registration year (which requires payment of registration fees and charges).

UVCB SUBSTANCE

A substance that is:

- a chemical of unknown or variable composition, or
- a complex product of a chemical reaction, or
- biological material, other than a whole animal or a whole plant.

VALUE OF RELEVANT INDUSTRIAL CHEMICALS IMPORTED

The value of relevant industrial chemicals imported by a person during a particular period (whether a financial year or NICNAS's registration year of September 1 to August 31). Means the amount, calculated to the nearest whole dollar, using this formula:

- value of all of relevant industrial chemicals, plus
- cost of the insurance and freight relating to those chemicals, plus
- customs duty payable on those chemicals.

VALUE OF RELEVANT INDUSTRIAL CHEMICALS INTRODUCED

The value of relevant industrial chemicals introduced by a person during a particular period (whether a financial year or NICNAS's registration year of September 1 to August 31). Means the sum of the value (if any) of industrial chemicals:

- imported by that person during that period, and
- manufactured by that person during that period.

VALUE OF RELEVANT INDUSTRIAL CHEMICALS MANUFACTURED

The value of relevant industrial chemicals manufactured by a person during a particular period (whether a financial year or NICNAS's registration year of September 1 to August 31). Means the factory cost of manufacturing the industrial chemicals.

VETERINARY CHEMICAL PRODUCT

A substance or mixture of substances that is:

- a means of directly or indirectly:
 - preventing, diagnosing, curing or alleviating a disease or condition in an animal or an infestation of an animal by a pest in relation to that animal, or
 - curing or alleviating an injury suffered by an animal, or
 - modifying the physiology of an animal so as to:
 - alter its natural development, productivity or reproductive capacity, or
 - make it more manageable, or
- prepared by a pharmacist or veterinary surgeon, in the course of the practice of their profession, to deal with a particular condition of a particular animal in a particular instance. Does not include a substance or mixture of substances of a kind declared by the regulations made under *Agricultural and Veterinary Chemicals Code Act 1994* not to be a veterinary chemical product for the purposes of that Act.

The regulation of veterinary chemicals in Australia is handled by The Australian Pesticides and veterinary Medicines Authority.

2.1.1 ADDENDUM: DESCRIPTION OF AN ARTICLE

Subsection 6 (2) of the Act (see Legislation and Regulations) defines an article as follows:

article means an object that:

(a) is manufactured for use for a particular purpose, being a purpose that requires that the object have a particular shape, surface or design; and

(b) is formed to that shape, surface or design during manufacture; and

(c) undergoes no change of chemical composition when used for that purpose except as an intrinsic aspect of that use;

but does not include a particle or a fluid.

A solid substance, manufactured or imported, formed to a particular shape (such as a polymer block, sheet, film or filament), which undergoes only limited further processing (such as cutting, bending, etc) into a finished article, is considered to be itself an article. 'Limited processing' does not include processes (such as

pulverising, melting and pelletising) in which the formed shape of the original article is destroyed.

Photographic film is an example of an article that has its chemical composition altered as a result of use but where the change of chemical composition is intrinsic to the intended use.

Fluids and particles are excluded from the definition of an article, regardless of shape or design.

The term 'fluids' refers to both liquids (including suspensions and solutions) and gases.

The term 'particles' refers to any solid chemical substance or mixture of substances that is in discrete aggregations of unspecified size, which may take the form of dust, powders, dispersions, granules, lumps and flakes.

In some manufacturing processes, the chemical substance synthesised is immediately subject to physical processing to form it into an article. An example is the process involving the manufacture of a polymer resin followed by its extrusion into a plastic bottle. For such manufacturing done in Australia, the chemicals used in the manufacturing process are considered as industrial chemicals and NICNAS must be notified. However, the final product, the plastic bottle, is an article

The contents of articles that are containers—such as bottles, jars, cans, aerosol cans, drums, barrels, tanks, bags, tubes and sachets—are chemical substances or mixtures of chemical substances.

2.2 APPENDIX B: ABBREVIATIONS AND ACRONYMS

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
AGD	Attorney-General's Department
AICS	Australian Inventory of Chemical Substances
APVMA	Australian Pesticides and Veterinary Medicines Authority
bw	Body weight
CAS	Chemical Abstracts Service
CEC	Commercial Evaluation Category permit for new chemicals (NICNAS)
COAG	Council of Australian Governments
Da	Daltons (units of molecular weight)
DIISRTE	Department of Innovation, Industry, Science, Research and Tertiary Education (former name of Australian Government Department of Industry)
DoHA	Australian Government Department of Health and Ageing (now Department of Health)
DSEWPaC	C Department of Sustainability, Environment, Water, Population and Communities (former name of Australian Government Department of the Environment)
EC50/EC	50 Half maximal effective concentration
ECHA	European Chemicals Agency
ECX	Effect concentration factor (x representing the percentage effect –see EC50 above))
EIP	Early Introduction Permit for new chemicals (NICNAS)
EOP	(controlled use) Export Only Permit for new chemicals (NICNAS)

EPHC	Environment Protection and Heritage Council
ErC50	EC50 (see above) in terms of reduction of growth rate
FGEW	Functional group equivalent weight
FSANZ	Food Standards Australia New Zealand
GHS	Globally Harmonised System of Classification and Labeling of chemicals (United Nations), Third edition
GLP	Good laboratory practice
HPV	High Production Volume (chemicals)
HVIC	(Australian) High Volume Industrial Chemicals (list)
IC50	Half maximal inhibitory concentration
IPCS	International Programme on Chemical Safety
LC50/LC	50 Median lethal concentration
LD50 / LD	50 Median lethal dose
LOAEL	Lowest observable adverse effect level
Log KOC	Organic carbon coefficient
Log Kow / Log K _{ow}	octanol/water partition coefficient
Log POW Log P _{OW}	/ n-octanol/water partition coefficient
LRCC	Low Regulatory Concern Chemicals (NICNAS)
LTD	Limited notification category for new chemicals (NICNAS)
LVC	Low Volume Chemical permit for new chemicals (NICNAS)
LVCR	Low Volume Chemical Permit Renewal for new chemicals (NICNAS)
MAN	Mutual Acceptance of Notification(s) (between countries)
Mm	Micrometre
MSDS	(Material) Safety Data Sheet
NAMW	Number-average molecular weight
NDPSC	National Drugs and Poisons Schedule Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOEC	No observed effect concentration
NOAEL	No observable adverse effect level
NOHSC	National Occupational Health and Safety Commission (now Safe Work Australia)
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative and toxic (chemicals)

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- PEC Priority Existing Chemical (NICNAS)
- PIC Prior Informed Consent (refers to Rotterdam Convention)
- PLC Polymer of Low Concern category for new chemicals (NICNAS)
- POP Persistent Organic Pollutants (refers to Stockholm Convention)
- QSAR Quantitative structure activity relationship (modeling software)
- REACH European Community's legislation for Registration, Evaluation, Authorisation and Restriction of Chemical substances
- RFG Reactive functional group
- SANHC Self-assessment for Non-Hazardous Chemical notification for new chemicals (NICNAS)
- SANHP Self-assessment for Non-Hazardous Polymer notification for new chemicals (NICNAS)
- SAPLC Self-assessment for Polymer of Low Concern notification for new chemicals (NICNAS)
- SDS Safety Data Sheet now Material Safety Data Sheet
- STD Standard notification category for new chemicals (NICNAS)
- SUSMP Standard for the Uniform Scheduling of Medicines and Poisons
- SWA Safe Work Australia
- TGA Therapeutic Goods Administration
- The Act Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth)
- The Director Director of National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- The Minister Minister for Health and Ageing
- US EPA United States Environmental Protection Agency
- UVCB (Chemical of) unknown or variable composition, complex reaction products or biological material
- WPMN Working Party on Manufactured Nanomaterials

2.3 APPENDIX C: CERTIFICATE CATEGORIES FOR NEW CHEMICALS

This appendix covers certificate categories for new chemicals. You should read it in conjunction with:

- Notification categories for new chemicals
- Notification processes and procedures for new chemicals
- Data requirements for new chemicals applications
- post-assessment obligations.

You can download forms and also find current fees and charges on the NICNAS website.

This appendix describes each certificate category, options for reduced notification requirements and fast tracked assessments (such as self-assessments and use of assessment reports for chemicals assessed overseas).

All certificate applications result in the:

- preparation of an assessment report
- issue of an assessment certificate
- publication of a notice in the Chemical Gazette
- publication of a full public report on the NICNAS website
- eventual listing of the chemical on the Australian Inventory of Chemical Substances (AICS).

Sections of this appendix:

- Polymer of low concern notification
- Standard or Limited notifications
- Extension of an original assessment certificate notification
- Self-assessment applications
- Modular notification categories reduced fee options
- Use of overseas assessments in the notification of New Chemicals

2.3.1 POLYMER OF LOW CONCERN NOTIFICATION

You can download the necessary forms for a Polymer of low concern (PLC) notification from the NICNAS website.

Your application must consist of:

- the completed application form for an assessment certificate (Form PLC-1) with new chemical data items listed
- any other information about the polymer available to you
- (where required) applications to exempt information based on confidentiality or to vary the schedule of data requirements
- any application for third party information (Form 5).

ASSESSMENT PROCESS AND OUTCOMES

In normal circumstances NICNAS assesses a PLC notification within 90 days of the date of accepting your completed application.

ADDITIONAL INFORMATION

You can find additional information on PLC criteria in Appendix D—Polymers of low concern: additional information.

Information related to the self-assessment option for PLC notifications is in Appendix C4.

2.3.2 STANDARD OR LIMITED NOTIFICATIONS

You can download the necessary forms for a Standard (STD) or Limited (LTD) notification.

Your application must consist of:

 the completed application form for an assessment certificate (Form-1), including the information about the chemical—comprising parts A, B and C* of the schedule (* for STD only, unless available for LTD), Part D for synthetic polymer or biopolymer, and Part E for an ultraviolet filter used in a cosmetic and applied to the skin

- any other information about the chemical available to you
- (where required) applications to exempt information based on confidentiality or to vary the schedule of data requirements
- any application for third party information (Form 5).

ASSESSMENT PROCESS AND OUTCOMES

NICNAS assesses a STD or LTD notification within 90 days of the date of accepting your completed application.

ADDITIONAL INFORMATION

You can find additional information on data requirements for STD and LTD notifications in Appendix F—Data requirements for New Chemicals applications.

Information related to self-assessment options for non-hazardous chemicals and polymers is in Appendix C4.

2.3.3 EXTENSION OF AN ORIGINAL ASSESSMENT CERTIFICATE NOTIFICATION

You can download the necessary forms for an extension of an assessment certificate (non self-assessment under STD, LTD or PLC).

Your application must consist of:

- the completed application form for an extension (Form EXT-1)
- supplementary information on matters affecting occupational, public and environmental exposure (if the application contains significant differences from the original assessment)
- any new health and environmental effects information available about the notified chemical
- confirmation that you have access to the public assessment report for the notified chemical
- written agreement of all holders of the original assessment certificate for the extension application (Form 14)—one form is required for each holder of the original assessment.

ASSESSMENT PROCESS AND OUTCOMES

Under an Extension of an Original Assessment Certificate Notification, the original assessment report is modified within 45 days of the date of acceptance of a complete application.

ADDITIONAL INFORMATION

Any information you claim as confidential in your extension application will not be disclosed to the original applicant (if you are not the original applicant).

For extension/s to certificates for 'Chemicals other than polymers and polymers with a number-average molecular weight (NAMW) <1000 Da' assessed in the LTD notification category, the total volume introduced by all certificate holders (including extension applicants) must not exceed the 1 tonne/year limit.

2.3.4 SELF-ASSESSMENT APPLICATIONS

Which chemicals are eligible for self-assessment applications?

You can submit a self-assessment application for a PLC, non-hazardous chemicals and non-hazardous polymers. However, your application will not be accepted if the chemical or polymer can be predicted to be

persistent and bioaccumulative, or if there are breakdown products that can be predicted to be persistent and bioaccumulative.

Application requirements

You can download the necessary forms and guidance documents for a self-assessment application.

Prepare your application using the appropriate electronic template (this does not mean you submit online, but rather that the form is available as an online form to be downloaded). You must complete all sections of the template.

Supporting data

Record all information to support your application on the electronic template. Other than the (M)SDS, do not send any supporting data—such as physicochemical and toxicological studies—with the application. If supporting data are submitted, NICNAS will not consider the application to be self-assessed.

Even though you do not submit it with your application, as a notifier you must hold supporting data for a period of five years for audit purposes.

Variation of data requirements

You cannot vary data requirements with self-assessment applications, including waivers of test requirements or substitution of analogue or product results. NICNAS needs to examine these case-by-case.

Data requirements that are not feasible or relevant (for example, particle size when a polymer is not extracted from solution) are not considered to be a variation.

Joint self-assessed applications

The Act makes no provision for joint self-assessed applications.

Third party confidential information

Under the Act, you must keep records to support any statement, based on third party information, made in, or in connection with, your self-assessed application. As such, NICNAS cannot accept an application where data are provided by a third party and confidential from the notifier.

Changing from the self-assessed to non self-assessed category

If your application is not accepted as a self-assessment, NICNAS will write to you explaining why. You can ask for your self-assessment application to be moved to the non-self assessed category, provided you pay the difference in fees. NICNAS may require more information if you do so.

Requesting additional information

There may be cases where a polymer fully meets the PLC criteria, but NICNAS requires additional information to address residual concerns. This is mostly in cases where exposure is high—such as where polymers with significant water solubility are released directly to the environment (for example, cosmetic or water treatment applications) or where polymers are constituents of products deliberately applied to the body (for example, cosmetics) or in food contact applications. Residual concerns can also relate to effects observed during toxicological or eco-toxicological studies, if these are relevant to exposure conditions.

NICNAS can ask you for additional information to address these types of concerns. You will generally be informed of this need 14 days after NICNAS receives your application.

If NICNAS identifies a significant health or environmental concern during screening, the self-assessment process will lapse and the assessment will revert to the normal 90-day timeframe (assessment clock).

Assessment process and outcomes

NICNAS will prepare a self-assessment report, including the public report and certificate for the applicant/notifier and will, in general, forward these by day 28 of the assessment clock.

A self-assessment report could also contain information prepared by NICNAS on other matters, such as residual concerns. On receiving this report, you can advise NICNAS of confidentiality concerns within 14 days, after which time the public report is published on the NICNAS website.

Annual reporting and record keeping

You must keep records to support any statement made in, or in connection with, your application for five years from the date your certificate is issued.

You must submit a report to NICNAS before or on 28 September of the following registration year, stating:

- the name of the chemical for which the certificate is issued;
- the volume of the chemical introduced during the year; and
- any adverse effect of the chemical on occupational health and safety, public health or the environment of which you have become aware during the year.

Health criteria for non-hazardous chemicals and polymers (non PLC)

For self-assessment applications, you must establish that a chemical (other than a polymer) is a nonhazardous chemical with respect to mammalian toxicity and have available the data listed in Table C4 (regardless of import volume).

Although NICNAS might not require full toxicological data for current limited category notifications, data will be required for self-assessments.

For each test, the result must lead to the chemical not being considered hazardous according to the NICNAS definition (see Appendix A).

With genotoxicity testing, you need the results of two genotoxicity tests, and both must be independently negative.

You also have to list the relevant test guidelines, which are normally obtained from the Organisation for Economic Co-operation and Development (OECD). These are listed, along with indicative results for toxicity testing, in the following table.

OECD test guidelines and indicative results for toxicity testing

ENDPOINT	INDICATIVE RESULTS FOR TOXICITY TESTING	TEST GUIDELINE
1. Rat, acute oral**	LD50 >2000 mg/kg bw	OECD TG 401 OECD TG 423
2. Rat, acute dermal	LD50 >2000 mg/kg bw	OECD TG 402
3. Rat, acute inhalation (aerosols or particulates) (gases or vapours)	LC50 >5 mg/L/4 hour LC50 >20 mg/L/4 hour	OECD TG 403
4. Rabbit, skin irritation**	slightly to non-irritating	OECD TG 404
5. Rabbit, eye irritation	slightly to non-irritating	OECD TG 405
6. Skin sensitisation	no evidence of sensitisation	OECD TG 406 (Buehler and Maximisation tests) OECD TG 429 (local lymph node assay)
7. Rat, repeat dose toxicity*	oral no observed adverse effect level (NOAEL) >50 mg/kg bw/day dermal NOAEL >100 mg/kg bw/day inhalation NOAEL >0.25 mg/L, 6h/day	OECD TG 407–409, 422 OECD TG 410–411 OECD TG 412–413
8. Genotoxicity—bacterial reverse mutation**	non mutagenic	OECD TG 471–472
9. Genotoxicity—in vitro	non genotoxic	OECD TG 473, 476, 479–482

* You only need data from one repeated dose mammalian toxicity test.

** For synthetic polymers with an NAMW ≥1000 Da, you are normally only required to have data items 1, 4 and 8 in the table. However, where the polymer contains one or more high concern RFGs with a functional group equivalent weight <5000, as defined in the PLC criteria (except un-substituted positions ortho and para to phenolic hydroxyl or partially-hydrolysed acrylamides), you are also required to show evidence of item six test results.

For a polymer, all the requirements in the table hold for biopolymers and low molecular weight synthetic polymers (with an NAMW <1000 Da).

If you have data other than that included in the table, you must report it. NICNAS will not accept the chemical for self-assessment if any such data leads to the chemical or polymer being classified as a hazardous substance.

You cannot request waivers of test requirements or substitution of analogue or product results with selfassessments, as these would require case-by-case NICNAS assessment.

You are not required to submit acute inhalation toxicity results if the chemical:

- has a vapour pressure <1.5 kPa
- (as introduced) has <25% of particles having <10 μm diameter
- is not purposely aerosolised during use (except where this constitutes a 'controlled use').

You are required to list the results of the toxicity testing in the report template, along with any discussion of observed results below classification thresholds. NICNAS may ask that your notification be changed to a non self-assessed category if the information reveals concerns that need further assessment.

In the above table, 'slightly irritating' refers to irritation test results where the effects observed are below classification thresholds. 'Non mutagenic' and 'non genotoxic' refer to negative results as defined for individual test guidelines.

Environmental criteria for non-hazardous chemicals and polymers (non PLC)

You must establish that the chemical or polymer is non-hazardous with respect to environmental toxicity. The chemical or polymer must:

- have one of these characteristics:
 - dissolves in water without dissociation or association and is not surface active and the partition coefficient (n octanol/water) at 20°C as log P_{ow} does not exceed 3;
 - solubility in water is >1 mg/L; and
 - molecular weight (or number average molecular weight (NAMW) in the case of a polymer) is >1000;
- be readily biodegradable; and
- have a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC₅₀ or EC₅₀ 100mg/L or greater.

NICNAS will not accept chemicals meeting criteria for persistence and/or bioaccumulation for selfassessment.

You must present all relevant environmental data and a full set of physico-chemical data in the self-assessment report.

2.3.5 MODULAR NOTIFICATION CATEGORIES -REDUCED FEE OPTIONS

NICNAS has a number of modular notification categories with reduced fees, where a previous (or concurrent) assessment can be utilised in the NICNAS assessment. These are available for non self-assessed Standard, Limited and Polymer of low concern applications, where:

Similar Chemical: the notified chemical or polymer is similar^[1] to a chemical or polymer previously assessed by NICNAS, or

Group Assessment: the notified chemical or polymer is being notified at the same time as a similar chemical or polymer (primary chemical or polymer) and for a similar use, or

Approved Foreign Scheme: an assessment of the notified chemical in Canada (under a comparable schedule) is available, or

Comparable Agency: an assessment of the notified chemical by:

- the Therapeutic Goods Administration (TGA), under the *Therapeutic Goods Act 1989*, is available, or
- the Australian Pesticides and Veterinary Medicines Authority (APVMA), under the Agricultural and Veterinary Chemicals Code Act 1994, is available, or
- Food Standards Australia New Zealand (FSANZ), under the Food Standards Australia New Zealand Act 1991, is available, or
- a chemicals notification and assessment scheme from the USA, EU (pre-REACH), Canada (where the criteria for the Approved Foreign Scheme category are not met), or OECD member country, is available.

[1] The term 'similar' is defined by specific criteria in the sections below.

General application requirements

If submitting an application under one of the modular notification categories, indicate this on the STD/LTD or PLC notification Form-1 and, as indicated, on the form, complete and submit the modular attachment. The attachment relates solely to the application under this category. Completing it does not, however, fulfil the requirements of the notification itself.

In all cases you must:

- have consent from the original notifier and the holder of the data for the original assessment to use the assessment report for a NICNAS assessment
- address all relevant schedules of data requirements for the relevant assessment category and provide copies of all available toxicity data in English—except in the case where the chemical has been previously assessed by NICNAS.

Modular notification—similar to chemical previously assessed by NICNAS

CRITERIA FOR SIMILAR CHEMICAL

For NICNAS to regard a chemical (polymers are considered separately, below) as similar to another chemical for the purposes of reducing fees, the chemical must be *prima facie* structurally identical or similar and must have been assessed at the same or a higher-level (that is, STD) notification category. An exception may be where the full scheduled suite of ecotoxicity and environmental fate data was assessed in the original lower level (that is, LTD) notification.

These identity and physico-chemical criteria must be met for the similar chemical:

- contains identical substructure/s that may play a critical functional role
- has the same or similar molecular weight
- has the same, or expected to be the same, molecular properties (for example, lipophilicity, electronic or steric parameters)
- has an octanol-water partition coefficient (K_{ow} not log K_{ow}) within the range of 50% to 200% of the previously assessed chemical.

In addition, the differences in identity must not be known to affect the toxicity profile of the chemical. This can be typically demonstrated where the chemical meets these criteria in comparison with the other chemical (although a comparison of other toxicity endpoints may be warranted in certain cases):

- acute oral toxicity—LD₅₀ within the range of 50% to 200%
- aquatic toxicity—LC₅₀ or EC₅₀ within the range of 50% to 200%.

The chemicals must have the same classification in accordance with the Approved Criteria for Classifying Hazardous Substances or GHS.

EXAMPLES

These examples illustrate the types of chemicals that could meet the criteria for 'similar chemical':

1.Salts

Salts often demonstrate a similar pattern of activity when the active chemical form is independent of the counterion found in the preparation (that is, where the counterion toxicity is equivalent), and consequently identical *in vivo*.

Therefore, salts formed when the hydrogen of an acid is replaced by an alkali metal or a cation of equivalent solubility (for example, NH_4^+) may be suitable. Thus the Na^+ salt is reasonably expected to be closely similar in activity to that of the K⁺ salt but quite different in activity to the Pb⁺ salt. NICNAS will assess amine salts case-by-case.

2. Positional isomers

While an isomer has the same number and kind of atoms and hence the same molecular weight, it differs in the arrangement or configuration of the atoms. Positional isomers have the same empirical formula and unchanged chemical functional groups but have at least a single variation to the branch point of a hydrocarbon chain—for example, normal-, iso- and anteiso- isomeric forms—or a change to the aromatic ring substitution position.

However, in heterocyclic ring systems, both the ring size and the number and ring position of heteroatoms should not change. The change in branching or substitution position should not be known to affect the toxicity profile of a chemical. For example, 2-ethyl hexanoic acid is classified with the risk phrase 'Possible risk of harm to the unborn child (R63)' whereas octanoic acid is not. The position of substitution of aromatic amines is known to affect the genotoxicity profile.

3. Stereoisomers

While a stereoisomer has identical chemical constitution, it differs in the arrangement of the atoms or groups in space (for example, optical and geometric isomers). Stereoisomers may meet the criteria for the similar chemical. However, the change in stereochemistry should not be known to affect the toxicity profile of the chemical (for example, where *in vivo* inter-conversion occurs).

4. Bio-isosterism

Chemicals related by a simple recognised change between two known groups with similar physical or chemical properties that impart similar biological properties to a chemical (for example, chlorine -CI group replaced by a trifluoromethyl -CF₃ group or cyano -C \equiv N group) may meet the criteria for similar chemical.

5. Essential oils

Often essential oils from plants of the same species are regarded as different chemicals (with different CAS numbers), when separation has resulted in slightly different chemical profiles. Often these differences may have little or no impact on both the toxicological and eco-toxicological activity of the chemical.

6. Fatty acid resins

In many cases for chemicals that have a fatty acid chain such as alkyd resins, the fatty acid is not a determinant of chemical properties. Where the saturation profiles are similar (such as in the case of sunflower oil and soybean oil, or tung oil and linseed oil) one fatty acid may be substituted for another without significantly changing the properties of the chemical.

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7. Animal and plant derived fatty acids

Fatty acid saturation profiles derived from animals and plants differ slightly; in cases where the saturation profile of the fatty acid has little impact on the pattern of activity, either type may meet the criteria as a similar chemical for the other.

CRITERIA FOR SIMILAR POLYMER

For NICNAS to regard one polymer as similar to another, the polymer must be assessed in the same notification category. In addition, the change in polymer identity must not be known to affect the toxicity profile of the polymer (for example, toxicity to algae is known to be highest for polyanionic polymers when the acid is on alternating carbons of the polymer backbone).

For NICNAS to regard one polymer as similar to the originally assessed polymer or primary polymer, the notified polymer must be covered by one of these situations:

- the notified polymer contains one polymer constituent less than the originally assessed polymer or primary polymer
- the notified polymer contains a polymer constituent which is similar to a polymer constituent in the originally assessed polymer or primary polymer with all other polymer constituents the same. In this case all but one polymer constituent should be the same. Where there is a difference in a polymer constituent, the substituted one must meet the criteria for similar chemical. You need to provide data on the original and substituted polymer constituent to demonstrate this.
- the notified polymer is structurally identical to the originally assessed polymer or primary polymer. In some cases, a polymer may be manufactured by different reaction pathways and, in some cases, using different reactants. This can lead to the identification and naming of a particular polymer in more than one way, with different CAS registry numbers, although the polymers may be structurally identical (that is, contain the same linkages and functional groups). You need to provide information to support this.

In addition, the identity and physicochemical criteria (given below) must be met:

- contain the same linkages and functional groups, and
- water solubility within the range of 50% to 200%.

Notification requirements

You need to follow the normal notification procedures for a STD, LTD or PLC notification. Read the description of relevant notification categories found earlier in this appendix and in Volume 1, NICNAS Handbook, Chapter 6: Information on General Notification Procedures for further information.

You must address all NICNAS schedule of data requirements for the relevant assessment category. Where a variation of schedule requirements was accepted for particular endpoint/s in the original notification, you are not required to apply for a variation of schedule of data requirements for the same endpoint/s.

DATA REQUIREMENTS

You must include all available data on the notified chemical or polymer as part of your submission. You can use information in the original assessment report to address particular endpoints under the schedule of data requirements.

You need to demonstrate that the criteria for similar chemical or polymer are met with the following (which will also be used for risk assessment):

- identity and composition of the chemical or polymer
- introduction and use concentrations
- use information

- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health
- label and (M)SDS for the chemical or polymer in the form in which it is introduced
- melting(or boiling) point, particle size, and partition coefficient in the case of chemicals
- particle size and water solubility in the case of polymers
- acute oral toxicity (typically for STD notifications)
- acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

Notes:

- As there will always be a level of uncertainty associated with any chemical or polymer for which a complete suite of toxicological and eco-toxicological tests have not been performed, a conservative approach to the assessment is necessary to minimise potential risks. NICNAS may ask you for additional data where new chemicals or polymers are of particular or known concern (for example, because of toxicity profile, persistence, or significantly different use patterns which may increase environmental and/or public exposure).
- Although preferred, acute aquatic toxicity data may not be required in circumstances where the predicted environmental concentration (PEC) for the notified chemical is the same as in the original assessment that is, volume and use is the same and where the Risk Quotient (Q = PEC/PNEC) in the original assessment is ≤0.1.

Your application should consist of:

- a completed modular attachment to the relevant STD or LTD or PLC form, as appropriate
- the assessment reference for example, STD/XXX for the chemical or polymer that has been previously assessed (included in the attachment)
- justification of why the chemical or polymer meets the 'similar' criteria (included in the attachment)—where the original notification used read across data the suitability of the read across data for the notified chemical should also be demonstrated
- a list of other available information (for example, toxicity or environmental test data) on the previously assessed chemical or polymer that was not provided in the original NICNAS assessment (included in the attachment)—you must provide a copy of this data as part of the notification
- consent for you to use the data on company letterhead from the notifier(s) and any other owners of data supplied in the original assessment (if you are not the original notifier).

ASSESSMENT PROCESSES

During screening, NICNAS will verify that the chemical or polymer meets the criteria for similar chemical or polymer. You will be advised of the results in a screening letter.

Modular notification—group assessment

This certificate category is for a chemical or polymer notified at the same time as one that is similar and has a similar use (including notification of inseparable mixtures).

This category applies if two or more chemicals or polymers both meet the similar criteria (see previous section) and are notified for a non self-assessed certificate at the same time. You pay the full fee for one application, and a reduced fee for the others.

CRITERIA FOR SIMILAR USE

Overall, a similar use is:

• one that does not require a change to the original exposure assessment and assessment conclusions and recommendations

• where the original assessment report states specific Secondary Notification circumstances of which the NICNAS Director must be notified (Subsection 64(1) of the Act), the new use would not be considered similar whereby these circumstances would be met.

Specifically the following must be the same:

- industry sector in which the chemical is used
- routes of human exposure
- types of workers exposed and the extent to which they are exposed
- routes of environmental release
- potential for public exposure
- volume range— <1 tonne, 1–3 tonnes, 3–10 tonnes, 10–30 tonnes, 30–60 tonnes and 60–100 tonnes. (Note: a use would not be considered similar if the increase in volume would lead to a change in the original risk assessment).
- the mode of introduction (for example, import or manufacture).

APPLICATION REQUIREMENTS (EXCEPT IN THE CASE OF INSEPARABLE MIXTURES)

You must follow the normal procedures for a STD, LTD or PLC notification for the chemical or polymer considered to be the primary one. Read the relevant notification categories described earlier in this appendix and also Submission tips for new chemical notifications, for further information.

For secondary chemicals or polymers you need to complete the attachment to the relevant STD, LTD or PLC form.

DATA REQUIREMENTS

You must provide all available data on both primary and secondary chemicals and polymers as part of your submissions. All relevant schedule of data requirements must be addressed for the relevant assessment category. If the schedule of data requirements is fulfilled from data on the primary and secondary chemicals or polymers, you do not have to apply for a variation of schedule requirements. If an application for variation of schedule requirements is required, one application (and hence one fee) covers all notifications.

If you are applying for exempt information based on confidentiality, you typically only have to complete one application (and hence pay one fee) for all notifications.

You need to submit the following for the secondary chemical or polymer, to demonstrate that the criteria for similar chemical or polymer and similar use is met (this will also be used for the risk assessment):

- information on the identity and composition of the chemical or polymer
- information on use
- information on introduction and use concentrations
- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health
- label and (M)SDS for the chemical or polymer in the form that it is introduced
- melting(or boiling) point, particle size, and partition coefficient in the case of chemicals
- particle size and water solubility in the case of polymers
- acute oral toxicity (typically for STD notifications)
- acute aquatic toxicity for the most sensitive organism (typically for STD notifications).

Notes:

1. As there will always be a level of uncertainty associated with any chemical or polymer for which a complete suite of toxicological and eco-toxicological tests have not been performed, NICNAS takes a conservative

approach to assessment—to minimise risks. Where new chemicals or polymers are of particular or known concern—for example, because of toxicity profile, persistence or significantly different use patterns which may increase environmental as well as public exposure—you may be asked for additional data.

2. Although preferred, acute aquatic toxicity data may not be required in circumstances where the Risk Quotient (Q = PEC/PNEC) for the primary chemical is ≤ 0.1 .

APPLICATION REQUIREMENTS (INSEPARABLE MIXTURES OF SIMILAR CHEMICAL/POLYMERS)

A reduction in fees applies with inseparable mixtures where the components meet the criteria for similar polymer (with the exception of the water solubility criteria) or these criteria for chemicals:

- contains an identical substructure or substructures that may play a critical functional role (the difference in structure or substructure must not be known to effect the toxicity profile of the chemical)
- has the same or similar molecular weight (for example, minor variation in chain length)
- has the same, or expected to be the same, molecular properties (for example, lipophilicity, electronic or steric parameters).

You must follow the normal notification procedures for a STD, LTD or PLC notification for the chemical or polymer of highest concentration (the primary one). You need to complete the attachment to the relevant STD/LTD or PLC form for all secondary chemicals or polymers.

Each of your notification packages—for both primary and secondary chemicals and polymers—must contain:

- information on the identity and composition of the chemical or polymer
- information on use
- information on introduction and use concentrations
- estimated manufacture and import volume
- matters affecting occupational health and safety, environmental impact and public health.

Your notification package for the primary chemical or polymer must contain:

- required physico-chemical and toxicological / eco-toxicological data—in accordance with the Schedule of Data Requirements—on the inseparable mixture, and
- the Label and (M)SDS for the chemical or polymer in the form that it is introduced.

You do not have to include this information in your notification package for the secondary chemicals or polymers.

You must address all NICNAS schedule data requirements for the relevant assessment category. You do not need to apply for a variation if the schedule data requirements are met from your data on the inseparable mixture. If you need to apply for a variation of schedule requirements, you only need to complete one application (and hence pay one fee) to cover all notifications.

If you are applying for exempt information based on confidentiality, you typically only have to complete one application (and hence pay one fee) for all notifications.

ASSESSMENT PROCESSES (INCLUDING INSEPARABLE MIXTURES)

During screening, NICNAS will verify that the chemical or polymer meets the criteria for similar chemical or polymer and/or similar use. You will be advised of the results in a screening letter. NICNAS will then produce an assessment report covering both the primary and secondary chemicals or polymers. The normal statutory 90-day assessment time frames apply.

Modular notification accosed by a comparable agoncy

(APVMA, TGA or FSANZ)

You must follow the normal notification procedures for a STD, LTD or PLC notification, address all NICNAS schedule data requirements for the relevant assessment category, and provide all available data on the notified chemical or polymer as part of your submission.

NICNAS is currently working with other Australian Government regulators including the Australian Pesticides and Veterinary Medicines Authority (APVMA), Food Standards Australia New Zealand (FSANZ), and the Therapeutic Goods Administration (TGA) to develop ways for these bodies to provide their assessment reports to NICNAS.

Contact NICNAS if you wish to use this modular notification option.

2.3.6 USE OF OVERSEAS ASSESSMENTS IN THE NOTIFICATION OF NEW CHEMICALS

There are five arrangements in place for NICNAS to consider overseas assessments conducted elsewhere, as noted below:

Approved Foreign Scheme—Canada

Modular Notification (Comparable Agency)—Canada

Modular Notification (Comparable Agency)—United States

Modular Notification (Comparable Agency)—European Union (EU)

OECD Parallel Process

Under these arrangements, NICNAS can consider, and use in its assessment report, an overseas health and environment hazard assessment, from one of these countries, for a new chemical. NICNAS must have access to the overseas assessment report/s. The other elements of the risk assessment and recommendations on safe use of the chemical in Australia will still be carried out by NICNAS.

Arrangements for considering overseas assessments

The arrangements in place for NICNAS to consider overseas assessments are described below.

Approved Foreign Scheme category—Canada

Applications under the Approved Foreign Scheme category can be made for a chemical that was notified and assessed in Canada as a new chemical under a comparable schedule (see table below) to a STD, LTD or PLC notification in Australia.

SUMMARY OF COMPARABLE NOTIFICATION CATEGORIES IN AUSTRALIA AND CANADA

NICNAS category	Canada category (current regulations—2005)	Canada category (older regulations—1994)
Limited	5 or 10	ll or VII
Standard	6 or 11	III or VIII
PLC*	9 (only reduced regulatory requirements—RRR)	VI or VII (only low concern polymers)

* Must meet Australian PLC criteria to be considered under the Approved Foreign Scheme.

The Approved Foreign Scheme provision does not apply—but the notification will be considered under the Modular Notification (comparable agency) category—in these types of cases:

- the Canadian assessment was based on information that cannot be released to NICNAS or published
- the assessment was based on third party analogue data
- the information used in the Canadian assessment does not fulfil the data requirements for the notified category in Australia
- significant additional information has become available since the Canadian assessment (for example, additional toxicological or ecotoxicological studies)
- additional data is required—for the PLC category only— due to significant potential releases to the environment or intended wide dispersive use by the public (for example, cosmetics).

If you are unsure whether your application fulfils the requirements of the Approved Foreign Scheme category it is best to apply under the Modular Notification (comparable agency) category—Canada (see below). Contact NICNAS if you are not sure which category is appropriate.

After receipt of the notification and screening, NICNAS will advise you if your application will be assessed under an Approved Foreign Scheme or Modular Notification category.

MODULAR NOTIFICATION (COMPARABLE AGENCY) CATEGORY—CANADA OR THE UNITED STATES

Applications under this modular notification category (STD, LTD or PLC) are for new chemicals previously notified and assessed in Canada or the United States.

For chemicals previously assessed in Canada the Modular Notification category is suitable for chemicals not assessed under a comparable notification category, or where other circumstances, as outlined above, apply. If you are unsure, NICNAS strongly recommends you apply under the Modular Notification category.

MODULAR NOTIFICATION (COMPARABLE AGENCY)—EUROPEAN UNION

Application under this modular notification category covers LTD and STD applications where the chemical was previously assessed in the EU and you can provide NICNAS with the EU assessment report to be used in the Australian notification. You also need to submit a validation letter from the EU authority. Contact NICNAS if you wish to use this category. The arrangements apply to new chemicals assessed pre-REACH^[1], as similar reports are not likely to be available under REACH.

[1] REACH is the European Community Regulation on chemicals and their safe use. It deals with the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emical substances. The law entered into force on 1 June 2007.

Outline of the process

NOTIFICATION CATEGORY

You can apply under the Approved Foreign Scheme or the Modular Notification (comparable agency) categories for the STD, LTD and PLCs. You cannot, however, apply for a self-assessed assessment certificate under these provisions.

PROVISION OF OVERSEAS ASSESSMENT REPORTS

A key requirement is that you must be able to arrange for the information and/or assessment reports to be released to Australia from Canada (Environment Canada) or the United States (United States Environmental Protection Agency [US EPA]).

For Canada you need to request to release information at least 60 days before you submit your notification to NICNAS.

To request release of the Canadian or US reports to NICNAS you should:

- Contact your affiliate in Canada or USA to arrange release of the assessment reports. Only the notifier for assessment of the chemical in Canada or USA can authorise release of the reports for use in Australia. Where the chemical was assessed overseas as a foreign supplier notification, authorisation for release of the reports in Australia must be obtained from both the notifier and the foreign supplier.
- Request release of the overseas reports using the pro-forma documents available from NICNAS:
 - the *pro-forma* letter for Canada—you should forward this completed letter to Environment Canada at least 60 calendar days before you make notification to NICNAS.
 - the pro-forma agreement for the United States is available from NICNAS by emailing newchemicals@nicnas.gov.au.
- Send a copy of the request letter that was sent to Canada, to NICNAS for the attention of Admin, New Chemicals, with information about the new chemicals notification that will be made to NICNAS (for example: name of the Australian notifier, category of notification in Australia).

EU reports should be provided with the NICNAS notification.

NOTIFICATION FORMS

- Use the relevant notification form for the assessment category (that is STD, LTD or PLC)
- Complete the modular attachment form
- PLC submissions: complete all sections of the template
- STD and LTD submissions: complete all sections except for the hazard assessment elements (unless there is additional toxicological or ecotoxicological data that was not considered in the overseas assessment).

You need to provide this information with your template notification:

- A copy of all available information provided to the EU, Canada or the United States, including:
 - all test data
 - all other information submitted in the technical dossier
 - any information provided in response to a request for further information.
- A copy of any other available information about the chemical (for example, toxicity test data, environmental test data and information) not provided for notification to Canada, the EU or the United States, or information or data generated since the foreign assessment. Address all NICNAS schedule data

requirements for the relevant assessment category. You can also apply to vary the data requirements.

- Information relevant to occupational health and safety in Australia.
- Information about the use, volume, manufacture and disposal of the chemical, including exposure information in Australia.
- Confirmation that the chemical notified to NICNAS is the same as the chemical assessed in the overseas assessment. For PLC notifications, the polymer must meet the NICNAS PLC criteria and have a similar molecular weight profile and monomer composition to the polymer assessed overseas.
- An application for exempt (confidential) information where you want certain information not published, noting that information treated as confidential overseas is not automatically treated as such in Australia.

The NICNAS Director may ask for further information to enable an adequate assessment of the chemical.

FEES

You pay a specific reduced fee (either Approved Foreign Scheme or Comparable Agency). NICNAS will determine if your application fulfils the requirements for an Approved Foreign Scheme. If not, you can have it considered under the modular (comparable agency) category which will attract additional fees. If unsure, it is best to make the application under the Modular Notification (comparable agency) category.

OECD parallel process under its clearing house on new chemicals

The Organisation for Economic Co-operation and Development (OECD), through its Clearing House for New Chemicals, has encouraged efforts to maximise work-sharing arrangements in notifying and assessing new industrial chemicals, with a goal of Mutual Acceptance of Notifications. The Parallel Process was developed to facilitate these multilateral arrangements.

The Parallel Process reduces the time required for notifying new industrial chemicals to multiple jurisdictions. This work-sharing process also aims to improve decision making by sharing knowledge and expertise in the area of new chemical assessments, increasing work efficiencies among OECD member countries, and building on the efforts of all countries involved. Procedures are in place for confidentiality.

In the Parallel Process, a company notifies a new chemical to multiple jurisdictions (of their choice), providing an agreed set of data to all participating countries, namely, a lead country and secondary countries. In principle, the lead country conducts the hazard assessment, secondary countries provide input into the process, and then—once the hazard assessment is accepted by the notifier—each participating country uses the hazard assessment in conducting its own risk assessment.

PHASES OF THE PARALLEL PROCESS

The Parallel Process consists of three phases: Pre-notification, Notification and Assessment. These phases are described here.

1. Pre-notification phase

You identify and contact the potential lead country authority seeking their agreement to participate and be the lead authority. You then contact other selected country authorities seeking their agreement to participate as secondary countries. If any authority declines to participate, you revise your plans accordingly.

You can also identify countries to engage as observers. Observer status allows a country to receive information and monitor how assessments are conducted and provide informal input on the hazard assessment, without affecting the timing or content of the process.

In preparing for a Pre-Notification Consultation (PNC), you gather a draft Pre-determined Set of Information (PSI) for the chemical, structuring it around the OECD Minimum Pre-marketing Dataset (which is similar to the standard NICNAS notification package).

Contents of the PSI should address, as appropriate, physical and chemical properties, environmental fate parameters (including biodegradation and bioaccumulation), ecotoxicity and health effects information, and

any additional information you have. You may need to revise the PSI after PNC discussions.

You provide the draft PSI package to all participating authorities before the PNC so they can review it. The lead country chairs the PNC meeting, or teleconference, to lead discussion of the PSI and seek agreement on its content. The decision to accept any proposed testing and approaches—including how they satisfy participating country's jurisdictions—may require more than one meeting or teleconference before final acceptance by all countries. Participants are expected to work promptly to complete this process, within a timeframe agreed at the start of the PNC process.

2. Notification phase

You submit your notification package to the lead country, including any specific notification form required and payment of fees. The lead country assesses the notified substance within the legally required assessment time clock, following their national regulatory assessment procedures.

3. Assessment phase

The lead country prepares a draft hazard assessment report and sends it to secondary countries for comment. The lead authority develops a second draft hazard assessment incorporating comments as appropriate. The lead country issues this to you for comment, and then finalises and distributes the report to you.

After receiving the final hazard assessment, you supply national notification forms and the completed collective hazard assessment to all secondary countries, with fees required by them (although commonly notification forms and secondary country specific information—such as environmental release and occupational exposure data—are submitted to the secondary countries earlier).

FEES

Normal fees apply if Australia is the lead country. A reduced fee applies if Australia is the secondary country contact NICNAS for further details. No fee applies if Australia is an observer only.

FURTHER INFORMATION

More information on the OECD Parallel Process, including detailed Standard Operating Procedures, is available on the OECD website at: http://www.oecd.org/chemicalsafety/assessmentofchemicals/proceduresfornotificationofnewchemicals.htm.

Overview of international assessment options

There are several options from which notifiers can choose when seeking to submit a new chemical for assessment.

OVERVIEW OF OPTIONS FOR USE OF OVERSEAS ASSESSMENTS AND INTERNATIONAL WORK-SHARING IN NICNAS NEW CHEMICAL ASSESSMENTS

Option	Approved Foreign Scheme— Canada only	Modular Notification (comparable agency)— Canada	Modular Notification (comparable agency)— United States	Modular Notification(c omparable agency)— European Union	OECD Parallel Process (work- sharing)
Status of chemical overseas	Previously assessed as a new chemical in Canada (Environment Canada)	Previously assessed as a new chemical in Canada (Environment Canada)	Previously assessed as a new chemical in the United States (US EPA)	Previously assessed as a new chemical in EU (ELINCS) Does not apply to REACH	Planned to be notified in two or more OECD countries
Linkage with company in overseas country	Required— Canadian notifier authorises release of Canadian reports to NICNAS	Required— Canadian notifier authorises release of Canadian reports to NICNAS	Required— United States notifier authorises release of US EPA information to NICNAS	Required— EU notifier provides assessment report and letter of validation from EU authority to NICNAS	Required— co-notification involves relevant government and industry representative s
NICNAS assessment category	STD, LTD or PLC	STD, LTD or PLC	STD, LTD or PLC	Usually STD or LTD	STD, LTD or PLC
Timing	Request to Environment Canada 60 days before notification to NICNAS	Request to Environment Canada 60 days before notification to NICNAS	Report provided to NICNAS before the start of NICNAS assessment	Report and validation letter to be provided to NICNAS at time of notification	Depends on preparation of hazard assessment by lead country
Other requirements	Conditions apply, including that the chemical must have been assessed in Canada in a comparable assessment category to that of the	Can be used if requirements for Canada Approved Foreign Scheme are not met (for example, if notification is not in a comparable	_	Of most benefit if assessed in a comparable assessment category	Dataset acceptable to all countries agreed during the process

	NICNAS notification	category)			
Fee benefit	Specific Approved Foreign Scheme upfront fee applies	Specific modular (comparable agency) upfront fee applies	Specific modular (comparable agency) upfront fee applies	Specific modular (comparable agency) upfront fee applies	Usual upfront fee applies if Australia is the lead country. Otherwise a reduced fee applies (contact NICNAS for details)

2.4 APPENDIX D: POLYMERS OF LOW CONCERN: ADDITIONAL INFORMATION

This appendix details the requirements under the Act (see Legislation and Regulations) for notifying Polymers of Low Concern (PLCs).

Please read this in conjunction with Notification categories for new chemicals.

Sections of this appendix:

- Reactive functional groups
- Functional group equivalent weight
- Molecular weight
- Cationic polymers
- Hazard classification
- Elemental criteria
- Degradable or unstable polymers
- Water absorbing polymers
- Polyesters

2.4.1 REACTIVE FUNCTIONAL GROUPS

The number of Reactive Functional Groups (RFGs) in a polymer is important in determining whether it meets the PLC criteria.

You need to take RFGs into account when considering the low molecular weight species of a polymer and when determining whether cationic polymers are PLCs.

A RFG is defined as: 'an atom or associated group of atoms in a chemical substance that is intended or can be reasonably anticipated to undergo facile chemical reaction'.

RFGs are divided into three categories—low, moderate and high concern—to reflect the comparative reactivity of each functional group (see table below).

The criterion for determining the category is more qualitative than quantitative, and is based on the presence of chemically or metabolically-reactive or toxic (including eco-toxic) functional groups within the polymer.

LOW

RFGs in the low concern category generally lack reactivity, or have low adverse reactivity, in a biological setting.

There is no Functional Group Equivalent Weight (FGEW) cut-off for low concern RFGs under the PLC criteria.

MODERATE

RFGs in the moderate concern category have evidence of reactivity in a biological setting but the effects are not severe enough to place the functional group in the high concern category. Sufficient information must be available to be confident that the RFG is of moderate concern.

For a polymer to meet the PLC criteria, the FGEW cut-off for moderate concern RFGs is 1000.

HIGH

RFGs in the high concern category have evidence of human health hazard—adverse effects in humans or conclusive evidence of severe effects in animals.

Where there is no information, or insufficient or contradictory information, on a RFG it defaults to the high concern category until sufficient information becomes available for it to be moved to another category.

For a polymer to meet the PLC criteria, the FGEW cut-off for high concern RFGs is 5000.

If a polymer does not meet the cut-off for moderate or high concern RFGs to meet the PLC criteria, it could still be considered a PLC if sufficient additional information is provided to negate concern caused by the RFGs present. This information should generally consist of toxicological studies on the notified polymer or a suitable analogue addressing the particular concern raised by the RFGs present.

For example, if a polymer contains sulfonyl halide RFGs with a FGEW <5000 then it would not be eligible to be a PLC under the PLC criteria as sulfonyl halides are potential sensitisers. However, if toxicological tests on the notified polymer or a suitable analogue show that the notified polymer was unlikely to be a sensitiser then it may still be acceptable for notification as a PLC.

A number of functional groups are not considered to be RFGs. These include carboxylic esters, ethers, amides, urethanes, sulfones and the nitro groups. This is provisional on the functional group not being modified to enhance its reactivity (for example, the dinitrophenyl ester of a carboxylic acid).

RFGs in their respective categories are listed in the regulations under the Act. The list is updated by notice in NICNAS's *Chemical Gazette*.

REACTIVE FUNCTIONAL GROUP CATEGORIES

Low concern	Moderate concern	High concern
Carboxylic acid		Pendant acrylates and methacrylates
Aliphatic hydroxyl		Aziridines
Unconjugated olefinic considered 'ordinary'		Carbodiimides
Butenedioic acid		Halosilanes, Hydrosilanes, Alkoxysilanes ¹
Conjugated olefinic groups contained in naturally occurring fats, oils and carboxylic acids		Hydrazines
Blocked isocyanates (including ketoxime-blocked isocyanates)		lsocyanates, isothio-cyanates
Thiols		Alpha or beta lactones
Unconjugated nitriles		Vinyl sulfones or analogous compounds
		*Acid halides
	Conjugated olefinic groups <u>not</u> contained in naturally occurring fats, oils and carboxylic acids	*Acid anhydrides
		*Aldehydes
		*Hemiacetals
		*Methylolamides, -amines ² or – ureas
		*Cyanates

Halogens (except reactive		
halogen containing groups such as benzylic or allylic halides)		*Epoxides
		*Un-substituted positions ortho and para to phenolic hydroxyl
		*Allyl ethers
		*Imines (ketimines and aldimines)
		Partially-hydrolysed acrylamides
		Other RFGs not in low or moderate concern groups

1 Alkoxysilanes with alkoxy groups >C2 are listed as moderate concern by the United States Environmental Protection Agency (US EPA)

2 Amines are regarded as high concern RFGs. Polymers containing them are generally considered under cationic polymers.

*Denotes the group that is in the US EPA moderate concern category for which data and information to support placement in this category is unavailable to NICNAS. These RFGs will default to the high concern category pending provision of such data and information by industry and/or other parties to NICNAS.

2.4.2 FUNCTIONAL GROUP EQUIVALENT WEIGHT

The FGEW is used to determine if the RFGs in a polymer are substantially diluted by polymeric material to allow the polymer to be a PLC.

The FGEW of a polymer is defined as the ratio of the Number Average Molecular Weight (NAMW) to the number of functional groups in the polymer. It is the weight of a polymer that contains one formula weight of the functional group.

The level of low concern RFGs in the polymer is not restricted. Low concentrations of RFGs are permissible in polymer molecules, but the quantity is restricted by the reactivity of the functional group/s in question.

HOW TO CALCULATE FUNCTIONAL GROUP EQUIVALENT WEIGHT

Unless the FGEW can be determined empirically by recognised, scientific methodology (typically titration), a worst-case estimate must be made for the FGEW.

All moderate and high concern functional groups must be taken into account when calculating FGEW.

Guidance for estimating FGEW using specific methods is in D2.1 and D2.2, including illustrative examples for each (end-group analysis and per cent charged method).

Method 1—End-group analysis

FOLIATION 1. CALCULATING EGEW BY SIMPLY COLINTING THE NUMBER OF REGS

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AND DIVIDING INTO THE NAMW

 $FGEW = \frac{NAMW}{v}$

where n = the number of $RFGs^{[1]}$ in the monomer^[2]

[1] Reactive functional groups [2] Atom or small molecule that may bind chemically to other monomers to form a polymer

LINEAR POLYMERS

Linear polymers have the simplest polymer architecture: a *linear* chain: a single backbone with no branches.

For linear polymers, such as some condensational polymers (for example, polyesters and polyamides) the only RFGs are at the end of the chain because the others are used up in the condensation reaction. For linear polymers, where there are two RFGs per monomer, the FGEW is half the NAMW.

For example, for a polyamide of NAMW 1500 made from ethylenediamine and adipic acid, an amine group would be expected at each end of the polymer chain. Therefore, FGEW = 1500/2 = 750.

BRANCHED POLYMERS

For polymers where branching occurs, the RFGs at the end of each branched chain must be counted.

For example, consider the polymerisation of pentaerythritol (4 reactive groups) with polypropylene glycol (2 reactive groups) and an excess of isophorone diisocyanate (2 reactive groups) to give a polymer of NAMW 3000.

Due to the branching of pentaerythritol and excess diisocyanate, the resultant polymer will theoretically have six isocyanate end groups. Therefore, FGEW = 3000/6 = 500.

Method 2—Per cent charged method

Some condensation and addition reactions create polymers where not all RFGs along the backbone of the polymer are consumed during the reaction, so an accurate FGEW cannot be determined through a simple end-group analysis.

In many of these cases, calculating the FGEW may be more complex. For example, in some condensation and addition reactions, some RFGs along the polymer backbone are unchanged during polymerisation. Also, in some cases, the structural formula of the final polymer is not accurately known.

In these cases, FGEW can be calculated according to Equation 2 or 3, using the weight percentage monomer in the polymer (W), the formula weight of the monomer (FW) and the number of RFGs on the monomer (n).

EQUATION 2



For example, for an acrylic polymer containing 7.5% acryloyl chloride monomer (FW 90.5), the FGEW of acid chloride groups in the polymer is:



EQUATION 3

If the various RFGs in a polymer arise from multiple monomers, the following equation can be used:



Where $FGEW_n$ is the FGEW for each functional group in the polymer.

EXAMPLES

 Consider the reaction between ethanediamine (MW 60) (charged at 30%) and diglycidyl ether (MW 130) (70%) to give a polymer of NAMW 5000. The epoxides in the backbone are reacted to give an aliphatic alcohol (low concern). The amine groups remain intact, with their FGEW proportional to the charged amount of ethanediamine. As the diglycidyl ether is in excess, it can be assumed that the polymer is epoxide-terminated.

Using equation 2, the FGEW for the amine group is $(100 \times 60)/(30 \times 2) = 100$. The FGEW for the epoxide group can be calculated using end group analysis (Equation 1), that is, 5000/2 = 2500.

Then, using equation 3, FGEWcomb = inverse of [1/100 + 1/2500] = 96.

1. Consider a p-cresol-formaldehyde condensation polymer which is reacted with 1.5% epichlorhydrin to give an epoxide-capped resin. As a worst-case scenario, it is assumed that the polymer is phenol-terminated and that epoxy rings from the epichlorhydrin (MW 92.5, 1 epoxy group) are also present. A NAMW of 10 000 is assumed.

Using equation 2, the FGEW for the epoxide group is $(100 \times 92.5)/(1.5 \times 1) = 6167$. The FGEW for the phenol group can be calculated using end group analysis (Equation 1), that is, $10\ 000/2 = 5000$.

Then, using equation 3, FGEWcomb = inverse of [1/6167 + 1/5000] = 2762.

1. Consider the addition reaction involving the polymerisation of three acrylates, glycidyl methacrylate (10%, MW 142, 1 RFG), hydroxymethyl acrylamide (2%, MW 101, 1 RFG) and acrylic acid (88%).

In this case, it can be assumed that each monomer is completely incorporated into the polymer, with the RFGs of concern being the epoxide group from glycidyl methacrylate and the hydroxymethyl amide group from the acrylamide. The carboxylic acid moiety from acrylic acid is of low concern and need not be included in FGEW calculations.

Using equation 2, the FGEW for the epoxide group is $(100 \times 142)/(10 \times 1) = 1420$. Again using equation 2, the FGEW for the hydroxymethyl amide group is $(100 \times 101)/(2 \times 1) = 5050$.

Then, using equation 3, $FGEW_{comb}$ = inverse of [1/1420 + 1/5050] = 1108.

2.4.3 MOLECULAR WEIGHT

Unless a new polymer is a polyester manufactured from the list of allowable reactants, the NAMW of a PLC must be 1000 Da or greater (see: polyesters). A PLC must also meet the percentage of low molecular weight species requirements.

For the purposes of the Act, the low molecular weight species in a polymer includes the oligomer content with NAMW <1000 Da, where oligomer is defined as the low molecular weight species derived from the polymerisation reaction.

This definition is consistent with that used by the US EPA in its polymer exemption criteria. It means that residual monomers and other reactants are not included when determining the content of low molecular weight species.

For polymers with an NAMW between 1000 and 10000, the allowable low molecular weight species is 10% under 500; and 25% under 1000, provided that the polymer contains:

- only low concern RFGs;
- moderate concern RFGs with a combined FGEW of 1000 or more (provided no high concern groups are present); or
- high concern RFGs with a combined FGEW of 5000 or more (the calculated FGEW must include moderate concern groups if present).

For polymers with an NAMW >10000, the allowable low molecular weight species is 2% under 500; and 5% under 1000. There is no limit on the number of RFGs in a polymer with an NAMW >10000.

Examples

1. Consider a polymer of NAMW 8000, 15%

Is the polymer a PLC? First, it meets the molecular weight criteria. The FGEW is 8000/2 = 4000. As the RFGs are in the high concern category, the polymer does not meet the criterion as the FGEW is below 5000. Therefore, the polymer is not a PLC.

2. Consider a polymer of NAMW 18000, 15%

Is the polymer a PLC? First, there is no restriction on RFGs so the number of epoxide groups does not matter. However, as the polymer does not satisfy the criterion for low molecular weight species, it is not a PLC.

2.4.4 CATIONIC POLYMERS

To be eligible as a PLC, a polymer must have a low charge, or cationic, density.

Cationic polymers and polymers reasonably anticipated to become cationic in a natural aquatic environment are not eligible as PLCs. The main concern is their toxicity towards aquatic organisms such as fish and algae.

For the purposes of the Act, and this guidance, these definitions apply:

- A polymer is a low charge density polymer if it is:
 - not a cationic polymer or is not reasonably anticipated to become a cationic polymer in a natural aquatic environment (4<pH<9), or
 - a solid material that is not soluble or dispersible in water and will only be used in the solid phase (for example ion exchange beads), or
 - cationic (or potentially cationic) and the combined (total) FGEW of cationic groups is 5000 or above (see: How to calculate functional group equivalent weight).

- A *cationic polymer* is a polymer containing a net positively-charged atom/s or associated group/s of atoms covalently linked to its polymer molecule. Examples are the ammonium, phosphonium and sulfonium cations.
- A *potentially cationic polymer* is a polymer containing groups reasonably anticipated to become cationic. Examples are all amines (primary, secondary, tertiary, aromatic, etc.) and all isocyanates (which hydrolyse to form carbamic acids, then decarboxylate to form amines).
- *Reasonably anticipated* means aknowledgeable person would expect a given physical or chemical composition or characteristic to occur, based on factors such as the nature of the precursors used to manufacture the polymer, the type of reaction, the type of manufacturing process, the products produced in the polymerisation, the intended uses of the substance and associated use conditions.

EXAMPLE

Consider a polyamide of NAMW 7000 manufactured from equimolar amounts of ethanediamine and isophthalic acid.

On average, the polymer will have one unreacted amino group at one end of the polymer chain and an unreacted carboxylic acid group at the other end. The amino group is potentially cationic so—as FGEW is defined as the ratio of the NAMW to the number of RFGs—the FGEW for the amino group is 7000/1.

Therefore, the polymer meets the criteria for low charge density as the FGEW is above 5000. If the NAMW had been <5000, or if the polymer had two free amine groups, then the polymer would not be eligible as a PLC.

2.4.5 HAZARD CLASSIFICATION

A polymer can only be a PLC if it is not classified as a hazardous chemical (see: Appendix A: Definitions).

2.4.6 ELEMENTAL CRITERIA

A PLC must contain, as an integral part of its composition, at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon and sulphur.

Excluding impurities, a PLC must only contain the following:

- carbon,hydrogen, nitrogen, oxygen, silicon and sulphur
- sodium,magnesium, aluminium, potassium, calcium, chlorine, bromine and iodine as the monatomic counter-ions Na⁺, Mg²⁺, Al³⁺, K⁺, Ca²⁺, Cl⁻, Br⁻ or Γ
- fluorine, chlorine, bromine or iodine covalently bound to carbon
- <0.2%(by weight) of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin and zirconium.

No other elements are allowed, except as impurities. Specifically, the fluoride anion F^- is not allowed as it has a high acute toxicity.

This requirement refers to monatomic species only. For example, a polymer containing the ammonium counter ion may be a PLC provided it meets the other PLC criteria.

Regarding the binding of halogens to carbon, it should be noted that the perchlorate anion CIO_4^- would not be allowed because the chlorine is not covalently bound to carbon, but the trichloroacetate anion $CCI_3CO_2^-$ would be allowed.

2.4.7 DEGRADABLE OR UNSTABLE POLYMERS

A PLC must be a stable polymer.

A polymer is not eligible to be a PLC if it is designed or reasonably anticipated to degrade, decompose or depolymerise substantially. This includes polymers that could substantially decompose after manufacture and use, even though they are not intended to do so.

For the purposes of the Act, and this guidance, this definition applies:

Degradation, decomposition or depolymerisation means a type of chemical change in which a polymeric substance breaks down into simpler, smaller weight substances as the result, for example, of oxidation, hydrolysis, heat, sunlight, attack by solvents or microbial action.

Reasonably anticipated - see definition in this appendix.

Substantially means 'considerably', 'meaningfully' or 'to a significantly large extent'. It is not intended to include the slow, natural biodegradation that occurs during, say, the weathering of paint.

Examples of polymers that would not meet this criterion include those that:

- are designed to be pyrolysed or burnt during normal use
- are explosive
- substantially biodegrade in the environment (for example, starch).

2.4.8 WATER ABSORBING POLYMERS

Water absorbing polymers with NAMW 10000 and greater—meaning a polymer capable of absorbing its own weight in water—do not qualify as PLCs.

This criterion is for water absorbing polymers in particulate form only and is directed towards polymers known as 'super absorbents', such as those used in disposable nappies and paper towels.

The concerns for water absorbing polymers are based on data showing that cancer was observed in a twoyear inhalation study in rats on a high molecular weight (HMW) water-absorbing polyacrylate polymer.

Water-soluble and water dispersible polymers are not considered to be water absorbing polymers. Moreover, it is assumed that particles of these polymers are adequately cleared from the lungs by normal mucociliary clearance mechanisms after inhalation.

2.4.9 POLYESTERS

A polyester is defined as a chemical substance meeting the definition of polymer in the Act with polymer molecules containing at least two carboxylic acid ester linkages, at least one of which links internal monomer units.

Polyesters manufactured from an approved list of monomers or other reactants are eligible for notification as PLCs, provided they satisfy all other PLC criteria. This provision is independent of the NAMW.

The list of approved monomers and other reactants from which polyester may be made is in the table below.

A number of reactants on this list are not on the Australian Inventory of Chemical Substances (AICS). Therefore, the manufacture of polyesters from these reactants cannot be carried out in Australia without notification to and assessment of the reactants by NICNAS.

On the other hand, polyesters manufactured from these reactants overseas could be imported, as the reactant

itself would not be introduced.

Note: Polyesters manufactured from the anhydride of an acid on the polyester list—for example, succinic anhydride (butanedioic acid)—are allowed, provided there are no pendant anhydrides in the polymer.

In summary, certain polyesters will not be eligible for notification as PLCs, including:

- biodegradable polyesters, which do not meet the degradation criterion
- water-absorbing polyesters
- polyesters manufactured from any monomer or other reactant not on the list of allowable reactants, including such a reactant at <2%.

LIST OF APPROVED MONOMERS AND OTHER REACTANTS FROM WHICH POLYESTER MAY BE MADE

Reactant	CAS no.
Monobasic acids and natural oils	
Benzoic acid	65-85-0
Canola oil	120962-03-0
Coconut oil	8001-31-8*
Corn oil	8001-30-7*
Cottonseed oil	8001-29-4*
Dodecanoic acid	143-07-7
Fats and glyceridic oils, anchovy	128952-11-4*
Fats and glyceridic oils, babassu	91078-92-1*
Fats and glyceridic oils, herring	68153-06-0*
Fats and glyceridic oils, menhaden	8002-50-4*
Fats and glyceridic oils, sardine	93334-41-9*
Fats and glyceridic oils, oiticica	8016-35-1*
Fatty acids, C_{16-18} and C_{18} -unsaturated	67701-08-0*
Fatty acids, castor-oil	61789-44-4*
Fatty acids, coco	61788-47-4*

Fatty acids, dehydrated castor-oil	61789-45-5*
Fatty acids, linseed oil	68424-45-3*
Fatty acids, safflower oil	93165-34-5
Fatty acids, soya	68308-53-2*
Fatty acids, sunflower oil	84625-38-7*
Fatty acids, sunflower-oil, conjugated	68953-27-5*
Fatty acids, tall-oil	61790-12-3*
Fatty acids, tall-oil, conjugated*	
Fatty acids, vegetable oil	61788-66-7*
Glycerides, C_{16-18} and C_{18} -unsaturated	67701-30-8*
Heptanoic acid	111-14-8
Hexanoic acid	142-62-1
Hexanoic acid, 3,3,5-trimethyl-	3302-10-1
Linseed oil	8001-26-1*
Linseed oil, oxidized	68649-95-6*
Nonanoic acid	112-05-0
Oils, cannabis*	
Oils, palm kernel	8023-79-8*
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Oils, perilla	68132-21-8*
Oils, walnut	8024-09-7
Safflower oil	8001-23-8*
Soybean oil	8001-22-7*
Sunflower oil	8001-21-6*
Tung oil	8001-20-5*
Di and tri basic acids	
1,2-Benzenedicarboxylic acid	88-99-3
1,3-Benzenedicarboxylic acid	121-91-5
1,3-Benzenedicarboxylic acid, dimethyl ester	1459-93-4
1,4-Benzenedicarboxylic acid	100-21-0
1,4-Benzenedicarboxylic acid, diethyl ester	636-09-9
1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6
1,2,4-Benzenetricarboxylic acid	528-44-9
Butanedioic acid	110-15-6
Butanedioic acid, diethyl ester	123-25-1

Butanedioic acid, dimethyl ester	106-65-0
2-Butenedioic acid (E)-	110-17-8
Decanedioic acid	111-20-6
Decanedioic acid, diethyl ester	110-40-7
Decanedioic acid, dimethyl ester	106-79-6
Dodecanedioic acid	693-23-2
Fatty acids, C18-unsaturated, dimers	61788-89-4*
Heptanedioic acid	111-16-0
Heptanedioic acid, dimethyl ester	1732-08-7
Hexanedioic acid	124-04-9
Hexanedioic acid, dimethyl ester	627-93-0
Hexanedioic acid, diethyl ester	141-28-6
Nonanedioic acid	123-99-9
Nonanedioic acid, dimethyl ester	1732-10-1
Nonanedioic acid, diethyl ester	624-17-9
Octanedioic acid	505-48-6
Octanedioic acid, dimethyl ester	1732-09-8

Pentanedioic acid	110-94-1
Pentanedioic acid, dimethyl ester	1119-40-0
Pentanedioic acid, diethyl ester	818-38-2
Undecanedioic acid	1852-04-6
Polyols	
1,3-Butanediol	107-88-0
1,4-Butanediol	110-63-4
1,4-Cyclohexanedimethanol	105-08-8
1,2-Ethanediol	107-21-1
Ethanol, 2,2´-oxybis-	111-46-6
1,6-Hexanediol	629-11-8
1,3-Pentanediol, 2,2,4-trimethyl-	144-19-4
1,2-Propanediol	57-55-6
1,3-Propanediol, 2,2-bis(hydroxymethyl)-	115-77-5
1,3-Propanediol, 2,2-dimethyl-	126-30-7
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-	77-99-6

1,3-Propanediol, 2-(hydroxymethyl)-2-methyl	77-85-0
1,3-Propanediol, 2-methyl	2163-42-0
1,2,3-Propanetriol	56-81-5
1,2,3-Propanetriol, homopolymer	25618-55-7
2-Propen-1-ol, polymer with ethenylbenzene	25119-62-4
Modifiers	
Acetic acid, 2,2´-oxybis-	110-99-6
1-Butanol	71-36-3**
Cyclohexanol	108-93-0
Cyclohexanol, 4,4´-(1-methylethylidene) bis	80-04-6
Ethanol, 2-(2-butoxyethoxy)-	112-34-5
1-Hexanol	111-27-3
Methanol, hydrolysis products with trichlorophenylsilane and trichlorophenylsilane	72318-84-4*
1-Phenanthrenemethanol, tetradecahydro-1,4a- dimethyl-7-(1-methylethyl)-	13393-93-6
Phenol, 4,4´-(1-methylethylidene)bis-, polymer with 2,2´-[(1-methylethylidene)bis(4,1- phenyleneoxymethylene)]bis[oxirane]	25036-25-3
Siloxanes and Silicones, dimethyl, diphenyl,	

polymers with phenyl silsesquioxanes, methoxy- terminated	68440-65-3*
Siloxanes and Silicones, dimethyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- terminated	68957-04-0*
Siloxanes and Silicones, methyl phenyl, methoxy phenyl, polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated	68957-06-2*
Silsesquioxanes, phenyl propyl	68037-90-1*

*Designates chemical substance of unknown or variable composition, complex reaction products, and biological materials (UVCB substances). The CAS Registry Numbers for UVCB substances are not used in chemical abstracts and its indexes.

**1-Butanol may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters which may be formed by reaction of these reactants.

2.5 APPENDIX E: PERMIT CATEGORIES FOR NEW CHEMICALS

Please read this appendix in conjunction with:

- Notification categories for new chemicals
- Notification processes and procedures for new chemicals

Also read:

- Data requirements for new chemicals applications
- Post-assessment obligations.

Forms and checklists referred to can be downloaded from the forms webpage and current fees and charges can also be found on the NICNAS website.

This appendix describes each permit category.

Note: All permit applications result in the issuing of a permit and publication of a notice in the Chemical Gazette.

Sections of this appendix:

- Commercial evaluation chemical permit
- Low volume chemical permit
- Controlled use (export only) permit
- Controlled use permit
- Early introduction permit
- Renewal of permits

2.5.1 COMMERCIAL EVALUATION CHEMICAL PERMIT

The Commercial Evaluation Chemical (CEC) permit allows you to use the chemical for a specified performance or product trial only (for example, to test a new polymer in a surface coating when a large quantity is required to fill paint lines or to evaluate a new process that requires a new industrial chemical). This type of permit is not issued for chemicals in retail products such as cosmetics.

The permit specifies how the chemical can be used, the period of introduction and the maximum quantity permitted.

Your application for a CEC permit will be refused if you do not provide sufficient evidence that the chemical is for commercial evaluation only. It is unlikely that a company could obtain a series of CEC permits to cover importation over a period of years.

Details for you to consider:

VOLUME

The maximum introduction volume is four tonnes, but you should only apply for quantities that reasonably reflect your needs for commercial evaluation. You must justify your claims.

DURATION

The maximum duration of a permit is two years. Use of the chemical under the permit may continue beyond the period of introduction, providing it is used for commercial evaluation.

If the CEC permit is issued for a duration of less than two years, you can seek permission from NICNAS to extend the introduction to a total of up to two years by providing an explanation.

USER AGREEMENTS

To ensure adequate safeguards, you need to provide User Agreements in place between yourself and all users for conducting the evaluation of the chemical.

Only proposed users who have completed a User Agreement can use the chemical.

Under these agreements, all users are bound by the conditions of the permit.

You can submit User Agreements to NICNAS after you have made the initial CEC permit application.

In some instances, you may wish to have permits issued before User Agreements are made. Applications for this will be considered case-by-case, but it is likely NICNAS will impose a further permit condition, such as that the chemical must not be passed on to—or used by—another person without a User Agreement first being forwarded to NICNAS.

If you do not submit a User Agreement with your application for a CEC, you need to explain to NICNAS what customer/user arrangements you have in place.

The CEC permit cannot be issued for chemicals to be evaluated through retail sale (for example, for end-use consumer products such as cosmetics and domestic cleaners) where a User Agreement cannot be obtained.

APPLICATION REQUIREMENTS

You can download the forms you need to apply for a CEC permit application from the NICNAS website.

With each notification for a CEC permit, you must include:

- application Form 1-CEC
- total quantity of chemical to be introduced, including a written explanation justifying the quantity (this should relate to the chemical entity)
- 150/323

- total time period for introduction
- use of the chemical, clearly indicating the purpose for which it is being evaluated—describe distribution arrangements and clearly identify all users, including end-users
- details of previous or current permits for the chemical, with particulars, if you know of permits previously issued in Australia for the chemical under any legislation, including the Act
- a User Agreement (Form 8) that you and each proposed user of the chemical have signed, indicating you will comply with permit conditions
- a summary of the chemical's occupational health and safety, public health and environmental effects
- information about the chemical, comprising the data items listed in paragraphs 6(a)(i) to 6(N), 7,8, 11 and 12 of Part B of the Schedule
- any application for exempt (confidential) information, with the required fee
- the CEC checklist indicating which items on Form 1-CEC you have completed and items for which you are applying for confidential information
- a statement that you are entitled to use and to give NICNAS all the data in the notification statement (include this with Form 1-CEC)
- a declaration that you have submitted all available information (include Form 1-CEC)
- the required fee.

ASSESSMENT PROCESS AND PERMIT CONDITIONS

There is no statutory deadline for issuing CEC permits, but NICNAS usually completes the process within 14 days of the date your completed application is accepted.

CEC permits include standard conditions (plus additional chemical-specific recommendations), including the need to:

- adhere to the maximum quantity of chemical you can introduce for commercial evaluation and the period during which you can introduce it
- advise NICNAS in writing before the permit expires if the period of commercial evaluation is to extend beyond the permit's duration
- forward outstanding User Agreement forms to NICNAS before the chemical is distributed to users
- ensure the chemical is used in accordance with all relevant state or territory occupational health and safety, public health environmental and poisons legislation
- implement necessary control measures, where a suitable and sufficient workplace risk assessment requires it, to prevent the risks to human health (adequate control of exposure to workers must be in accordance with the hierarchy of controls) or , where this is not practicable minimise, such risks
- ensure that workers exposed to the chemical and products containing it are informed it is being introduced into Australia under a permit
- make available the (Material) Safety Data Sheet ((M)SDS) at all sites where the chemical is used
- ensure the (M)SDS for the chemical and products containing it carry advice that the chemical is being manufactured or imported under a CEC permit granted under Section 21G of the *Industrial Chemicals* (*Notification and Assessment*) Act 1989 (the Act); suggested wording to use:
 - [name of chemical] is being introduced under a Commercial Evaluation Chemical permit granted under section 21G of the Act
- ensure that waste is disposed of in accordance with Australian Government, state and territory government and local government regulations
- keep records at the site/s of use for the quantity of the chemical used and any adverse occupational health and safety, public health and environmental effects resulting from use
- report adverse occupational health and safety, public health and environmental effects to NICNAS as soon as possible
- advise NICNAS, at the end of the evaluation, of:

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- quantities used
- means of disposal of excess quantity
- adverse occupational health and safety, public health and environmental effects during permit use
- the outcome of the commercial evaluation.

NICNAS may, by written notice, impose further permit conditions or revoke or vary any condition, after issuing you the permit.

Under the Act, there is a penalty if you contravene a permit condition without good reason. NICNAS may also, by written notice, cancel a permit.

Chemicals that are the subject of a CEC permit are not eligible to be listed on the Australian Inventory of Chemical Substances (AICS).

If a CEC permit is in force, you cannot be issued with a second permit for the same chemical. The proposed user of the chemical cannot be issued with a second CEC permit either.

If the commercial evaluation of the chemical is satisfactory and you wish to continue importing the chemical for full-scale commercial use, you should allow sufficient time to obtain an assessment certificate.

Joint applications may be submitted with the fee shared between all applicants or notifiers.

PUBLICATION

Notice of the granting of a CEC permit are published in the Chemical Gazette, including:

- name of the chemical or trade name
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued
- volume of chemical that may be introduced
- duration of the permit (maximum two years)
- general use of the chemical.

FINAL REPORT

At the end of the commercial evaluation each permit holder must provide a final report to NICNAS, with contents as specified in the permit conditions.

ANNUAL REPORTING AND RECORD KEEPING

You must keep records to support any statement made in, or in connection with, your application for five years from the date your certificate is issued.

You must submit a report to NICNAS before or on 28 September of the following registration year, stating:

- name of the chemical for which the permit or certificate is issued
- volume of the chemical introduced during the year
- any adverse effect of the chemical on occupational health and safety, public health or the environment of which you have become aware during the year.

RENEWING YOUR CEC PERMIT

You can only renew your CEC permit once and only if certain criteria are met (more information in a later section of this appendix).

2.5.2 LOW VOLUME CHEMICAL PERMIT

A Low Volume Chemical (LVC) permit allows a chemical to be introduced at a maximum quantity of 100 kg per year, or 1000 kg where certain criteria are met, for a maximum of three years.

More than one company can hold a LVC permit allowing the introduction of the maximum quantity per year for the same chemical. However, if two or more companies submit a joint application, the maximum quantity would be shared among the applicants.

ELIGIBILITY CRITERIA

The LVC permit allows the chemical to be introduced at a maximum quantity of 1000 kg a year where the lowhazardous criteria in the table are met (if they are not met, the volume limit is 100 kg) or the polymer criteria (see table below) are met:

LOW HAZARDOUS CRITERIA FOR CHEMICALS INCLUDING POLYMERS WITH A NUMBER-AVERAGE MOLECULAR WEIGHT (NAMW) <1000 DA

Endpoint	Criteria
Acute oral toxicity	Not classified as hazardous*
Acute dermal toxicity	Not classified as hazardous*
Acute inhalation toxicity	Not classified as hazardous*
Skin irritation	 Not classified as hazardous* or classified: R38 (irritating to skin) under the Approved criteria; or Skin irritation – category 2 under the GHS Note: irritation must be reversible
Eye irritation	 Not classified as hazardous* or classified: R36 (irritating to eyes) under the Approved criteria; or Eye irritation – category 2A under the GHS Note: irritation must be reversible
Respiratory irritation	Not classified as hazardous*
Sensitisation	Not classified as hazardous*
Repeat dose toxicity	Not classified as hazardous*
Mutagenicity	Not classified as hazardous*
Carcinogenicity	Not classified as hazardous*
Developmental and reproductive toxicity	Not classified as hazardous*
Other toxicological endpoints	Not classified as hazardous*

	Toxicity to fish (LC50 ^[1]), as determined using the Fish Acute Toxicity Test, is >100 mg/L	
Aquatic toxicity	Toxicity to aquatic invertebrates (EC50 ^[2]), as determined using the <i>Daphnia</i> sp, Acute Immobilisation Test, is >100 mg/L	
	Toxicity to algae (i.e., EC50), as determined using the Algal Growth Inhibition Test, is >100 mg/L	
Flammability	Not a dangerous good or classified as a Class 3 flammable liquid only	
Other physical and chemical properties	Not a dangerous good	

* In accordance with the Globally Harmonised System of Classification and Labelling of Chemicals, 3rd edition (GHS) or Approved Criteria for Classifying Hazardous Substances 3rd edition (Approved Criteria), NOHSC:1008(2004)

[1] Median lethal concentration / dose - test specified in the Act. See Appendix F 3.6.1, 3.6.2 and 3.6.3 for details.[2] Half maximal effective concentration – see details as for above footnote.

Based on their known health and environmental concerns, these chemicals are not eligible for a LVC permit for volumes exceeding 100 kg a year:

- chemicals likely to be persistent and/or bioaccumulative, or have breakdown products with these characteristics (see Appendix Q: Stockholm convention (1) international persistent organic pollutants criteria and (2) national environmental persistent bioaccumulative and toxic criteria for further information)
- chemicals covered by the NICNAS position paper on data requirements for notification of new chemical substances containing a per fluorinated carbon chain (see later appendix)
- chemical classes with an exposure standard (for example isocyanates or tin compounds).

LOW HAZARDOUS CRITERIA FOR POLYMERS WITH A NAMW THAT IS 1000 DA OR GREATER

These polymers must:

- have<10% by mass of molecules with molecular weight that is <500 Da
- have <25% by mass of molecules with molecular weight that is <1000 Da
- have a low charge density, that is:
 - not cationic or not likely to become cationic in an aquatic environment that has a pH value >4 and <9, or
 - a solid that is not soluble or dispersible in water and is to be used only in its solid phase, or
 - for a polymer that includes 1 or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000, and

In addition these polymers must not have certain hazard classifications (under the Approved Criteria), or hazard classes (under the GHS), as set out in the following table:

Risk phrases/Hazard classes low hazardous polymers must NOT have

Hazard	Risk Phrase under Approved Criteria	Hazard Class in the GHS
Carcinogenic effects	R40, R45, R49	Carcinogen - category 1A, 1B or 2
Mutagenic effects	R46	Germ cell mutagen - category 1A or 1B
Reproductive effects	R60-64	Reproductive toxicant – category 1A, 1B or 2; or Effects on or via lactation
Very toxic and toxic acute lethal effects	R23-28	Acute toxicity – category 1, 2 or 3
Corrosive effects	R34, R35, R41	Skin corrosion – category 1A, 1B or 1C; or Eye damage – category 1
Sensitising effects	R42, R43	Respiratory sensitiser – category 1A or 1B; or Skin sensitiser – category 1A or 1B
Non-lethal irreversible effects after a single exposure	R39, R68	Specific target organ toxicity single – category 1 or 2; or Germ cell mutagen – category 2
Severe effects after repeated or prolonged exposure	R48	Specific target organ toxicity repeat – category 1 or 2

Based on known health and environmental concerns, these polymers are not eligible for a LVC permit for volumes exceeding 100 kg a year:

- polymers likely to be persistent and/or bioaccumulative, or have breakdown products with the characteristics outlined in the appendix on International persistent organic pollutants criteria and national environmental persistent bioaccumulative and toxic criteria for further information
- polymers covered by the NICNAS position paper on data requirements for notification of new chemical substances containing a perfluorinated carbon chain (see the relevant appendix)
- polymer classes with an exposure standard (for example isocyanates or tin compounds).

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SPECIAL REQUIREMENTS FOR AZO COLOURANTS

Azo colourants are a class of concern for their potential induction of mutagenicity and carcinogenicity. Several azo dyes have been demonstrated to be skin sensitisers in humans, using clinical patch tests.

You must meet special requirements for these colourants. In addition to genotoxicity and sensitisation data proving the chemical meets the low hazardous criteria, you must prove that the chemical contains negligible aromatic amine content (impurities).

You also need to provide information on the identity and genotoxicity profile of the potential metabolic breakdown products, that is the component amines, to demonstrate the chemical meets the low-hazardous criteria.

APPLICATION REQUIREMENTS

Download the LVC permit application form.

When applying, you must submit your completed form to NICNAS with your fee.

Joint applications can be made by manufacturers and/or importers.

You can apply to have certain information exempt from being published in the *Chemical Gazette* (for confidentiality reasons) on Form1-LVC. If accepted, only certain information will be published. You do not have to request exemption for data items not published.

When applying you must summarise the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) health effects.

If the chemical or polymer contains a structural alert for a certain human health endpoint (for example, sensitisation) you need to provide data for this endpoint in applications for substances >100 kg a year.

However, for polymers, you may not need to provide data for an endpoint where there is a structural alert, where the percentage by mass of molecules with a molecular weight <1000 Da is less than the concentration cut-offs (used to determine whether a mixture is hazardous on the basis of its ingredients) for that endpoint. A list of structural alerts is included in Appendix J: Structural alerts for permit categories.

Where a repeat dose study has been conducted, you must provide a copy of the study summary (not the full study report) to NICNAS. For all other endpoints, you only need to provide the original data to NICNAS where a structural alert exists for this endpoint.

NICNAS may ask for copies of original data to determine no unreasonable risk.

You can also provide data sourced from published literature, but this must be accompanied by a copy of the relevant source (such as a journal article or document). It must be in English and attached to your application.

For applications for >100 kg a year you must provide evidence to demonstrate that you have satisfied each environmental hazard criterion. Acceptable evidence is one of the following:

- an ecotoxicity test report for the chemical
- published literature data for the chemical
- an ecotoxicity test report for an accepted close analogue
- published literature data for an accepted close analogue
- quantitative structure activity-relationship (QSAR) data generated for the chemical by an appropriate, validated QSAR model.

You must also provide a copy of all available eco-toxicological data to NICNAS.

Evidence you supply for close analogues must include a sound scientific argument for why the analogue should be acceptable, including discussion of comparability of the physico-chemical properties of the chemical and

proposed analogue.

For data generated by QSAR (including ecotoxicity data) to be considered, you must supply full details of the QSAR model used (including the version), and input values used by the model, including the Simplified molecular input line entry specification string (SMILES). These requirements would be satisfied, for example, if you provide an electronic copy of the full report generated by the United States Environmental Protection Agency's EPISuite (United States Environmental Protection Agency 2008. Estimation Programs Interface Suite[™] for Microsoft® Windows, v3.20).

ASSESSMENT PROCESS AND PERMIT CONDITIONS

NICNAS issues LVC Permits within 20 days of receiving a complete notification, provided it satisfies all requirements.

Your permit is granted with the requirement that you notify NICNAS if:

- the function or use of the chemical has changed—or is likely to change—significantly
- the amount of the chemical being manufactured or imported has exceeded—or is likely to exceed—the volume limit per year
- a chemical subject to a LVC permit for import only has begun to be manufactured in Australia
- the method of manufacture has changed—or will be changed—resulting in a possible increased risk of adverse occupational health and safety, public health or environmental effects
- you become aware of additional information relating to adverse occupational health and safety, public health or environmental effects of the chemical.

As the holder of the permit, you must notify NICNAS within 28 days of becoming aware of any changed circumstances.

LVC permits include these standard conditions (in addition to those specific to individual chemicals):

- total quantity of chemical that can be introduced in a year
- length of time the permit will remain in force
- need to:
 - use the chemical in accordance with all relevant state or territory occupational health and safety, public health and environmental and poisons legislation
 - prevent or, where this is not practicable minimise, the risks to human health where a suitable and sufficient workplace risk assessment indicates that control measures are necessary and that control of exposure to workers is adequate
 - inform workers who will be exposed to the chemical and products containing it that it is being introduced into Australia under a permit
 - make the (M)SDS for the chemical available at all sites where the chemical is used
 - include in the (M)SDS for the chemical, and products containing it, advice that the chemical is being manufactured or imported under a LVC permit granted under Section 21U of the Act, with this suggested wording:
 - [name of chemical] is being introduced under a low volume chemical permit granted under Section 21U(2) of the Industrial Chemicals (Notification and Assessment) Act 1989.
 - dispose of waste in accordance with Australian Government, state and territory government and local government regulations.

NICNAS may, by written notice, cancel a permit, impose further conditions or revoke or vary any condition after the permit has been issued. Under the Act you can be penalised if you contravene a permit condition without good reason.

Note: Chemicals that are the subject of a LVC permit are not eligible to be listed on the AICS.

PUBLICATION

Notice of the granting of LVC permits are published in the Chemical Gazette, including:

- name of the chemical (or trade name)
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued
- duration of the permit (maximum three years)
- general use of the chemical.

ANNUAL REPORTING AND RECORD KEEPING

You must keep records to support any statement made in, or in connection with, your application for five years from the date your permit is issued.

You must submit a report to NICNAS before or on 28 September of the following registration year, stating:

- name of the chemical for which the permit is issued
- volume of the chemical introduced during the year
- any adverse effect of the chemical on occupational health and safety, public health or the environment of which you have become aware during the year.

RENEWING YOUR LVC PERMIT

You can renew your LVC permit any number of times provided certain criteria are met.

2.5.3 CONTROLLED USE (EXPORT ONLY) PERMIT

Eligibility criteria

Industrial chemicals will be eligible for the Controlled Use (Export Only) Permit (EOP) if the entire quantity of the new chemical:

- imported into Australia will be exported
- imported into Australia for use in formulating products will be exported
- manufactured in Australia will be exported
- manufactured in Australia for use in formulating products will be exported.

An EOP is available where you can demonstrate the chemical is low risk. Under the highly controlled criteria, you must have sufficient control measures in place to prevent exposure to workers and the public and release to the environment.

An EOP lasts for a maximum of three years. You can renew it if there is no significant change in circumstances.

Chemicals prohibited or severely restricted under Australia's international obligations are not eligible for an EOP (for example, new chemicals with persistent organic pollutant characteristics, which include persistence and bioaccumulation).

APPLICATION REQUIREMENTS

You can download the application form (Form EOP-1) for an EOP from the NICNAS website.

When applying, you must submit your completed form to NICNAS with your fee.

For introduction volumes exceeding 10 tonnes per year, you need to provide all available toxicological and eco-toxicological data with your application. NICNAS may ask for additional toxicological and eco-toxicological information to determine 'no unreasonable risk'.

Joint applications can be made by manufacturers and/or importers.

You can apply to have certain information exempt from being published in the *Chemical Gazette* (for confidentiality reasons) on Form1-EOP. If accepted, only certain information will be published. You do not have to request exemption for data items not published.

ASSESSMENT PROCESS AND PERMIT CONDITIONS

There is no statutory deadline for NICNAS to issue an EOP. However, NICNAS aims to complete the process within 20 days of receiving your completed application, provided you have met the requirements of the Act.

You are bound by the permit conditions, which require you to notify NICNAS if:

- the function or use of the chemical has changed, or is likely to change, significantly
- a chemical subject to an EOP permit for import has begun to be manufactured
- the method of manufacture has changed, or will be changed, resulting in possible increased risk of adverse occupational health and safety, public health or environmental effects
- you become aware of additional information relating to adverse occupational health and safety, public health or environmental effects of the chemical.

You must notify NICNAS within 28 days of becoming aware of any changed circumstances.

EOPs include these standard permit conditions (in addition to recommendations specific to individual chemicals):

- total quantity of chemical that can be introduced in a year
- length of time the permit will remain in force
- need to:
 - use the chemical in accordance with all relevant state or territory occupational health and safety, public health, environmental and poisons legislation
 - prevent or, where this is not practicable minimise, the risks to human health where a suitable and sufficient workplace risk assessment indicates that control measures are necessary and that control of exposure to workers is adequate
 - inform workers who will be exposed to the chemical and products containing it that it is being introduced into Australia under a permit
 - make the (M)SDS for the chemical available at all sites where the chemical is used
 - include in the (M)SDS for the chemical, and products containing it, advice that the chemical is being manufactured or imported under an EOP permit granted under Section 22F (Controlled Use - Export only) of the Act, with this suggested wording: '[name of chemical] s being introduced under a permit granted under Section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989.*'
 - dispose of waste in accordance with Australian Government, state and territory government and local government regulations.

NICNAS may, by written notice, cancel a permit, impose further conditions or revoke or vary any condition. Under the Act, you can be penalised if you contravene any permit condition without good reason.

Note: Chemicals that are the subject of an EOP permit are not eligible to be listed on the AICS.

PUBLICATION

Notice of the granting of EOP permits are published in NICNAS's Chemical Gazette, including:

- name of the chemical (or trade name)
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued
- duration of the permit (maximum three years)
- general use of the chemical.

ANNUAL REPORTING AND RECORD KEEPING

You must keep records to support any statement made in, or in connection with, your application for five years from the date your certificate is issued.

You must submit a report to NICNAS before or on 28 September of the following registration year, stating:

- name of the chemical for which the permit or certificate is issued
- volume of the chemical introduced during the year
- any adverse effect of the chemical on occupational health and safety, public health or the environment of which you have become aware during the year.

RENEWING YOUR EOP PERMIT

You can renew your EOP permit any number of times provided certain criteria under the Act are met (see later section of this appendix).

2.5.4 CONTROLLED USE PERMIT

Eligibility criteria

Industrial chemicals meeting these criteria will be eligible for the Controlled use Permit (CUP):

• the chemical does not have any of the hazard classifications (under the Approved Criteria), or hazard classes (under the GHS) set out in the table below

TABLE 1: RISK PHRASES/HAZARD CLASSES CHEMICALS MUST NOT HAVE FOR CUP

Hazard	Risk Phrase under Approved Criteria	Hazard Class in the GHS
Carcinogenic effects	R40, R45, R49	Carcinogen - category 1A, 1B or 2
Mutagenic effects	R46	Germ cell mutagen - category 1A or 1B
Reproductive effects	R60-64	Reproductive toxicant – category 1A, 1B or 2; or Effects on or via lactation
Very toxic and toxic acute lethal effects	R23-28	Acute toxicity – category 1, 2 or 3
Corrosive effects	R34, R35, R41	Skin corrosion – category 1A, 1B or 1C; or Eye damage – category 1
Sensitising effects	R42, R43	Respiratory sensitiser – category 1A or 1B; or Skin sensitiser – category 1A or 1B
Non-lethal irreversible effects after a single exposure	R39, R68	Specific target organ toxicity single – category 1 or 2; or Germ cell mutagen – category 2
Severe effects after repeated or prolonged exposure	R48	Specific target organ toxicity repeat – category 1 or 2

- the chemical does not have toxicity to:
 - fish—expressed as a median lethal concentration (LC50[1])—that is ≤10 mg per litre, as determined using the Fish Acute Toxicity Test[2] (continuous exposure of fish to a series of concentrations of the chemical in water for four days)
 - aquatic invertebrates—expressed as an EC50[3]—that is ≤10 mg per litre, as determined using the Daphnia sp, Acute Immobilisation Test (daphnids exposed to a series of concentrations of the chemical in water over two days)
 - algae—expressed as IC50[4]—that is ≤10 mg per litre, as determined using the Algal Growth Inhibition Test (algae exposed to a series of concentrations of the chemical in water for at least three days)

- [1] Median lethal concentration
- [2] Details of this, the Acute Immobilisation Test, and the Algal Growth Inhibition Test are in Appendix G8.2.
- [3] Half maximal effective concentration
- [4] International Programme on Chemical Safety
- for human exposure:
 - no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance
 - worker exposure likely to occur will be adequately controlled through use of engineering controls, work
 practices and personal protective equipment
- for environmental exposure: all routine releases from manufacture, processing and use (including releases associated with cleaning of equipment and from disposing or cleaning of containers and packaging) have been considered and adequate controls are in place to ensure no:
 - ambient release to surface water resulting in concentrations of the chemical above one part per billion
 - ambient release to air above one microgram per cubic metre average annual concentration
 - release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Two controlled use exposure scenarios have been developed by NICNAS in consultation with industry. These are for containment and controlled reformulation, and site-limited and closed system manufacture.

Typically a chemical being used as described in the controlled use scenarios will meet the exposure criteria set out above (exceptions may occur where a chemical has particular physicochemical characteristics, for example, where it is highly volatile or persistent).

Other use scenarios may meet the criteria set out above. For such other uses NICNAS prefers to work with industry to develop additional exposure scenarios.

More information on the human and environmental exposure criteria and two controlled use scenarios is in the appendix on Exposure criteria and scenarios for Controlled use permit: additional information.

The CUP lasts for a maximum of three years. You can renew provided there is no significant change in circumstances.

Chemicals prohibited or severely restricted under Australia's international obligations are not eligible for a CUP—for example, new chemicals with persistent organic pollutant characteristics, which include persistence and bioaccumulation (see later appendix—International persistent organic pollutants criteria and national environmental persistent, bioaccumulative and toxic criteria for further information).

DOWNSTREAM USERS

You can supply a chemical introduced under a CUP to downstream users, as long as you know of them and are confident in their practices. When applying for a CUP, you must describe the operations at the proposed downstream user's site. You are responsible for the accuracy of information provided.

Only users whose details have been provided to NICNAS will be able to use the chemical (their names will be listed on the permit). You must satisfy NICNAS that the user is aware of the conditions of the permit, including that use is highly controlled.

The permit places conditions on both yourself and the downstream user.

APPLICATION REQUIREMENTS

You can download the application form (Form CUP-1) for a CUP from the NICNAS website.

When applying, you must submit your completed form to NICNAS with your fee.

Joint applications can be made by manufacturers and/or importers.

You can apply to have certain information exempt from being published in the *Chemical Gazette* (for confidentiality reasons) on Form1-CUP. If accepted, only certain information will be published. You do not have to request exemption for data items not published.

As the applicant or notifier, you should consider the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) effects when summarising the health effects on your application.

You need to provide data with your application where the chemical or polymer contains a structural alert for a certain endpoint, such as sensitisation. However, for polymers, you may not need to provide data for an endpoint where there is a structural alert, where the percentage by mass of molecules with molecular weight that is <1000 Da is less than the concentration cut-offs (used to determine if a mixture is hazardous on the basis of its ingredients) for that endpoint.

A list of structural alerts is included in Appendix J—Structural alerts for permit categories.

You must provide evidence to demonstrate that you have satisfactorily addressed each environmental hazard criterion.

NICNAS considers these types of evidence as acceptable to address hazard criteria for the chemical:

- (eco)toxicityt est report
- published literature data
- (eco)toxicity test report for an accepted close analogue
- published literature data for an accepted close analogue
- QSAR data generated for the chemical by an appropriate, validated QSAR model.

For introduction volumes exceeding 10 tonnes per year, you must provide all available toxicological and ecotoxicological data with your application. You should only provide original data to NICNAS where a structural alert exists for this endpoint. NICNAS can request toxicological and eco-toxicological information.

You can also provide data sourced from published literature, but this must be accompanied by a copy of the relevant source (such as a journal article or document). It must be in English and attached to your application.

Evidence you supply for close analogues must include a sound scientific argument for why the analogue should be accepted, including discussion of comparability of the physico-chemical properties of the chemical and proposed analogue.

For data generated by QSAR (including ecotoxicity data) to be considered, you must supply full details of the QSAR model used (including the version), and input values used by the model, including the Simplified molecular input line entry specification string (SMILES). These requirements would be satisfied, for example, if you provide an electronic copy of the full report generated by the United States Environmental Protection Agency's EPI Suite (United States Environmental Protection Agency 2008, Estimation Programs Interface Suite[™] for Microsoft® Windows, v3.20).

ASSESSMENT PROCESS AND PERMIT CONDITIONS

You can expect your CUP assessment to be completed within 28 days of NICNAS receiving your complete notification, provided it fulfils the requirements of the Act.

You are granted a permit on the condition that you will notify NICNAS if:

• the function or use of the chemical has changed—or is likely to change—significantly

- a chemical subject to a CUP for import has begun to be manufactured in Australia
- the method of manufacture has changed, or will change, resulting in a possible increased risk of adverse occupational health and safety, public health or environmental effects
- you become aware of additional information relating to adverse occupational health and safety, public health or environmental effects of the chemical.

You must notify NICNAS within 28 days of becoming aware of any changed circumstances. You should have mechanisms in place to ensure you become aware of changes in circumstances resulting from downstream user site operations.

CUPs include these standard conditions (in addition to those specific to individual chemicals):

- total quantity of chemical that can be introduced in a year
- length of time the permit will remain in force
- chemical can only be supplied to companies listed in the permit schedule
- need to:
 - provide a copy of the permit to all companies listed in the permit schedule, with instructions that they
 are to retain the permit
 - use the chemical in accordance with all relevant state or territory occupational health and safety, environmental and poisons legislation
 - use the chemical in accordance with the controls specified in the application
 - prevent or, where this is not practicable minimise, the risks to human health where a suitable and sufficient workplace risk assessment indicates that control measures are necessary and that control of exposure to workers is adequate
 - inform workers who will be exposed to the chemical and products containing it that it is being introduced into Australia under a permit
 - make the (M)SDS in the chemical available at all sites where the chemical is used
 - include in the (M)SDS for the chemical, and products containing it, advice that the chemical is being manufactured or imported under a CUP permit granted under Section 22F Controlled Use of the Act. Suggested wording is: '[chemical name] is being introduced under a Low Volume Chemical Permit granted under Section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989.*'
 - disposal of waste should be in accordance with Australian Government, state and territory government and local government regulations.

NICNAS may, by written notice, cancel a permit, impose further conditions or revoke or vary any condition, after the permit has been issued. Under the Act, you can be penalised if you contravene any permit condition without good reason.

Note: Chemicals that are the subject of a CUP permit are not eligible to be listed on the AICS.

PUBLICATION

Notice of the granting of CUP permits are published in NICNAS's Chemical Gazette, including:

- name of the chemical (or trade name)
- whether the chemical is a hazardous substance
- name and postcode of the company to which the permit is issued
- duration of the permit (maximum three years)
- general use of the chemical.

ADDITIONAL DOWNSTREAM USERS

- You can only supply the chemical to downstream users listed on the permit. You are required to advise NICNAS in writing of any additional downstream users after a permit has been issued.
- NICNAS will normally revise your permit to include newly-identified downstream user sites, but only where
 you demonstrate the site applies the same risk management controls as the users already identified on
 the permit application. You need to complete a new CUP application for new uses and circumstances
 where an additional downstream user is not applying these same risk management controls.

ANNUAL REPORTING AND RECORD KEEPING

You must keep records to support any statement made in, or in connection with, your application for five years from the date your permit is issued.

You must submit a report to NICNAS before or on 28 September of the following registration year, stating:

- name of the chemical for which the permit is issued
- volume of the chemical introduced during the year
- any adverse effect of the chemical on occupational health and safety, public health or the environment of which you have become aware during the year.

RENEWING YOUR CUP PERMIT

You can renew your CUP permit any number of times provided certain criteria are met (see the next section of this appendix on Renewal of permits).

2.5.5 EARLY INTRODUCTION PERMIT

An early introduction permit (EIP) allows introduction of a chemical into Australia before the assessment certificate is issued. You can apply for one under certain circumstances, in conjunction with a certificate notification. Section 30A EIPs are for new industrial chemicals meeting certain hazard or use criteria and section 30 permits are for new chemicals where it can be shown their immediate introduction is in the public interest.

Section 30A permits

Chemicals that might be eligible for an EIP are:

- a polymer of low concern (PLC);
- non-hazardous chemicals or polymers;
- chemicals and polymers meeting low-hazardous criteria; or
- low-risk, highly controlled chemicals or polymers.

The criteria listed under 'Eligibility criteria' below must be met. In all cases the chemical's introduction must be consistent with the reasonable protection of occupational health and safety, public health and the environment. Chemicals and polymers likely to be persistent and/or bioaccumulative, or that have breakdown products with these characteristics, are not eligible for an EIP (see later appendix on International persistent organic pollutants criteria and national environmental persistent bioaccumulative and toxic criteria for further information).

Application requirements

You can apply for an EIP at the same time as you apply for a Standard Notification, Limited Notification or PLC Notification, or you can apply later (but you must do so *before* the assessment is completed).

You can download the application forms for EIPs in conjunction with limited or standard notifications from the NICNAS website. Forward your completed Form EIP-1 to NICNAS with the required fee (this amount is

additional to the normal notification and assessment fee).

Joint applications may be submitted, with the fee shared between the applicants or notifiers.

There is no fee for EIPs for PLC and non-hazardous chemicals. You do not need to complete a Form EIP-1 for polymers of low concern.

You must provide supporting information for an EIP as part of the certificate application.

Eligibility criteria

POLYMERS OF LOW CONCERN

A polymer that qualifies for notification and assessment as a PLC under the current PLC criteria would satisfy the criteria for an EIP application. The largest component of the polymer must be carbon or silicon.

NON-HAZARDOUS CHEMICALS/POLYMERS (OTHER THAN PLC)

To be considered a non-hazardous chemical or polymer, the chemical must:

- not be a hazardous chemical according to the NICNAS definition (see Appendix A);
- not be a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail; and
- have one of these characteristics:
 - dissolves in water without dissociation or association and is not surface active and the partition coefficient (n octanol/water) at 20°C as log P_{ow} does not exceed 3;
 - solubility in water is >1 mg/L; or
 - molecular weight (or number average molecular weight (NAMW) in the case of a polymer) is >1000.
- be readily biodegradable; and
- have a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is, LC50 or EC50 100 mg/L or greater.

CHEMICALS AND POLYMERS MEETING LOW-HAZARDOUS CRITERIA

To be considered a low-hazardous chemical or polymer, NICNAS must be satisfied that the low-hazardous criteria are met.

Different requirements exist for chemicals (including polymers with an NAMW <1000) and polymers with an NAMW that is 1000 or greater. These are:

- For chemicals (including polymers with an NAMW <1000), the chemical cannot:
 - be a hazardous chemical according to the NICNAS definition (see Appendix A), OR is a hazardous chemical classified as either:
 - irritating to eyes (R36 in Approved Criteria, or Eye irritation—category 2A in GHS)—irritation reversible; or
 - irritating to skin (R38 in Approved Criteria, or Skin irritation—category 2 in GHS) irritation reversible.
 - be a dangerous good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) or is a dangerous good that is a Class 3 flammable liquid as defined in the ADG Code; or

have a very low aquatic toxicity to fish, aquatic invertebrates and algae, that is LC50 or EC50 100
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- For polymers with an NAMW that is 1000 or greater, the polymer must:
 - have <10% by mass of molecules with a molecular weight that is <500;
 - have <25% by mass of molecules with a molecular weight that is <1000;
 - have a low-charge density (is not cationic or not likely to become cationic in an aquatic environment that has a pH value >4 and <9, or is a solid that is not soluble or dispersible in water and is to be used only in its solid phase, or for a polymer that includes one or more cationic groups, the total combined functional group equivalent weight of any cationic group is at least 5000); and
 - not have certain hazard classifications (under the Approved Criteria), or hazard classes (under the GHS), as set out in Table 1 below.

Table 1: Risk phrases/hazard classes low hazardous polymers must NOT have

HAZARD	RISK PHRASE UNDER APPROVED CRITERIA	HAZARD CLASS IN THE GHS
Carcinogenic effects	R40, R45, R49	Carcinogen—category 1A, 1B or 2
Mutagenic effects	R46	Germ cell mutagen—category 1A or 1B
Reproductive effects	R60–64	Reproductive toxicant—category 1A, 1B or 2; or Effects on or via lactation
Very toxic and toxic acute lethal effects	R23–28	Acute toxicity—category 1, 2 or 3
Corrosive effects	R34, R35, R41	Skin corrosion—category 1A, 1B or 1C; or Eye damage— category 1
Sensitising effects	R42, R43	Respiratory sensitiser—category 1A or 1B; or Skin sensitiser— category 1A or 1B
Non-lethal irreversible effects after a single exposure	R39, R68	Specific target organ toxicity single—category 1 or 2; or Germ cell mutagen—category 2
Severe effects after repeated or prolonged exposure	R48	Specific target organ toxicity repeat—category 1 or 2

LOW-RISK, HIGHLY CONTROLLED CHEMICALS AND POLYMERS CRITERIA

For an industrial chemical to be considered a low-risk, highly controlled chemical or polymer, NICNAS must be satisfied that the following criteria are met:

- the chemical or polymer does not have any of the hazard classifications (under the Approved Criteria), or
- hazard classes (under the GHS) set out in Table 2 below.

Table 2: Risk phrases/hazard classes chemicals or polymers must NOT have for low risk, highly controlled criteria

HAZARD	RISK PHRASE UNDER APPROVED CRITERIA	HAZARD CLASS IN THE GHS
Carcinogenic effects	R40, R45, R49	Carcinogen—category 1A, 1B or 2
Mutagenic effects	R46	Germ cell mutagen—category 1A or 1B
Reproductive effects	R60–64	Reproductive toxicant—category 1A, 1B or 2; or Effects on or via lactation
Very toxic and toxic acute lethal effects	R23–28	Acute toxicity—category 1, 2 or 3
Corrosive effects	R34, R35, R41	Skin corrosion—category 1A, 1B or 1C; or Eye damage— category 1
Sensitising effects	R42, R43	Respiratory sensitiser—category 1A or 1B; or Skin sensitiser— category 1A or 1B
Non-lethal irreversible effects after a single exposure	R39, R68	Specific target organ toxicity single—category 1 or 2; or Germ cell mutagen—category 2
Severe effects after repeated or prolonged exposure	R48	Specific target organ toxicity repeat—category 1 or 2

- the chemical does not have a toxicity to:
 - fish, expressed as an LC50 that is ≤10 mg/L, as determined using the Fish Acute Toxicity Test (continuous exposure of fish to a series of concentrations of the chemical in water for four days);
 - aquatic invertebrates, expressed as an EC50 that is ≤10 mg/L, as determined using the *Daphnia* sp, in an Acute Immobilisation Test and Reproduction Test (daphnids exposed to a series of concentrations of the chemical in water); or
 - algae expressed as IC50 that is ≤10 mg/L, as determined using the Algal Growth Inhibition Test (algae exposed to a series of concentrations of the chemical in water for at least three days).

- for human exposure:
 - no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance; and
 - worker exposure likely to occur is adequately controlled through engineering controls, work practices and personal protective equipment.
- for environmental exposure, all routine releases from manufacture, processing and use (including releases associated with cleaning equipment and from disposing of or cleaning containers and packaging) have been considered, and adequate controls are in place to ensure no:
 - ambient release to surface water resulting in concentrations of the chemical above 1 part per billion;
 - ambient release to air above 1 microgram per cubic metre average annual concentration; and
 - release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Two controlled-use exposure scenarios have been developed by NICNAS in consultation with industry. These are for containment and controlled reformulation, and site-limited and closed system manufacture (see Appendix I).

Typically, a chemical being used as described in these controlled use scenarios will meet the exposure criteria set out above (exceptions might occur where a chemical has particular physicochemical characteristics, for example where it is highly volatile or persistent).

Other use scenarios might meet the criteria set out above. For such other uses NICNAS prefers to work with industry to develop additional exposure scenarios.

You can supply a chemical introduced under the EIP to downstream users, as long as you know of them and are confident in their practices. When applying for an EIP, you must describe the operations at the proposed downstream user's site. You are responsible for the accuracy of information provided.

Assessment process

In deciding whether to grant an EIP, NICNAS needs to be satisfied that the chemical is either a PLC, a nonhazardous chemical or polymer, a chemical or polymer meeting low-hazardous criteria, or a low-risk, highly controlled chemical or polymer.

Only users whose details have been provided to NICNAS will be able to use the chemical under the EIP. These users will be listed on the permit.

CHEMICALS (INCLUDING POLYMERS WITH AN NAMW <1000 DA)

To be satisfied the chemical (including polymers with an NAMW <1000 Da) meets the human health hazard criteria for non-hazardous and low-hazardous chemicals, you need to provide NICNAS with test data for the notified chemical or an accepted close analogue, normally for these endpoints:

- acute oral toxicity;
- acute dermal toxicity;
- skin irritation;
- eye irritation;
- sensitisation;
- repeat dose toxicity;
- genotoxicity-bacterial reverse mutation; and
- genotoxicity in vitro.

For genotoxicity you need two tests and the results of both should be independently negative.

In addition, you will need an Acute Inhalation Toxicity test result unless the chemical:

- has a vapour pressure <1.5 kPa;
- as introduced, has <25% of particles having <10 μ m diameter; and
- is not purposely aerosolised during use (except where this constitutes a 'controlled use').

For NICNAS to be satisfied that a chemical (including polymers with an NAMW <1000 Da) meets the human health hazard criteria for a low-risk, highly controlled chemical, you would normally be required to provide data where there is a structural alert for a certain endpoint (Appendix J—Structural alerts for permit categories).

For NICNAS to be satisfied that a chemical meets the environmental hazard criteria, you would normally be required to provide data for all three trophic levels. Where data is not available for limited notifications, the chemical/polymer might be eligible for an EIP if certain release criteria are met ('Matters taken into account' below).

POLYMERS WITH A NAMW >1000 DA (OTHER THAN A PLC)

To be satisfied that a polymer with an NAMW \geq 1000 Da (other than a PLC) is non-hazardous, you normally need to provide test data for the notified polymer—or an accepted close analogue—for these endpoints:

- acute oral toxicity;
- skin irritation; and
- genotoxicity—bacterial reverse mutation.

Where the polymer contains one or more high concern reactive functional groups with functional group equivalent weight <5000, as defined in the PLC criteria (except un-substituted positions ortho and para to phenolic hydroxyl or partially-hydrolysed acrylamides), you must provide data on skin sensitisation.

For NICNAS to be satisfied that a polymer meets the human health hazard criteria for low-hazardous polymers and low-risk, highly controlled polymers, you need to provide test data for the notified chemical or an accepted close analogue, where there is a structural alert for a certain endpoint.

You might not need to provide data for an endpoint where there is a structural alert, where the percentage by mass of molecules with molecular weight that is <1000 Da is less than the concentration cut-offs (used to determine if a mixture is hazardous on the basis of its ingredients) for that endpoint.

For NICNAS to be satisfied that a polymer (other than a PLC or polymer meeting the low-hazard criteria) meets environmental hazard criteria, you would normally be required to provide data for all three trophic levels. Where data are not available—that is for limited notifications—the chemical/polymer might be eligible for an EIP if certain release criteria are met (see 'Matters taken into account').

Matters taken into account

In deciding whether to grant the EIP, NICNAS will take into account a number of matters, including the proposed use of the chemical and information about its occupational health and safety, public health and environmental effects and the likelihood of release of the chemical into the aquatic environment.

For standard and limited notifications, NICNAS will consider direct release into a natural waterway. For limited notifications, where there are no ecotoxicity or ready biodegradability data to support the application, NICNAS will take into account release into a water treatment works at a rate more than 10 kg per year from an individual source, or 50 kg in total.

In taking into account the likelihood of the chemical being released into water, NICNAS will only consider releases resulting from normal use practices, rather than from spills, etc. Qualitative or semi-quantitative estimates of release to water, rather than detailed calculations, are normally sufficient.

Under normal circumstances, NICNAS will make a decision on your application for an EIP within 28 days.

Permit conditions

EIPs for PLCs, non-hazardous chemicals/polymers and chemicals/polymers meeting the low hazardous criteria, include these standard conditions (in addition to those specific to the individual chemical):

- the EIP is in force only until the assessment certificate is obtained
- if the application for an assessment certificate is withdrawn, the permit lapses
- if full assessment of the chemical cannot start or is stopped due to outstanding data for a specified period, the permit lapses
- the need to:
 - use the chemical in accordance with all relevant state or territory occupational health and safety, environmental and poisons legislation;
 - prevent or, where this is not practicable minimise, the risks to human health where a suitable and sufficient workplace risk assessment indicates that control measures are necessary and that control of exposure to workers is adequate;
 - inform workers who will be exposed to the chemical and products containing it that it is being introduced into Australia under a permit;
 - make the (M)SDS (containing the information that the chemical is introduced under an EIP permit) available at all sites where the chemical is used;
 - dispose of waste in accordance with Australian Government, state and territory government and local government regulations; and
 - keep records of use at the site/s and report to NICNAS, at the end of the period for which this permit is issued, any adverse occupational health and safety, public health and environmental effects, reported from the use of this chemical.

Publication

Notice of the granting of EIPs permits are published in NICNAS's Chemical Gazette, including the:

- name of the chemical (or trade name); and
- name and postcode of the company to which the permit is issued.

Section 30 Permit

Section 30 permits are for new chemicals where it can be shown that their immediate introduction is in the public interest. Chemicals that do not meet the requirements for a section 30A permit might be eligible for a section 30 permit if the Minister is satisfied that:

a) the chemical is of special benefit to the public in some way (for example, its import may be critical during an environmental emergency); and/or

b) it is in the public interest that the chemical be introduced immediately and that its introduction be consistent with the protection of occupational health and safety, public health and the environment.

Application requirements

You must submit an assessment certificate application with your section 30 permit application. Joint applications may be submitted, allowing NICNAS's assessment fee to be shared between applicants/notifiers.

Section 30 permits are issued only under exceptional circumstances. You must write to the Minister outlining why you are applying for one, specifying:

- the reasons the chemical's introduction is in the public interest;
- why the introduction must be without delay; and

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• how introducing the chemical will impact on occupational health and safety, public health and the environment.

In your application, you should justify the amount of the chemical required for introduction. Also submit all other supporting information and the required fee.

Assessment process and permit conditions

In deciding whether to grant a section 30 permit, the Minister usually seeks advice from NICNAS, taking into account a number of matters, including the proposed use of the chemical, information about its health and environmental effects and the volume of chemical required.

Section 30 permits are subject to the conditions stated in the permit. There is no set limit on the amount of chemical for which a section 30 permit may be granted, but it will specify limits on amount and time. You must adhere to the conditions in the permit, including the reasonable protection of occupational health and safety, public health and the environment.

If the application for an assessment certificate is withdrawn, the permit lapses.

Publication

Notice of the granting of section 30 permits are published in NICNAS's Chemical Gazette, including:

- name of the applicant/notifier;
- name of the chemical, as shown to the public; and
- terms of the permit, including period in force.

Applicants can appeal to the Administrative Appeals Tribunal against a decision to publish information.

2.5.6 RENEWAL OF PERMITS

You can renew existing permits (except EIPs) provided you meet certain criteria. You can renew LVC, EOP and CUP permits any number of times, but a CEC permit can only be renewed once.

CEC PERMIT RENEWAL

You can download the necessary application forms to renew a CEC permit renewal from the NICNAS website.

Your renewal application must consist of:

- Form CEC-1R
- a copy of your current permit, including conditions
- new User Agreements (Form 8)—you and each proposed user must sign a User Agreement indicating you will comply with permit conditions
- any application, with the required fee, for information to be exempt based on confidentiality—you do not need to resubmit an application for exemption if one was included with your original permit submission
- a statement indicating you are entitled to use, and will give NICNAS on request, all the data in your notification statement (Form CEC-1R)
- a declaration you have submitted all relevant information available to you (Form CEC-1R)
- the required fee.

Criteria for CEC renewal

- your existing permit must still be current and not previously renewed
- you must lodge your application for renewal no earlier than three months and no later than two weeks 174/323

before your current permit expires

- the function or use of the chemical must be the same and not likely to change significantly
- the amount of the chemical being introduced must be the same and not likely to increase significantly
- the chemical must not be manufactured in Australia if it was not manufactured or proposed to be manufactured in Australia when your permit was issued
- the method of manufacture of the chemical in Australia must be the same and not likely to change in a way that may result in increased risk of an adverse effect on occupational health and safety, public health or the environment
- you must not have not received or become aware of additional information on the adverse effects of the chemical on occupational health and safety, public health or the environment
- you must have complied with all conditions of your current permit during the period of the permit
- you do not require any changes to the permit conditions
- you must have met all reporting requirements for the existing permit.

LVC, CUP AND EOP PERMIT RENEWAL

You can download the necessary application forms to renew a LVC permit from the NICNAS website.

Contact NICNAS for CUP and EOP renewal application forms.

Your renewal application for LVC, CUP and EOP permits must consist of:

- the correct form—Form LVC-1R, Form EOP-1R or Form CUP-1R
- a copy of your current permit, including conditions
- any application, with the required fee, for information to be exempt based on confidentiality—you do not need to resubmit an application for exemption if one was included with your original permit submission
- a statement indicating you are entitled to use, and will give NICNAS on request, all the data in your notification statement included on your application form (Form LVC-1R, CUP-1R or EOP-1R)
- a declaration that you have submitted all relevant information available to you on your application form (Form LVC-1R, CUP-1R or EOP-1R)
- the required fee.

Conditions for LVC, CUP and EOP renewal

- your existing permit must still be current and not previously renewed
- you must lodge your application for renewal no earlier than three months and no later than two weeks before your current permit expires
- the function or use of the chemical must be the same and not likely to change significantly
- the amount of the chemical being introduced must be the same and not likely to increase significantly
- the chemical must not be manufactured in Australia if it was not manufactured or proposed to be manufactured in Australia when your permit was issued
- the method of manufacture of the chemical in Australia must be the same and not likely to change in a way that may result in increased risk of an adverse effect on occupational health and safety, public health or the environment
- you must not have received or become aware of additional information on the adverse effects of the chemical on occupational health and safety, public health or the environment
- you must have complied with all conditions of your current permit during the period of the permit
- you do not require any changes to the permit conditions
- you must have met all reporting requirements for the existing permit.

2.6 APPENDIX F: DATA REQUIREMENTS FOR NEW CHEMICALS APPLICATIONS

This appendix provides guidance on the information you must submit with your application for a new or existing chemical assessment.

Note:

- 1. The order of data requirements used here matches the order in the schedule supporting the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the ACT). The schedule may be read on this NICNAS website under Legislation and Regulations. The information that follows here is more detailed.
- 2. The required schedule information (if any) for each notification (certificate and permit) category is listed in other appendixes of the NICNAS Handbook.
- 3. When completing an application using a template provided by NICNAS—such as the templates provided for Limited and Standard notifications—you must submit all required schedule information requested. These templates provide additional guidance as well as example text for many data items.
- 4. For Polymer of low concern (PLC) applications you must submit the information listed in Form PLC-1.
- 5. Schedule data requirements represent the minimum data required. If you have access to additional information, you must provide it to NICNAS with your application.

Sections of this appendix:

• Schedule Part A

the set of information (identification of data requirements, health and environmental effects, how the chemical meets hazardous substance definition, overseas notification of the chemical) you must submit as part of Standard or Limited notification application

• Schedule Part B

the core set of information (chemical identity, use and exposure details, physico-chemical properties) you must submit as part of Standard or Limited notification application

• Schedule Part C

the health and environmental effects data you must submuit as part of Standard notification application

• Schedule Part D

the information you must provide to characterise a polymer, polymer mixture, its additives and adjuvants, as closely as possible

• Schedule Part E

details of additional data required for new industrial chemicals that are to be used as an untraviolet filter in a cosmetic (additional to toxicological endpoints in Schedule C)

• Variation to data requirements

test or data items that can be omitted if irrelevant, unnecessary or scientifically inapporpriate to an evaluation

2.6.1 SCHEDULE PART A

This part of the schedule specifies the set of information (including identification of data requirements, health and environmental effects, how the chemical meets hazardous substance definition and overseas notification of the chemical) that you must submit as part of your Standard or Limited notification application.

Identification of data requirements

You must identify what data you are supplying with your application. For New Chemicals, the data requirements for the different notification categories are in Appendix C. Contact NICNAS if you are unsure of what information to provide.

When a Priority Existing Chemical (PEC) is declared for further investigation through a notice in the *Chemical Gazette*, data requirements are often described in terms of the schedule.

Summary of health and environmental effects

You must summarise the occupational health and safety, public health and environmental effects of the chemical in all Standard notifications and Limited notifications. You must also discuss the effects and hazards of the chemical in the context of its proposed use.

In your summary, detail the results of the tests used to determine the toxic effects of the chemical, including its ecotoxicity (that is, a summary of the most significant results of Part C of the schedule, which specifies health and environmental effects).

In tests where no adverse effects are observed, you must comment on dosage levels. You must also highlight the physical and chemical hazards of the chemical (for example, flammability and reactivity).

Your summary must also explain why any information is missing from your notification.

Summary of how the chemical meets the definition of a hazardous substance

NICNAS legislation defines a hazardous substance as a 'hazardous chemical', which is then defined under the Act's regulations as a chemical that is:

- classified as a hazardous substance under the Approved Criteria for Classifying Hazardous Substances, 3rd edition, NOHSC:1008(2004)
- included in the Hazardous Substances Information System published on the Safe Work Australia website.

From 1 January 2012 new Work Health and Safety laws commenced in a number of Australian jurisdictions, which require classification in accordance with the GHS. If only GHS information is available to the introducer, NICNAS will consider a chemical as a hazardous chemical if it satisfies the criteria for a hazard class in the GHS, except where that chemical satisfies the criteria solely for one of the following hazard classes:

- a) flammable gases, category 2
- b) acute toxicity—oral, category 5
- c) acute toxicity—dermal, category 5
- d) acute toxicity—inhalation, category 5
- e) skin corrosion/irritation, category 3
- f) serious eye damage/eye irritation, category 2B
- g) aspiration hazard, category 2
- h) hazardous to the aquatic environment, category acute 1, 2 or 3
- i) hazardous to the aquatic environment, category chronic 1, 2, 3 or 4
- j) hazardous to the ozone layer.

Note: The GHS has been adopted in the Work Health and Safety legislation of many jurisdictions, with more to follow. A five year transition period will apply in which classifications under the Approved Criteria will be acceptable in addition to GHS.

You must state whether the notified chemical is a hazardous substance. If it is, you must provide a health hazard classification for it, determined in accordance with the GHS or Safe Work Australia's Approved Criteria. This must include the required risk and safety phrases and the basis of the classification (the toxicological endpoints considered).

You must also provide the health hazard classification of products containing the notified chemical in your application.

For the (Material) Safety Data Sheet ((M)SDS) on the chemical, provide a statement of hazardous nature using one of these sets of words:

- Hazardous according to the criteria of Safe Work Australia.
- Not classified as hazardous according to the criteria of Safe Work Australia.

Details of any notification made in relation to the chemical in a country other than Australia

You must summarise the status of the chemical in countries other than Australia, including:

- name of each country
- whether an assessment of the chemical was carried out in any country or, alternatively, whether the chemical is listed on one or more national inventories without being assessed
- date of the assessment (if one was carried out)
- whether a risk assessment report is available
- whether you wish the notification package to be considered under the Approved Foreign Scheme or modular assessment category (see the appendix on Use of overseas assessments in the notification of New Chemicals).

Bibliography

You must provide a complete listing of all publications referred to in your application statement, including:

- references for published and unpublished studies
- references for other information obtained from the scientific literature
- references to standards and codes of practice
- details of test methods used to generate data
- references to other notification and assessment schemes
- references for other reports on the chemical or class of chemicals.

2.6.2 SCHEDULE PART B

This part of the schedule specifies the core set of information (including chemical identity, use and exposure details, and physico-chemical properties) that you must submit as part of your Standard or Limited notification application.

Identity of the chemical

You must provide a complete and unambiguous identification of the chemical by addressing the requirements set out below.

For chemicals with a Chemical Abstracts Service (CAS) number or name, provide a CAS printout.

In the case of a synthetic polymer, provide the information listed under the relevant paragraphs below, for the constituent monomer/s.

Chemical name

You must provide the chemical name that will be used in the AICS, that is, the Chemical Abstracts (CA) Preferred Index name. If not available, provide the International Union for Pure and Applied Chemistry name.

For substances that are not pure chemicals (that is, chemicals of unknown or variable composition, a complex product of a chemical reaction, or a biological material), describe the chemical name as completely as possible.

Examples of chemicals of unknown or variable composition are fatty acids and cottonseed oil. An example of a complex product of a chemical reaction is polyethoxylated C12-20 alcohols. Typical biological materials are geranium oil and proteinase. For biopolymers, you must indicate the biological source.

Other names

You must provide common names by which the chemical is known or identified in the scientific or technical literature (for example, 2-propanone is commonly known as acetone).

Marketing name of chemical

You must provide the names under which the chemical has been, or will be, marketed, including trade names. Specify whether these names will be used for marketing purposes in Australia.

If you apply for the chemical name to be kept confidential, NICNAS will use the marketing name as the published name on the certificate and in the *Chemical Gazette*.

If there are several marketing names, indicate which name you prefer to be used as the published name.

CAS number

You must provide the CAS number for the chemical. This is a unique number assigned to it by the CAS and can be obtained by contacting CAS.

If a CAS number has not been allocated, you must state when you will apply for one.

Molecular and structural formulae

You must provide a molecular formula that gives the identity and number of atoms of each element in the molecule (for example, C_6H_6 for benzene, H_2SO_4 for sulphuric acid). When providing the molecular formula for synthetic polymers made using two or more monomers list the monomers in order from the highest carbon number to the lowest. Example:

 $(C_8H_6O_4.C_5H_{12}O_2.C_4H_2O_3.C_3H_8O_2)x$ for 1,3-Benzenedicarboxylic acid, polymer with 2,2-dimethyl-1,3-propanediol, 2,5-furandione and 1,2-propanediol.

Provide a structural formula indicating the location of atoms, ions or groups and the nature of bonds joining them.

For polymers, depict the probable bonds between monomers in the structural formula.

Molecular weight

You must provide the gram-molecular weight of the chemical. For polymers, provide both the number-average molecular weight and the weight average molecular weight (more information is in F4 Schedule, Part D).

Spectral data

You must provide copies of spectra to confirm the structural formula (for example, from infra-red spectroscopy, nuclear magnetic resonance spectroscopy, mass spectroscopy and ultraviolet-visible spectrophotometry). Indicate principal wavelengths and/or other significant data. Provide analytical details, such as the solvent used or the infrared matrix used (for example, nujol mull or potassium bromide disk).

For biological materials, accurately identify the source material and provide documentation for NICNAS verification.

Composition of the chemical

Purity

You must provide the degree of purity of the chemical (as a weight percentage). For chemicals containing water, give this percentage for the dried substance, unless water is an integral part of its composition.

Toxic or hazardous impurities

You must provide the identity and the weight percentage of all known (or reasonably anticipated) impurities (including isomers and byproducts) of a hazardous or toxic nature, with details of their toxic and hazardous properties.

Provide names of impurities classified as dangerous goods and substances listed on the Poisons Schedule (see the website of the Therapeutic Goods Administration).

Indicate the risk phrases for impurities classified as hazardous substances in the Safe Work Australia Approved Criteria, or GHS.

Where possible, identify all impurities by their CAS number and Chemical Abstracts Preferred Name Index name. If this is not available, provide the International Union for Pure and Applied Chemistry name or common chemical name.

Non-hazardous impurities

You must provide the identity and weight percentage for all non-hazardous impurities present at 1% by weight or more.

Additives/adjuvants

You must provide the maximum weight percentage of all additives and adjuvants incorporated into the main chemical substance.

Include additive and adjuvant substances such as stabilisers, inhibitors and modifiers.

Identify all additives and adjuvants by their CAS number, Chemical Abstracts Preferred Name Index name, common name and name under which the chemical is marketed.

Information on use

You must provide all proposed uses of the chemical (for example, solvent, dyestuff, adhesive, plasticiser or detergent). For each use, indicate the approximate percentage of the total amount manufactured in or imported into Australia.

Identify the industry in which the chemical is to be used (for example, paper and pulp).

Describe the fields of use and methods of application (for example, a spray-on paint stripper in the painting industry).

Provide, for all forms of the notified chemical—including final end-use products—the concentration of notified chemical in the mixture or product. This information is critical for the risk assessment. Be as complete as possible with the information you provide, to enable proper assessment of the chemical by NICNAS.

Physical state and appearance

You must describe the physical state and appearance of the chemical at 20°C and 101.3 kPa (ambient conditions)—for example, brown viscous-liquid or grey powder.

Provide the odour and odour threshold of the substance if it is available. For example, toluene is a liquid of low volatility with a characteristic aromatic odour, and an odour threshold at approximately 10 ppm v/v.
Estimated manufacture or import volume

You must specify if the chemical is to be manufactured in Australia, imported or both, and the amount in tonnes per year.

Provide the amount of the chemical being introduced for each of the first five years either as a maximum value or as a range (for example 1-10, 10-100, 100-1000, or over 1000 tonnes). Estimate quantities of the specific chemical, not of the product or formulation it is contained in.

Occupational health and safety

Occupational exposure data

You must include a comprehensive description of occupational exposure factors so NICNAS can adequately assess risk on occupational health and safety. If you do not use the chemical, source the relevant information from the downstream users.

For new chemicals that have been in use overseas, submit relevant occupational exposure information (for example, monitoring data for a similar use), if available from overseas sources.

Submit the following information at a minimum and include other relevant information relating to occupational exposure.

1. Category of workers

You must describe the category of workers likely to be exposed to the chemical or any product containing the chemical. Examples are workers employed in maintenance tasks involving equipment using chemicals, or those employed in packaging and storing the chemical.

Include all workers involved from the manufacturing process or importation onwards, and those involved in storing, handling, transporting and disposing of the chemical. Include workers using the final products (for example, beauticians and hairdressers for cosmetic products and farmers for fertiliser products).

2. Nature of work

You need to indicate the nature of the work carried out, or to be carried out, for each category (type) of worker exposed to the chemical.

For each category, briefly describe the:

- a) nature of work carried out with the chemical (ie. the operation description)
- b) maximum duration of exposure (hours per day and days per year)
- c) frequency of exposure

d) activities requiring protective clothing and equipment, indicating the physical form/s of the chemical during exposure (for example, hot liquid or fine powder).

3. Safety procedures to be observed when handling the chemical

You must provide information on methods and procedures to minimise or prevent worker exposure. Principles and procedures for the effective control of chemicals in the workplace are in the Safe Work Australia National Model Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace.

You can prevent worker exposure to a particular chemical by applying this hierarchy of controls:

- a) isolating the process or operation
- b) implementing engineering solutions, including local exhaust ventilation for vapours, gases or particulates
- c) adopting safe work practices, including changes to work methods

d) providing and using suitable approved personal protective equipment where other measures are not effective.

Provide an example of the isolation procedures and engineering controls used, or to be used, in minimising worker exposure to the chemical. This may include:

- a) isolation of a hazardous operation by the use of sealed reformulation apparatus
- b) modifications to the working environment, for example, ventilation or fume extraction
- c) enclosure, for example, spray painting within booths

d) preventive maintenance schedules designed to maintain plant, equipment and extraction systems to a high standard.

Describe the safe work practices to be observed by workers in handling the chemical, including:

- a) precautions during routine handling
- b) precautions during storage and transport
- c) precautions in handling spills
- d) practices with good housekeeping
- e) introduction of procedures to reduce duration and frequency of exposure for employees.

Specify the protective clothing and equipmentrequired for routine and non-routine tasks, including the type of:

a) respiratory equipment, in accordance with Australian Standards AS 1716 *Respiratory Protective Devices* and AS 1715 *Selection, Use and Maintenance of Respiratory Protective Devices* or equivalent internationally acceptable standards

b) protective clothing (for example, gloves, eye protection and/or footwear). Be specific (for example, flameproof cotton overalls). The general description of 'impervious gloves', for example, is not sufficient, but the more precise 'nitrile gloves' is. Consult the relevant Australian Standards (or equivalent). Examples: AS 2161.2—Occupational Protective Gloves Part 2: General Requirements; AS 1336—Eye Protection in the Industrial Environment; and AS 3765.1—Clothing for Protection against Hazardous Chemicals Part 1: Protection against General or Specific Chemicals.

Australian and international standards are updated from time to time, so check that you have consulted the most recent versions of each standard.

4. Training

You must briefly describe the core training conducted for employees to become proficient in safe working practices and include details about the training required to introduce the new chemical into the workplace.

Include this information:

- a) instructions on health and safety hazards of the chemical, including routes of entry into the body
- b) instructions on the correct use of all protective equipment required during handling of the chemical
- c) instructions on the correct use of relevant equipment
- d) instructions for emergency situations
- e) information on labelling of the chemical
- f) availability of the (M)SDS.

Indicate both duration and frequency of training.

5. Prevalence of work-related injuries and diseases related to workers exposed to the chemical

You must detail, for chemicals already in use overseas, any known effect on the occupational health and safety of workers exposed to the chemical before they are introduced to Australia.

Describe the type, frequency and severity of all work-related injuries and diseases resulting from worker exposure. Examples are incidences of health effects or disease and total work time lost.

Where possible, detail the duration, frequency and levels of exposure of workers. Where effects in workers have been seen, mention mitigating factors, such as concomitant exposure to other chemicals, that could have caused the observed effects as well as other relevant factors.

Fully describe adverse health effects experienced by workers exposed to the chemical, as required by Paragraph 6(b), Part B of the schedule, Health Conditions.

6. Other occupational hazards

You must provide any other information on occupational hazards that may occur during the complete lifecycle of the chemical within Australia that are not referred to in sections 1-4 (above).

Include, in particular, information on conditions that could increase the hazard of the chemical. This includes such items as:

- a) adverse working conditions (for example, heat or cold)
- b) work in confined spaces
- c) potential exposure to other hazardous substances
- d) possibility of reaction (for example, with other substances or with water)
- e) any other interaction (for example, interaction of chemicals and heat).

Health conditions

You must submit information with respect to health conditions, even though these are usually only available for chemicals already in use in another country. Include a list of health conditions reported or known, such as health conditions indicating that the chemical should not be used in circumstances where exposure is too great.

Submit information on all health conditions, such as asthma, broken skin, dermatitis, or therapeutic or recreational drug use.

Report evidence of specific health conditions associated with the chemical that might suggest it must not be used without special precautions (for example, exposure may cause severe dermatitis).

List health conditions that could reasonably be expected to occur (for example, by analogy with structurally similar chemicals, or analogues).

Mention health conditions aggravated by the chemical (for example, exposure to the chemical may increase the incidence of asthma in susceptible workers).

Occupational health monitoring

You must include details of both atmospheric and biological monitoring procedures to be used to measure worker exposure to the chemical. For chemicals already in use, you can obtain the methodology for the monitoring procedures from international sources. For new chemicals, a methodology may be developed by considering existing methodology for structurally similar existing chemicals.

Justify reasoning when no monitoring procedures are proposed, in terms of health and safety hazards and extent of worker exposure.

Provide information on existing or proposed exposure limits and known methods of atmospheric or biological 183/323

monitoring of the chemical.

1. Atmospheric monitoring

Include information on the type/s of atmospheric monitoring proposed, such as:

a) personal monitoring, where the time-weighted average concentration of actual worker exposure to the chemical is indicated

b) automatic continuous monitoring, where peak-level concentrations and time-weighted average concentrations of the chemical in the work areas are indicated

c) fixed-point monitoring, where time-weighted average concentrations of the chemical over a set period, for example, an eight-hour shift, are indicated for a fixed location in the work area

d) grab sampling, where instantaneous concentrations of the chemical are indicated.

Detail sampling techniques and sampling equipment (for example, passive monitor badges may be used for personal monitoring).

Briefly describe the analytical method/s used, including the principal technique (for example, gas chromatographic or gravimetric analysis).

Detail the type of instrumentation used.

2. Biological monitoring

Biological monitoring involves the quantitative measurement of the chemical or its metabolite in the appropriate body tissue, fluid or excretion product (for example, in blood, urine or expired air).

You must provide information on the test/s to be used, the program of activities, the relevant collection procedures and the analytical methods and instrumentation.

Observations on human exposure

Provide information held, or reasonably obtainable, on studies or observations of the effects of the chemical on humans, in particular, observations of health problems or adverse symptoms in humans exposed to the chemical. This may include information on specific incidents, such as acute exposure resulting from an accidental spillage.

Provide information on any epidemiological studies on workers who have been exposed to the chemical and, where possible, their health conditions (either positive or negative) relating to exposure levels.

Environmental impact

You must provide an assessment of the environmental impact of the chemical, including this information in your notification statement:

- manufacturing process
- release to the environment for each use, including that from manufacturing, reformulating, repackaging and end use
- storage and transport
- disposal.

If you do not use the chemical, seek information on the environmental impact from the user/s.

Manufacturing process

You are not required to provide information on the manufacturing process for chemicals manufactured outside Australia. However, you must provide information on the formulation process for imported chemicals if they are reformulated or repackaged in Australia (for example, into products for industrial or domestic use). 184/323 This includes the:

1. Identity of the site/s where the chemical will be manufactured or reformulated

Provide details of the location/s of each industrial site (manufacturing, processing or any other operation) you control and details of sites where repacking and/or reformulating the chemical is carried out.

2. Process description

Describe the process for each operation you control, including:

- a) a diagram of the major unit operation steps and chemical conversions
- b) the identity and entry points of all feed-stocks, including reactants, solvents and catalysts
- c) the location of the points of release of the chemical to the environment.

3. Details of the release of chemicals at each site

Include these details for each release point:

a) an estimate of the amount and concentration of chemical released directly to the environment or into control technology (in kg/day)

- b) the media to which the chemical is released (air, soil or water)
- c) a description of any control technology used to limit release
- d) the destination/s of releases to water, (for example, sewage treatment plant).

Release to the environment for each use

You must include, for each specific use or application identified, information on:

- estimated number of sites for each use
- broad process descriptions
- descriptions of situations in which environmental release of the chemical may occur. These could include through equipment cleaning. Other examples could be:
 - to ambient air (for example, through smoke stack emissions, car exhaust fumes, incineration gases, aerosols and fugitive refrigerant gases)
 - in water (for example, natural waterways or ground water, including release to waste water treatment facilities)
 - to surrounding land (for example, through overspray of paints, general wear and tear and deposition).
 - Provide the quantity, concentration and media of release for each situation.

Transport and storage

You must define the safe storage requirements (for example, location, temperature or incompatibility) for the chemical and its classification under the Australian Code for the Transport of Dangerous Goods by Road and Rail.

Describe all intended:

- storage facilities, including size, type and capacity of containers and potential for environmental exposure
- transport between storage facilities, including quantity to be transported, mode of transport and potential for environmental exposure.

Include technical details on storage and transport of the chemical in the (M)SDS.

Disposal

You must fully describe all disposal procedures, including for all contaminated packaging, by providing:

- route of disposal (for example, landfill or incineration)
- quantities to be disposed of by each route, including residues in contaminated packaging (where applicable and not already addressed in your responses under sections above
- identity any hazards of degradation products resulting from disposal.

State how disposal is in accordance with government regulation.

Public health

Public exposure may occur by:

- exposure during industrial use as the result of contamination of air, water, soil or food
- exposure as the result of an industrial accident
- exposure by domestic use of the chemical.

Describe potential public exposure to the notified chemical, based on the proposed uses of the notified chemical, the physical and chemical properties, the site of manufacture or reformulation in Australia and the release of the chemical into the environment at that site, the quantity, concentration and frequency of release of the notified chemical for each use of the chemical, the conditions of safe storage, the disposal procedures, and the consequences of accidental spillage.

Where it is possible (such as for cosmetics applied to the skin), quantify the exposure in terms of number of applications per day and amount used per application.

Physico-chemical data

You need to submit valid reproducible physico-chemical data and can do so following the Organisation for Economic Co-operation and Development's (OECD) Guidelines for the Testing of Chemicals.

Note: To assist, the numbers in brackets after each test detailed throughout the rest of this section are the OECD guideline method numbers (for example, TG 102 refers to Test Guideline number 102). Links to each are also provided.

Melting point or boiling point (TG 102, TG 103 or equivalent)

You need to provide the melting point or boiling point. However, for non-pure chemicals a temperature range may be more appropriate. For some chemicals the freezing point is more appropriate than the melting point.

Specific gravity or density (TG 109 or equivalent)

You need to provide the gravity or density (in kg/m³) for all chemicals and for:

- gases the specific gravity (air = 1), to help indicate the tendency of the chemical to settle or disperse when discharged at high concentrations into the atmosphere
- liquids both the liquid and vapour densities.

Vapour pressure (TG 104 or equivalent)

You must provide the:

 vapour pressure of the chemical, expressed as kilopascals (kPa) at 25°C 186/323 • effect on the measurement by impurities.

Vapour pressure is important for estimating the chemical's potential for inhalation exposure and for determining the application route/s for toxicity testing. It is environmentally relevant because it helps estimate the chemical's distribution between the environmental compartments (the phase transitions between soil and air, soil and water, and [with water solubility] water and air). It can also help predict atmospheric concentrations.

Water solubility (TG 105 or equivalent, TG 120 for polymers)

You must provide the saturation mass concentration of the chemical in water (in g/L at 20°C) and indicate the method of measurement. If the substance is insoluble in water, indicate the detection limit of the analytical method used and any water accommodated fraction of the chemical determined.

Water solubility is significant environmentally because:

- it largely determines the mobility of the chemical within and between air, soil and water compartments
- it can be important in determining appropriate emergency services responses
- water-soluble chemicals gain ready access to humans and other living organisms
- it significantly effects potential for bioaccumulation.

Hydrolysis as a function of pH (TG 111 or equivalent)

You need to provide this parameter only for water-soluble chemicals (water solubility $>10^{-6}$ g/L). The degree of hydrolysis at 25°C is required at pH values normally found in the environment (pH 4–9) and under more acidic conditions (pH 1–2) for physiological purposes. Hydrolysis is one of the main modes of abiotic degradation of substances in the environment.

Partition coefficient (n-octanol/water) (TG 107 or equivalent, TG 117)

You need to provide this parameter only for (pure) water-soluble chemicals that do not dissociate or associate and that are not surface-active. It is expressed as $\log P_{ow}$, at 20°C.

The partition coefficient of a substance between water and a lipophilic solvent (n-octanol) can indicate its potential for skin absorption or can be used to estimate the chemical's bioaccumulation potential in aquatic organisms.

Adsorption and desorption (TG 106 or equivalent)

You must provide information on adsorption and desorption, with results expressed in terms of the adsorption and desorption of the chemical in and from standard soils under standard test conditions.

These data are necessary for evaluating the tendency of chemicals to migrate into the air, water and soil or sediment compartments of the environment. Adsorption and desorption processes also have an effect on the transport of chemicals and on their bioavailability.

Dissociation constant (TG 112 or equivalent)

You must provide the dissociation constant (in pKa) for all chemicals that dissociate in water and the method of determination.

The extent of dissociation of a chemical in water governs the forms it will take in the aquatic environment. Knowledge of the dissociation constant, together with the pH of the systems in which a chemical is likely to be found, makes it possible to estimate the extent to which dissociated and undissociated forms will be present.

Particle size (distribution) or fibre length (TG 110 or equivalent)

You must provide the particle size or fibre length (for solids only). This is one factor influencing the distribution

and mass transport of insoluble and non-volatile particles in water, air and, in some cases, the upper soil layer. Furthermore, the tendency of a chemical to settle and penetrate biological tissue (for example, inhalation characteristics) depends on particle size.

1. Particle size

You must provide both the mean particle size and particle size range of the substance. In particular, indicate the inhalable fraction (<100 mm) and the respirable fraction (<10 mm).

2. Fibre length

For fibrous substances, you must provide the fibre length and length range.

Flashpoint – open cup / closed cup

You must provide the flash point (in °C) of the chemical, along with the method of determination (open or closed cup method).

Flammability limits (%) (explosive limits)

You must include the degree of chemical flammability:

- pyrophoric
- highly flammable
- flammable
- combustible
- not flammable.

For gases and vapours, you must provide the upper and lower percentage limits of flammability in air. These limits indicate the percentage concentrations of flammable vapour in air at which a flame can be propagated or an explosion will occur.

For solids, you must provide information on the ability of the chemical to propagate combustion.

Do not overlook the distinction between flammable and combustible. For example, sodium chloride, carbon tetrachloride and carbon dioxide are non-combustible and non-flammable, but sugar, cellulose and ammonia are combustible and non-flammable.

Provide details on the nature and identity of toxic and hazardous combustion products.

Auto-ignition temperature

You must provide the minimum temperature (in °C) for auto-ignition. This is the temperature required to initiate or cause self-sustained combustion in any substance in the absence of a high-temperature ignition source, such as a spark or flame.

Explosive properties

You must provide information on the chemical's potential to detonate as a result of heat, shock or friction.

Provide details on the nature and identity of hazardous explosion products.

Reactivity

You must provide information about the stability and reactivity of the chemical.

1. Oxidising properties

You must provide information on the oxidising properties of the chemical.

For the majority of substances, oxidising properties are not a concern and testing can be waived based on a consideration of the structure. The table below shows a non-exhaustive list of chemical classes associated with oxidising properties.

TABLE 1: CHEMICAL CLASSES ASSOCIATED WITH OXIDISING PROPERTIES*

Chemical class	Formula
Nitrates (salts or esters)	NO ₃ ⁻ M ⁺ O ₂ N-O-R
Nitrites (salts or esters)	NO ₂ -M ⁺ ON-O-R
<u>Organic nitro compounds</u> Nitroalkyl Nitroaryl	NO ₂ -R NO ₂ -Ar
Fluorodinitro	(NO ₂) ₂ -C-(F)-
Metal oxides	MO _n
Metal oxometallates	M ⁺ MO _n ⁻
N - Halogen compounds	N-X
N – Haloimides	-C(O)-NX-C(O)-
Difluoroamino	- NF ₂
Difluoroaminopolynitroaryl	(NO ₂) _n -Ar-NF ₂
Oxohalogen compounds Acyl hypohalites Hypofluorites Bis(fluoroxy)perhaloalkanes Perchlorates Chlorates	R C(O)-OX FO ⁻ F_3 CCI(OF) ₂ etc CIO ₄ ⁻ CIO ₃ ⁻ CIO ₂ ⁻

Chlorites	CIO-
Hypochlorites	BrO ₄ -
Perbromates	BrO ₂ -
Bromates	
Bromites	BrO ₂
Hypobromites	BrO
Periodates	10 ₄ -
lodates	10 ₃ -
Difluoroperchloryl salts	F ₂ ClO ₂ ⁺ Z ⁻
Dioxygenyl polyfluoro salts	$O_2^+ [MF_n]^- \text{ or } O_2^+ [EF_n]^-$
Interhalogen compounds Metal polyhalohalogenates	M ⁺ [XX'n] ⁻

* Adapted from Bretherick's Handbook of Chemical Reactive Hazards

For organic substances (with the exception of peroxides) testing does not need to be carried out for substances if:

- the substance does not contain oxygen, fluorine or chlorine; or
- the substance contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon

Inorganic substances that do not contain oxygen or halogens do not need to be tested.

For solids, testing should not be performed on explosive or highly flammable substances. Organic peroxides form a separate class of substances that are always oxidising.

If the screening procedure identifies the material as having potential oxidising properties, or there is any doubt, then, in the interests of safety, testing should be carried out.

2. Conditions causing instability

You must provide the particulars of conditions that could cause the chemical to react or decompose during its proposed use and lifecycle within Australia.

Report if the chemical is not stable in air under normal atmospheric conditions and other information such as the oxidising properties of the chemical and its incompatibility with other substances.

3. Decomposition products

You must report information on expected decomposition or reaction products from the chemical, including information on the hazardous properties of these products.

DATA PROVIDED FOR PHYSICAL AND CHEMICAL PROPERTIES

For all physical and chemical property data, you must specify:

- grade and nature of the chemical tested, including its purity (if the chemical is in a mixture, note this for all data provided)
- testing authority or organisation providing the data (where applicable)
- physical conditions used for all test data (for example, temperature or pressure).

Ensure the standard of testing you use to obtain data conforms to OECD'sPrinciples of Good Laboratory Practice.

When it is not possible to provide physico-chemical data through testing of the chemical or a suitable analogue then you can provide estimates derived from Quantitative Structure Activity Relationship (QSAR) calculations.

NICNAS will only accept QSAR calculations for physio-chemical properties if information on the input parameters and calculation methods used are provided. This way, NICNAS can ensure the methods used and results obtained are valid.

Methods of detection and determination

You must provide a list of the analytical methods used to detect and determine (assay) the chemical. State bibliographical references where standard methods are used. Otherwise, describe the method/s used in a way that a competent analytical chemist could repeat the measurements without support.

Label

You must include, in your application statement, a copy of the proposed label/s for the notified chemical, and all products containing it, that will be introduced into Australia. This must comply with the Safe Work Australia National Model Code of Practice for Labelling of Workplace Hazardous Chemicals.

(Material) Safety Data Sheet

The (M)SDS provides information needed to allow the safe handling of the chemical or products containing it. The sheets are used by employers to ensure employees have ready access to information on substances used at work.

You must provide a copy of the proposed (M)SDS for the chemical—this is required for all chemicals notified under NICNAS, not just hazardous ones.

Submit (M)SDS for chemicals available commercially from yourself in other products, such as an ingredient in a polymer mixture.

Submit (M)SDS for chemicals that exist in more than one form in your workplace, such as an ingredient in a solvent mixture.

Ensure all (M)SDSs you submit comply with the Safe Work Australia National Code of Practice for the *Preparation of Safety Data Sheets for Hazardous Chemicals* and include an original copy of the (M)SDS so NICNAS can publish it with the full public report on the chemical.

Emergency procedures

You must include information on emergency procedures, such as the United Nations Number, proposed Dangerous Goods Class/es and the Hazchem Code. Determine this information using the classification in the Australian Code for the Transport of Dangerous Goods by Road and Rail.

Occupational emergency procedures

You must fully describe the procedures used to render the chemical harmless in the workplace.

Include emergencies such as spillage or release of the chemical in the workplace, and personnel emergencies (for example, inhalation of leaking vapours by workers).

Environmental emergency procedures

You must fully describe the procedures used to render the chemical harmless outside the workplace, including those used for managing:

- workplace emergencies affecting the public at large (for example, a gas release affecting nearby residents)
- transport emergencies
- emergencies at storage facilities outside the workplace.

Include this information:

- recovery
- containment
- neutralisation
- destruction(for example, incineration).

2.6.3 SCHEDULE PART C

This part of the schedule specifies the health and environmental effects data you must submit as part of your Standard Notification application.

You must provide complete study reports.

Notes:

- 1. Ideally, toxicity tests must be carried out in accordance with OECD Guidelines for the Testing of Chemicals or equivalent guidelines.
- 2. To assist, the numbers in brackets after each test detailed below are the OECD guideline method numbers most appropriate to use for that endpoint, although they are not necessarily the only OECD guideline that can be used. Links to each are also provided.

Acute toxicity data

Information on the acute toxicity of the chemical will give a measure of the toxic effects following short-term exposure and may indicate specific toxic effects and possible mode of action.

Tests must be relevant to the physical properties of the chemical and consider the way in which the chemical is to be used.

Exact LD50 values are not mandatory requirements and procedures such as a limit test to determine a minimum LD50 are acceptable.

Acute oral toxicity (TG 401 or equivalent)

Acute oral toxicity testing provides information on the health hazards likely to arise from short-term exposure by the oral route. The results may provide information on the chemical's mode of toxic action.

- some quantitative measure of toxicity with an indication of accuracy
- test animal used, indicating number, species/strain and sex
- the nature of the dosed material (for example, solution or suspension—provide details of the vehicle used, if any)

- method
- results of testing, including:
 - tabulation of response data by number, sex and dose level
 - toxic effects seen, time of onset and duration
 - time of death after dosing
 - slope of dose-mortality curve, where possible
 - effects on the organs (for example, gross findings at autopsy and histological data).

Acute dermal toxicity (TG 402 or equivalent)

Acute dermal toxicity testing provides information on the health hazards likely to arise from short-term exposure to the skin. The results may provide information on dermal absorption and the chemical's mode of toxic action by this route.

You must provide information and data that covers:

- some quantitative measure of toxicity with some indication of accuracy
- test animal used, indicating number, species/strain and sex
- the nature of the dosed material (for example, solution or suspension—provide details of the vehicle used, if any)
- method
- results of testing, including:
 - tabulation of response data by number, sex and dose level
 - toxic effects seen, time of onset and duration
 - time of death after dosing
 - slope of dose-mortality curve, where possible
 - effects on the organs, (for example, gross findings at autopsy and histological data).

Acute inhalation toxicity (TG 403 or equivalent)

The acute inhalation toxicity of the chemical, such as a gas, volatile substance or aerosol/particulate, provides information on health hazards likely to arise from short-term exposure by inhalation. The results may provide additional information on the chemical's mode of toxic action.

- some quantitative measure of toxicity with some indication of accuracy
- test animal used, indicating number, species/strain and sex
- nature of dosed material, with particle size if aerosol or particulate
- method
- results of testing, including:
 - tabulation of response data by number, sex and dose level
 - toxic effects seen, time of onset and duration
 - time of death after dosing
 - slope of dose-mortality curve, where possible
 - $\circ~$ effects on the organs (for example, gross findings at autopsy and histological data).

Irritation and corrosion

You must provide information derived from irritation testing that indicates the hazards likely to arise from exposure of the skin, eyes and mucous membranes to the chemical.

Chemicals that have predictable corrosive potential based on physico-chemical properties, such as strong acidity or alkalinity, are often not tested in animals for irritation. Such chemicals are instead classified as hazardous based on their physico-chemical properties.

Skin irritation (TG 404 or equivalent)

A finding of dermal irritation by the chemical on the skin of mammals indicates that hazards are likely to arise from exposure of human skin to the chemical.

You must ensure the dermal irritation assessment is conducted in conjunction with an assessment of the nature, intensity and reversibility of the observed response.

You must provide information and data that covers:

- test animal used, indicating number, species/strain and sex
- method
- form of the dose
- results of testing, including:
 - tabulation of response data by number, sex and dose level for each observation time period (for example, 30 to 60 minutes, 24, 48 and 72 hours after patch removal)
 - description of any lesions observed, together with the onset time and recovery period.

Data from a validated *in vitro* test (such as TG 439) is also accepted by NICNAS. You must provide information and data that covers:

- the test system used
- method
- results of testing

Eye irritation (TG 405 or equivalent)

Results of animal eye irritation studies can help to predict hazards likely to arise from exposure of human eyes and associated mucous membranes. You must provide an assessment of the severity of acute eye irritation.

You must ensure the eye irritation test is conducted in conjunction with an assessment of the nature and reversibility of the response observed.

- test animal used, indicating number, species/strain and sex
- method
- physica nature and, where applicable, concentration and pH value for the test substance
- results of testing, including:
 - tabulation of response data by number and sex at each observation time (for example, 1, 24, 48 and 72 hours)
 - a description of the degree and nature of irritation and corrosion on the cornea, iris and conjunctiva, with time onset, severity and recovery period.

- Data from a validated *in vitro* test (such as TG 437 or 438) is also accepted by NICNAS. You must provide information and data that covers:
- the test system used
- method
- results of testing

Due to the validation status of the *in vitro* eye irritation methods, if the result from the *in vitro* test is negative animal testing will be required.

Sensitisation

Skin sensitisation (TG 406 or 429 or equivalent)

The potential of a chemical to provoke a skin sensitisation reaction (dermal sensitisation or allergic contact dermatitis) can help to predict the possible hazard to a human population repeatedly exposed to the chemical.

In animal studies, the preferred sensitisation test is the local lymph node assay (OECD TG 429). Other acceptable methods include the Magnusson and Kligman Guinea-Pig Maximisation Test, which uses an adjuvant, and the Buehler Test, also in guinea pigs, but without an adjuvant.

For animal studies, you must provide information and data that covers:

- test animal used, indicating number, species and/or strain and sex
- method
- results of testing, including:
 - tabulation of response data by number, sex and age of treated and control animals
 - dose level administered at each stage
 - whether irritation occurred during induction stages and any histological abnormality at test conclusion.

You must provide details of human patch test methods and results, if these have been conducted.

Respiratory sensitisation

No standard OECD guidelines are available for determining the respiratory sensitising potential of chemicals in animals. You must submit non-standard studies, if they are available, and any human evidence regarding this effect.

Repeated dose toxicity (TG 407, TG 410, TG 412 or equivalent)

Repeated dose toxicity data provides information on health hazards likely to arise from repeated exposures over a limited period. The basic study used for repeated dose toxicity is normally the 28-day oral study (TG 407 or equivalent). This study may provide information on neurological effects, immunological effects and reproductive organ toxicity.

Where toxicity arising from dermal absorption has been observed in acute toxicity studies and human skin contact is likely during use of the chemical, a 21-day to 28-day repeated dose dermal toxicity study (TG 410 or equivalent) must be conducted to provide information on possible health hazards likely to arise from repeated skin contact.

Similarly, where toxicity arising from inhalation has been observed in acute toxicity studies, and inhalation by humans is likely during use of the chemical, a 28-day repeated dose inhalation toxicity study (TG 412 or equivalent) must be conducted to provide information on health hazards likely to arise from repeated inhalation.

You must provide data from each study that includes:

- test animal used, indicating number, species and strain and sex
- dosing vehicle, if any
- route and frequency of administration
- method
- results of testing, including:
 - tabulation of toxic response data by number, sex and dose
 - description of effects observed on the animal and its organs, including clinical biochemistry and pathology investigations (signs of toxicity, their time and onset of duration, whether the effects were reversible and necropsy and histological findings)
 - discussion of study results and conclusions.

Genetic toxicology

The primary function of genotoxic testing is to investigate the potential of the chemical to induce mutations in the human genome and the potential for mutations to be transmitted through the germ cells to future generations.

You must organise for testing that demonstrates:

- the chemical's ability to induce point mutations in established microbial systems
- any production by the chemical of chromosome damage in mammalian cells grown in vitro.

You may select a number of tests in each group. You can source a list of tests from the OECD Guidelines on Genetic Toxicology Testing and Guidance on the Selection and Application of Assays or use equivalent or appropriate tests from other recognised protocols.

Select tests depending on the:

- nature of the chemical
- extent of its eventual distribution and use
- data from other toxicological tests and toxicokinetic studies
- available technical expertise.

If either of the *in vitro* tests gives positive results you will need to provide data from a relevant *in vivo* genotoxicity test. You should choose the relevant *in vivo* test based on the effects observed *in vitro*.

Induction of point mutations (TG 471 or equivalent)

You must provide data from a test to demonstrate the induction of point mutations (base-pair change and frame shift mutations) in established microbial test systems, with and without the use of appropriate metabolic activation systems.

Genotoxic damage in vivo (TG 474 or equivalent)

You must provide data from a suitable test to detect the production of genotoxic damage *in vivo*, for example test method **TG 474**, Mammalian Erythrocyte Micronucleus Test.

You may not need to provide this data if both in vitro tests (induction of point mutations and chromosome damage) are negative.

Chromosome damage (TG 473, TG 474, TG 479 or equivalent)

You must provide data from a test to demonstrate the production of chromosome damage in appropriate mammalian cells grown *in vitro*, with and without the use of metabolic activation systems. Suggested methods include **TG 473** *In vitro* Mammalian Chromosome Aberration Test and **TG 479** *In vitro* SisterChromatid Exchange Assay in Mammalian Cells.

Ecotoxicity data

You need to provide information on the ecotoxicity of the chemical, to give a measure of the toxic effects on biotic systems.

When it is not possible to provide ecotoxicity data through testing of the chemical or a suitable analogue you can provide estimates derived from QSAR calculations. However, NICNAS will only accept QSAR calculations for ecotoxicity properties when information on the input parameters and calculation methods used are available for analysis. This ensures the methods used and results obtained are valid.

Fish, acute toxicity test (TG 203 or equivalent)

This assessment of the acute toxicity of the chemical to fish is made after continuously exposing them to a series of concentrations of the chemical in water over four days. Mortalities and abnormal responses are recorded over this period.

You must provide information and data that covers:

- measure of toxicity, for example, LC50 (in mg/L), with confidence limits
- number and species of fish used
- duration of exposure
- no-effect level (in mg/L)
- method
- results of testing, including:
 - tabulation of mortality against concentration according to observation time
 - concentration-mortality curve at end of test.

Daphnia, acute immobilisation test and reproduction test (TG 202 or equivalent)

This assessment of the toxicity of the chemical to aquatic invertebrates is made by exposing daphnids to a series of concentrations of the chemical in water. This test has two phases:

- acute,which gives:
 - 24-hour EC50 value
 - highest concentration causing no immobilisation
 - lowest concentration causing 100% immobilisation
- reproduction, which gives:
 - EC50 (immobilisation) values over period of 1 to 14 days
 - no observed effect concentration (in mg/L)
 - other information based on reproduction observations.

- number and species of Daphnia used
- duration of exposure
- concentrations used
- description of the methods used
- tabulation of concentration-response time results.

You must provide a *Daphnia* sp.reproduction test, especially when acute toxicity and exposure to the aquatic compartment are both high. In the absence of this part of the test, you can submit a variation to the data requirements, along with a supporting scientific argument to fully justify the omission (for example, limited aquatic exposure).

Algal Growth Inhibition Test (TG 201 or equivalent)

This assessment of the potential effects of the chemical on the natural environment is made by exposing algae to a series of concentrations over at least three days.

Algae growth is determined after each day, and the algae concentration per mL is calculated for each time and concentration. An assessment can be based on the 72-hour EC50 value and the growth concentration curves.

You must provide information and data that covers:

- test organisms used (for example, origin, strain and method of cultivation)
- test conditions used, including concentrations used and duration of test
- results of testing, including:
 - EC50 value
 - no observed effect concentration
 - · assessment of time-effect relationship
 - cell concentrations and concentration-effect relationship
 - other observed effects.

Biodegradation

You must provide test results of an assessment of the potential of the chemical to biodegrade in the environment, including the method used and the name of the organisation that conducted the test.

Ready biodegradability (TG 301A-F or equivalent)

This assessment of the ability of the chemical to rapidly biodegrade in the environment is made by studying chemical biodegradation in aqueous solutions over a period of up to 28 days.

You must provide data that includes full details of the method used in the test and tabulation of the time-effect results. For some chemicals not readily biodegradable, you may need to submit data on the inherent and ultimate biodegradability (TG 302A-C or equivalent).

Notes: Although not a scheduled item, it is increasingly common that biodegradation data obtained under anaerobic conditions are available. If so, provide this data, particularly if the notified material is likely to become associated with aquatic sediments. Similarly, provide data on biodegradation in seawater, if available.

Bioaccumulation

You must provide the results of an assessment of the potential of the chemical to bioaccumulate in the environment, both aquatic and terrestrial. A full bioaccumulation test is not a schedule requirement, but results must be provided if available.

The assessment must take into consideration:

- partition coefficient for n-octanol/water
- fat solubility
- water solubility
- ready biodegradability.

If the chemical has a low partition coefficient and/or is readily biodegradable, then no bioaccumulation testing is required. Refer to the OECD Testing Guidelines on Degradation and Accumulation for more information.

DATA PROVIDED FOR SCHEDULE PART C

For all toxicological and eco-toxicological data you must specify the:

- guidelines being used to conduct the study—if the study was not conducted using a recognised guideline then provide sufficient information about the method used to allow NICNAS to determine if the results obtained are valid
- raw data generated during testing in the form of a test report (a summary of results is not sufficient).

The standard of testing to obtain data should conform to the OECD Principles of Good Laboratory Practice.

2.6.4 SCHEDULE PART D

This part of the schedule covers polymers. The numbering used is consistent with the numbering in the schedule to the Act.

The information you provide under this schedule must characterise the polymer as closely as possible (identity and composition). The information must complement the information given under Part B, paragraphs 1 and 2, where details of the complete polymer mixture—that is, the polymer and its additives and adjuvants—are provided (or, the information must complement the details you provide on the complete polymer mixture, that is, the polymer and its additives and adjuvants.)

All monomers and other reactants must be identified according to the guidelines in Appendix D2.1.

Weight-percentage of ingredients

You need to provide the maximum weight-percentage of each monomer and all other reactants used to manufacture the polymer.

Include all substances used in manufacturing the polymer that become part of the polymer composition. Reactants include chain transfer and cross-linking agents, modifying groups and other end groups incorporated into the polymer. Also include post-reacting agents used in the manufacture of post-reacted polymers.

The weight-percentage of reactant must be based on the dry weight of polymer.

Number-average molecular weight of the polymer

If more than one molecular weight composition of the polymer is to be manufactured, you need to provide the number–average molecular weight of the lowest molecular weight composition. Also provide the weight–average molecular weight and an indication of the molecular weight distribution (polydispersity).

Indicate the method used to determine the molecular weight (for example, size exclusion chromatography). Include a report of the analysis in your notification statement.

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Maximum weight perceptage of residual menomer/s and all
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other reactants

You need to provide the maximum weight–percentage of all residual monomers and other reactants at the completion of manufacture or at the time of importation.

Indicate the method used to determine the concentrations of reactants (for example, gas chromatography) and the name of the organisation that conducted the test. Include a report of the analysis with your application.

Low molecular weight polymer

You need to provide the maximum weight-percentage of the low molecular weight fraction of the polymer—that is, the fraction with molecular weight below 1000 daltons and the fraction with a molecular weight below 500 daltons. The low molecular weight fractions are usually determined in the one analysis with the weight–average and number–average molecular weights.

Indicate the method used to determine the low molecular weight fractions. Include a report of the analysis with your application (for example, for a GPC analysis include the slice data).

Degradation products

You need to provide information on all products resulting from the degradation, decomposition or depolymerisation of the polymer.

Include details on the conditions under which degradation, decomposition or depolymerisation take place. Provide the rate and mode for each and the likely proportion of products formed. In particular, provide information on all dangerous and hazardous products.

Include information on the degradation products likely to be produced during or after the disposal of the polymer.

Loss of monomers, other reactants, additives and impurities

You must provide information on the natural loss of monomers, reactants, additives and impurities from the polymer, to assess health and environmental effects during its use. Data must include loss by:

- volatility,for example, monomer
- exudation, for example, additive
- leaching,for example, by water or oil.

Indicate the conditions under which such loss may occur.

2.6.5 SCHEDULE PART E

Part E of the schedule provides details of additional data required for new industrial chemicals that are to be used as an ultraviolet filter in a cosmetic to be applied to the skin.

This data is in addition to the toxicological endpoints specified in Part C (See Section F3 above). The additional data requirements and the guidance below substantially align the requirements with those applying to new active ingredients for sunscreens under the Therapeutic Goods Administration (TGA).

Where the new UV filter has been previously assessed by TGA and the report of that assessment can be provided to NICNAS, the NICNAS assessment may be carried out in the modular category, with partial rebate of fees (See Section C5.3).

Suggested guidance documents and test guidelines are included below for the individual endpoints. For some endpoints, OECD test guidelines are available. For others, reference is made to EU guidelines adopted by TGA. If a particular guideline is not applicable or if other data are available to adequately address the endpoint, alternative approaches based on adequate scientific justification will be considered by NICNAS.

As with other parts of the Schedule there is provision for application for variation of schedule data requirements, as appropriate and where supported by scientific justification. Where the UV filter is to be used to stabilise a cosmetic product applied to the skin, rather than being a sunscreening agent to protect the skin, justification for variation of schedule data requirements may be based on the following issues:

- the toxicological profile of the chemical, and
- low concentration of use.

General comments on photosafety

Photosafety testing is carried out for several endpoints (phototoxicity, photoallergy, photogenotoxicity and photocarcinogenicity) to detect the adverse effects of substances in the presence of light. Photosafety testing is generally warranted for those chemicals that absorb light in the wavelength of 290-700 nm and are topically applied. These criteria would apply to chemicals covered by Schedule E.

General guidance on photosafety testing from the European Medicines Agency and the EU Scientific Committee on Consumer Safety can be accessed at the following web locations:

i) Note for Guidance on Photosafety Testing: http://www.tga.gov.au/pdf/euguide/swp039801en.pdf

ii) Concept Paper on the Need for Revision of the Note for Guidance on Photosafety Testing: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003358.pdf

iii) Questions and answers on the *Note for guidance of photosafety testing:* http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/04/WC500105109.pdf

iv) Section3-4.10 of the SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation, 7th Revision at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_004.pdf

Photostability

You must provide data to demonstrate stability of the chemical in light. This is especially relevant because of the intended use of the products containing the chemicals under Schedule E. *General European Union guidance on determining photostability* can be found at: http://www.tga.gov.au/pdf/euguide/vol3aq18aen.pdf . Comparison of UV absorption spectra before and after stability studies may indicate the degree of degradation.

Phototoxicity

You must provide data on phototoxicity or photoirritation testing, which provides information on acute lightinduced skin responses to a photoreactive chemical. An appropriate test method is OECD TG 432: *In Vitro* 3T3 NRU Phototoxicity Test.

Also see photosafety guidance documents listed in the introduction to this section.

Photosensitisation

You must provide data on photosensitisation or photoallergy testing, which is carried out to detect immunologically mediated reactions to a chemical, that are initiated by the formation of photoproducts. *In vitro* test methods are currently not available, and at present photosensitisation is mainly tested via modified guinea pig protocols (for example modified version of OECD TG 406 Skin Sensitisation).

Also see photosafety guidance documents listed in the introduction to this section.

Bioavailability

You must provide data on bioavailability via the oral and dermal routes, in order for NICNAS to determine what proportion of the dose of a chemical is available systemically, and to enable interpretation of the toxicity studies. NICNAS does not require ADME studies.

General guidance from the European Medicines Agency on *The Assessment of Systemic Exposure* can be accessed at: http://www.tga.gov.au/pdf/euguide/vol3bs10aen.pdf

Determination of systemic exposure after oral dosing is described in the OECD TG 417 Toxicokinetics.

OECD TG 427 can be used for determining *in vivo* skin absorption and TG 428 for determining *in vitro* skin absorption.

General guidance from the OECD Series Testing and Assessment No. 156 *Guidance Notes on Dermal Absorption* can be accessed at: http://www.oecd.org/dataoecd/63/12/48532204.pdf

Repeated dose toxicity

Repeated dose toxicity data provides information on possible health hazards likely to arise from repeated exposures over a limited period of time. Under Schedule C a repeated dose 28-day study is already required. For chemicals to which Schedule E also applies, you must provide testing data for a longer period of time (3 months or 6 months) by both the oral and dermal routes. When longer studies are submitted under Schedule E, these will replace the need for you to submit 28-day studies by the same route of exposure.

Suitable test methods are OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents and OECD TG 411 Subchronic Dermal Toxicity: 90-Day Study.

Further information from the European Medicines Agency on carrying out repeated dose studies is available:

Note for Guidance on Repeated Dose Toxicity is at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003102.pdf and

Guideline on Repeated Dose Toxicity is at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/03/WC500079536.pdf

OECD Test Guidelines for longer (chronic) studies are OECD TG 452 *Chronic Toxicity Studies* and OECD TG 453 *Combined Chronic Toxicity / Carcinogenicity Studies*.

Photomutagenicity

Testing for photomutagenicity / photogenotoxicity is carried out to detect any genotoxic response after exposure to a chemical photoactivated by UV or visible light. The main purpose of testing is to make an assessment of the potential of a substance to turn into a photochemical carcinogen. The studies you wouldneed to submit are a photomutagenicity test in bacteria and photogenotoxicity in a chromosomal aberration test.

Also see photosafety guidance documents listed in the introduction to this section, which include test strategies. It is noted that there are recent concerns about the applicability of photomutagenicity / photogenotoxicity studies and the above recommendations on testing may change in future.

Reproductive toxicity

You must provide data on the potential of the chemical to cause developmental and fertility effects, including toxicity to male fertility. The potential for endocrine disruption should also be evaluated, which could be done as part of repeat dose and/or reproductive toxicity studies.

European Union general guidance Detection of Toxicity to Reproduction for Medicinal Products including Toxicity to Male Fertility is at: http://www.tga.gov.au/pdf/euguide/vol3bs4aen.pdf

Several OECD Test Guidelines are applicable to reproductive toxicity. Preferred protocols cover at least two generations to adulthood, and measure both developmental and fertility effects.

Carcinogenicity and photocarcinogenicity

You must provide data from *in vivo* carcinogenicity and photocarcinogenicity bioassays or a justification for their omission.

For example, justification for not including *in vivo* carcinogenicity bioassays could be based around the following issues:

- the expected pattern of use (e.g. extent of contact with body)
- results of in vitro and in vivo mutagenicity assays
- lack of similarity to other molecules with known carcinogenic activity
- low persistence in the skin
- low in vivo absorption
- lack of photosensitisation or phototoxic potential
- proven photostability
- lack of possible adverse effects on the skin (e.g change to epidermis/dermis at the microscopic level or effects on skin seen in repeated dose studies)
- · length of submitted in vivo repeat dose toxicity studies, and
- lack of adverse activity in skin irritation and skin sensitisation studies.

General European Union guidance: *The Need for Carcinogenicity Studies of Pharmaceuticals* is at: http://www.tga.gov.au/pdf/euguide/vol3bs8aen.pdf and *Note for Guidance on Carcinogenicity: Testing for Carcinogenicity of Pharmaceuticals* is at: http://tga.gov.au/pdf/euguide/ich029995en.pdf

Specific photosafety testing strategies are described in the *Note for Guidance on Photosafety Testing*, referred to in the introduction.

Interaction potential

Formulations containing sunscreen may contain more than one active ingredient. You must provide data on the potential for interaction of the new chemical with any UV filter or filters that will be likely to be used in conjunction with the new chemical, in formulations to be applied to the skin. Evaluation of the interaction potential may be made via studies or published information, and information on the chemical characteristics of the UV filters.

2.6.6 VARIATION TO DATA REQUIREMENTS

If you consider a specified test or data item to be irrelevant, unnecessary or scientifically inappropriate in evaluating the potential occupational health, public health and environmental hazards of the chemical you can omit it, as long as you justify the omission under the appropriate item heading.

Examples may include, provision of a data item being scientifically inappropriate, not technically possible or not economically feasible. NICNAS can allow the variation or recommend that you substitute certain alternative data items.

Examples of variations to data requirements:

- If the chemical is a gas at room temperature, a feeding study cannot be carried out.
- An eye irritation test may be unnecessary for chemicals with a pH above 11.5 or below 2 as irritant effects are assumed.
- If data show that the chemical is a skin sensitiser in humans, then a skin sensitisation test in animals is not required.
- Acute inhalation toxicity results are not required if the chemical:
 - has a vapour pressure <1.5 kPa
 - $\circ~$ as introduced has <25% of particles having <10 μm diameter
 - is not purposely atomised during use (except where this constitutes a 'controlled' use).

You must fully justify omissions in data based on economic grounds if you consider or believe that:

- generating a particular data item required by the schedule is not economically feasible
- the data item is not essential for adequate occupational health and safety, public health and environmental assessment of the chemical
- the cost of generating the data may prohibit the introduction of the chemical
- the omission will not affect the preparation of an adequate assessment.

NICNAS will not consider claims for omitting data based solely on the administrative costs associated with preparing a submission.

2.7 APPENDIX G: DATA REQUIREMENTS FOR NOTIFICATION OF NEW CHEMICAL SUBSTANCES CONTAINING A PERFLUORINATED CARBON CHAIN

This appendix contains an action plan for assessment and management of chemicals which may degrade to perfluorinated carboxylic acids (PFCAs), perfluoroalkylsulfonates (PFASs), and similar chemicals.

It outlines NICNAS's default position for assessing potential health and environmental hazards for notification of new chemical substances containing a perfluorinated carbon chain, and additional data requirements, particularly for cases where a notifier believes that the default position should not apply for a specific chemical.

Sections of this appendix:

- Background
- Regulatory actions
- What perfluorinated chemicals are covered?
- What does this mean for a Notification?
- Refinement of NICNAS defaults
- What are the notification options for notifiers?
- Existing chemicals assessments

2.7.1 BACKGROUND

Perfluorinated chemicals are present in a variety of industrial, commercial and consumer products in Australia. The widespread occurrence of certain perfluorinated substances in the environment, in certain animal species and in humans has attracted regulatory concern and/or action globally. This is because perfluorinated substances are known to be persistent. Some of them are bioaccumulating, in particular those with long carbon chains, and some have been reported to cause toxic effects in laboratory animals, for which the relevance to human health cannot be dismissed.

One of this group of chemicals, perfluorooctane sulfonate (PFOS), has been subject to phase out on a global basis. PFOS is a fully fluorinated organic compound and is a member of a large family of perfluoroalkyl sulfonate (PFAS) based chemicals. The term PFAS refers to a general category of perfluorinated sulfonate compounds and includes compounds of carbon chain lengths greater than four; and the term PFOS refers to a subcategory of PFAS compounds that have an eight-carbon chain length.

2.7.2 REGULATORY ACTIONS **PFOS**

Australia has issued two NICNAS alerts on PFOS, available as NICNAS FactSheets in the Publications section of the NICNAS website. The alerts recommended that PFOS- and related PFAS-based chemicals be restricted to only essential uses, for which no suitable and less hazardous alternatives are available such as certain Class B fire fighting foams, and that, further, these foams not be used for training purposes in order to minimise dispersal into the Australian environment.

Since 2000, the US EPA has imposed a ban of PFOS, with exemptions for special uses in the aviation, photography and microelectronics industries. In June 2005, Sweden proposed a global ban on PFOS and its related substances under the Stockholm Convention on Persistent Organic Pollutants. Previously, both Sweden and Britain filed for national bans on PFOS to the European Commission (EC), and urged the EC to pursue an EU-wide ban. In December 2005, the EC issued a proposal for a Directive to restrict the use of PFOS in carpets, textiles, clothing and other items and this is currently under consideration by the Council.

PFOA

From July 2000, the OECD has been leading an international collaboration on the scientific assessment and surveys on perfluorinated chemicals, and NICNAS has been actively involved in these OECD activities. The details can be found at the NICNAS website and in the NICNAS Alert 1, 2 and 4. In Australia, following co-regulatory activity with NICNAS and Industry the imports of polymers containing PFOA has virtually ceased dropping from 27.5 tonnes in 2003 to approximately 20 kg in 2004, of which only 25 g has been used in the local manufacture of non-stick cookware. PFOA is not manufactured in Australia or imported as the base chemical.

Article 3 of the Stockholm Convention, which Australia ratified on 20 May 2004, requires parties to the Convention to take into account POPS characteristics when conducting assessments on new and existing chemicals. The POPS characteristics are persistence, bioaccumulation, potential for long-range environmental transport and adverse effects on human health and the environment. A notice in the Chemical Gazette of January 2004 indicated that additional data in accordance with the Information Requirements and Screening Criteria of Annex D of the Convention may be requested by NICNAS, in particular, information relating to persistence, bioaccumulation and toxicity (PBT).

In December 2005, Health Canada and Environment Canada proposed temporary prohibitions on the introduction of four new polymers containing fluorinated carbon chains based on the toxicological effects of their breakdown products, perfluorocarboxylic acids (PFCAs). In February 2006, Environment Canada and Health Canada also published a position paper: *Perfluorinated carboxylic acid (PFCAs) and precursors: A proposed action plan for assessment and management.* A *Canada Gazette* notice was published in June 2006.

In January 2006, the US EPA launched a global PFOA (perfluorooctanoic acid) stewardship program. The eight major companies that use or manufacture PFOA have committed to reduce facility emissions and product content of PFOA and related chemicals by 95 percent by no later than 2010, and to work toward eliminating emissions and product content by 2015.

The term PFOA and its related substances includes PFOA, PFOA precursors and related higher homologue chemicals. The precursors refer to chemicals that can break down to form another chemical, in this case, PFOA. The US EPA, in March 2006, also proposed amendment of polymer exemption rule of Premanufacture Notification (PMN) to exclude from eligibility polymers containing as an integral part of their composition certain perfluoroalkyl moieties consisting of a CF_{3^-} or longer chain length.

2.7.3 WHAT PERFLUORINATED CHEMICALS ARE COVERED?

A perfluorinated carbon chain refers to the structure of $F-(CF_2)_n$ in a chemical substance. The perfluorinated carbon chain could be a portion of the chemical or polymer. The perfluorinated carbon chain in polymers may be incorporated in the structures of monomers.

In molecules such as PFOS and PFOA, the perfluorinated carbon chain length (n) is eight and seven, respectively. However, chemicals with shorter perfluorinated carbon chains (n = 4, 5 or 6) are being introduced into commerce increasingly as new chemicals, as Industry seek to shift their technologies away

from PFOS and PFOA.

The US EPA PMN exemption rule has a cut-off of n=2 for fluorotelomers and n=1 for other perfluoroalkyl moieties in polymers. The US EPA also proposed significant new use rule on PFAS substances with a fluorinated chain equal and greater than five carbons. Environment Canada proposed restrictions on four chemicals with n³4 perfluorinated carbon chains.

Based on the scientific evidence and overseas regulatory agency actions, NICNAS has determined that the additional data requirements, in Australia, apply to new chemical substances with a perfluorinated carbon chain length (n) equal to or greater than four carbons, whether linear or branched.

An upper limit of a perfluorinated carbon chain length will be set on practical grounds, and where the perfluorinated chain length is greater than 24 carbons, these will no longer be considered to be covered by this action plan for assessment and management of PFCAs and PFASs.

NICNAS has determined that, for new chemical notifications, the additional data requirements apply to:

- 1. Perfluorinated chemicals and polymers listed in the 'Preliminary lists of PFOS, PFAS, PFOA and related substances' (consisting of approximately 600 chemicals), where these are being introduced to Australia for the first time.
- 2. Chemicals and polymers other than those on this list where these include a perfluorinated carbon chain of length (n) equal to or greater than four carbons, whether linear or branched, other than those in the categories listed below.

Importantly, the additional data requirements will **not** apply for:

 Chlorofluorocarbons(CFCs), hydrochlorofluorocarbons (HCFCs), hydrofluorocarbons (HFCs), perfluorocarbons (PFCs), hydrofluoroethers (HFEs), perfluoroethers (PFEs) and polymers with fluorinated backbone structures, except where these have side chains meeting the above description which are separated from the backbone by non-fluorinated segments.

In specific cases where it is not clear to a notifier whether these requirements apply, NICNAS will assist the notifier in reviewing the chemistry and advise of data requirements for notification.

2.7.4 WHAT DOES THIS MEAN FOR A NOTIFICATION? **Default data**

I) SCHEDULE DATA REQUIREMENTS

The normal set of Schedule Data Requirements for the notification category will be required for the chemical itself.

- The repeated dose study where required by the Schedule must address data on hepatotoxicity since the liver is the target organ for most perfluorinated compounds.
- The requirement for information on impurities and/or residual monomers is important for these chemicals and polymers, and analytical reports must be provided.
- Impurities and residual monomers containing perfluorinated chains will need to be characterised at ≥0.01%, except where the chemical or polymer is proposed to be used in a food contact application, in which case these impurities should be characterised at ≥1 ppm, due to the possibility of migration of the impurities into food.

Additional requirements beyond the Schedule may be requested by NICNAS where the chemical itself is predicted to be highly persistent, or to produce persistent breakdown products other than those discussed below. These are addressed in later Sections of this section.

II) DEGRADATION PRODUCTS

The perfluorinated sections of chemicals or polymers containing perfluorinated carbon chains are resistant to degradation. By the combined effects of hydrolysis and biodegradation, the perfluorinated chains are considered to produce a group of simpler perfluorinated chemicals, including perfluoroalkyl sulfonates (PFAS) and perfluoroalkyl carboxylic acids (PFCAs). Even comparatively slow degradation will result in increasing concentrations of these chemicals in the environment, due to their persistence.

NICNAS will, as a default, assume that:

- Perfluorinated chains terminated with a sulfonyl group (eg sulfonamide) will degrade to PFAS of the same chain length.
- Perfluorinated chains terminated with a hydrolysable group such as iodide or a silane will degrade to a PFCA containing one less perfluorinated carbon atom,
- Perfluorinated chains terminated with an alkyl or aryl group will degrade to form a mix of PFCAs with both the original chain length and one less perfluorinated carbon atom.

These assumptions will be used for assessment purposes except where the notifier can provide experimental information to indicate that these are not relevant.

III) TOXICITY INFORMATION ON DEGRADATION PRODUCTS

Toxicity information relating to a limited set of degradation products is currently available to NICNAS.

- For perfluorooctane sulfonic acid (PFOS) and its derivatives, the OECD hazard assessment report will be used as a default toxicity data source.
- For perfluorooctanoic acid (PFOA) and its derivatives, the US EPA preliminary risk assessment will be used as a default source
- For perfluorobutane sulfonic acid (PFBS) and its derivatives, the NICNAS hazard assessment for potassium perfluorobutane sulfonate will be used as a default source.

Default data sources may be subject to change as new toxicity data becomes available to NICNAS.

For degradation products other than those listed above, the PFOA hazard information will be used to estimate the hazard for PFCAs. For PFAS degradation products apart from PFBS, the PFOS hazard information will be used to estimate the hazard.

Notifiers should familiarise themselves with the relevant hazard information for the assumed breakdown products, as this will be used for assessment purposes except insofar as the notifier can provide experimental information to indicate that these are not relevant, as specified in Section B below.

The toxicity of impurities and residual monomers will also be considered using the default toxicity information unless additional relevant information is provided by the notifier.

IV) PERSISTENCE AND BIOACCUMULATION CHARACTERISATION

For perfluorooctane sulfonic acid (PFOS) and its derivatives, the OECD hazard assessment report will be used as a default data source. For perfluorooctanoic acid (PFOA) and its derivatives, the US EPA preliminary risk assessment will be used as a default source, while for perfluorobutane sulfonic acid (PFBS) and its derivatives, the NICNAS hazard assessment will be used as a default source. Default data sources may be subject to change as new data becomes available to NICNAS.

For degradation products other than those listed above, the PFOA hazard information will be used to estimate the persistence and bioaccumulation for PFCAs, subject to the assumption that bioaccumulation will be greater for PFCAs of more than eight carbon atoms. For PFAS degradation products apart from PFBS, the PFOS hazard information will be used to estimate the persistence and bioaccumulation, again subject to the assumption of greater bioaccumulation for PFAS of more than eight carbon atoms.

V) CONFIDENTIALITY

No claims of exempt information for the identities of the breakdown products will be accepted.

VI) ASSESSMENT OUTCOMES

Based on the hazard information for PFOA and PFOS, chemicals and polymers which produce PFCA and PFAS breakdown products apart from PFBS will be subject to the policy outlined in the NICNAS PFOS alert FactSheet which sets out that these chemicals should be restricted to only essential uses, for which no suitable and less hazardous alternatives are available. Justification should be provided as to why a use should be considered essential and why no substitutes are available.

Lack of degradation of a polymer and/or lower toxicity than shown by the default data sets for the critical effects of hepatotoxicity, developmental toxicity and carcinogenicity must be demonstrated prior to a certificate being issued for uses which are outside this policy.

Provision of alternative data by notifier

I) DEGRADATION PRODUCTS

In lieu of the default degradation assumptions, the notifier should provide information on the degradation pathways of the new chemical or polymer and the likely degradation products containing the perfluorinated carbon chain. In doing this a higher-tiered test such as an inherent biodegradability test report is required, as there is a greater possibility of degradation occurring in the presence of other nutrients than under the conditions of a ready biodegradability test, where only the test substance is present. This test should include characterisation of the degradation products and their rate of formation.

If the notifier claims that no degradation of the new chemical or polymer containing a perfluorinated carbon chain occurs, a report on analysis and characterisation of degradation products under relevant degradation conditions must be provided, as an inherent biodegradability test does not by itself give information on other degradation modes such as hydrolysis, or on formation of stable degradation products by a mechanism which does not involve mineralisation of a substantial proportion of the chemical or polymer, such as side chain cleavage.

If literature sources relating to surrogate data other than the default information used by NICNAS is provided, the notifier has to provide scientific justification on the applicability of the above studies to the notified chemical. NICNAS will determine if the surrogate data is applicable. An application for Variation of Schedule Requirements should be submitted under these circumstances.

II) TOXICOLOGICAL DATA

The repeated dose study needs to address data on hepatotoxicity since the liver is the target organ for most perfluorinated compounds. In addition, the notifier is required to provide reproduction/developmental toxicity study and carcinogenicity studies for the degradation products, or for representative degradation products in the case where a number of different products are predicted. The carcinogenicity test can be performed separately or combined with a chronic toxicity study. All these tests should be performed according to the OECD Guidelines for Testing of Chemicals. It is recognised that typically perfluorinated chemicals have not been reported to have genotoxicity potential and hence these tests are not required to be submitted. However, genotoxicity studies if available should be provided.

These data are required to be submitted for the chemical itself if this is predicted to be persistent, rather than being degraded or metabolised to PFAS or PFCA, or for persistent degradation products which are not in the PFAS or PFCA categories. The data requirements apply regardless of the notification category, except that these data are not required for the chemical itself in the case of notifications of polymers with Number Average Molecular Weight (NAMW) >1000.

If literature sources relating to surrogate data other than the default information used by NICNAS is provided, the notifier has to provide scientific justification on the applicability of the above studies to the notified chemical. NICNAS will determine if the surrogate data is applicable. An application for Variation of Schedule Requirements should be submitted under these circumstances.

2.7.5 REFINEMENT OF NICNAS DEFAULTS

It is proposed that NICNAS will approach companies that are likely to hold relevant toxicity data for chemicals other than PFOS, PFOA or PFBS to form a NICNAS Technical Working Group. This Working Group will facilitate provision of the data on the above toxicity endpoints to NICNAS.

NICNAS will then prepare and publish a hazard assessment report for any well characterised PFAS or PFCA chemical and this can be used as a default toxicology data set for one or more of the PFAS or PFCA breakdown products in future notifications of new perfluorinated chemicals.

This would ensure that NICNAS decisions will be based on the same data set, avoids duplication of assessment, avoids consideration of data of differing quality, and reduces the burden on industry to provide the same/similar data for all notifications.

2.7.6 WHAT ARE THE NOTIFICATION OPTIONS FOR NOTIFIERS?

Permit applications

If insufficient toxicity data is available on the new chemical and there is no direct public exposure to the chemical, introduction of small volumes of the chemical may be allowed under Low Volume Chemical or Controlled Use Permits for a limited time period. Control of release of breakdown products into the environment will have to be addressed.

Polymer of low concern applications

A polymer containing a perfluorinated group will NOT be considered under the Polymer of Low Concern (PLC) category, due to the potential health and/or environmental risks posed by the persistent breakdown products.

Assessment certificate applications

If the importation period or quantity for a permit is likely to be exceeded, the chemical or polymer may be notified in the Standard or Limited Certificate categories, subject to the above data requirements. Self Assessment options are NOT available for chemicals or polymers covered by this paper.

2.7.7 EXISTING CHEMICALS ASSESSMENTS

All information on perfluorinated compounds currently in use in Australia and those occurring as breakdown products is monitored by NICNAS and Existing Chemicals activity will be undertaken as necessary.

2.8 APPENDIX H: GUIDANCE AND REQUIREMENTS FOR NOTIFICATION OF NEW CHEMICALS THAT ARE INDUSTRIAL NANOMATERIALS

As of 1 January 2011, a new industrial chemical that falls under the working definition of an 'industrial nanomaterial' is not permitted to be introduced under some exemption and self-assessment categories.

This applies to any new chemical meeting the working definition of 'industrial nanomaterial' provided in NICNAS working definition of industrial nanomaterial.

Sections of this appendix:

NICNAS working definition of industrial nanomaterial

- Exemption categories
- Permit categories
- Certificate categories
- Specified conditions for requesting additional data requirements
- Guidance on providing additional data requirements
- Guidance on testing health effects of nanomaterials
- Guidance on testing the environmental fate and effects of nanomaterials

2.8.1 NICNAS WORKING DEFINITION OF INDUSTRIAL NANOMATERIAL

At present, there is no internationally agreed definition for nanomaterials. NICNAS has developed a working definition for regulatory purposes. This working definition is broadly consistent with other available international definitions.

The NICNAS working definition is:

"...industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"

Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- 'unique properties' refers to chemical and/or physical properties that are different because of a material's nanoscale features when compared with the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications
- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.

See Nanomaterials / Nanotechnology for additional information.

2.8.2 EXEMPTION CATEGORIES

New chemical exemptions are underpinned by section 21 (4) and section (6) of the Act. Section 21AA imposes annual reporting obligations on persons introducing chemicals under section 21 (4) and section (6).

From 1 January 2011, nano-forms of new chemicals are not permitted to be introduced under exemption categories where human and/or environmental exposure can reasonably be anticipated, these being:

- low volume cosmetic and non-cosmetic exemptions—section 21(4)
- low concentration (<1%) non-hazardous cosmetic exemption—section 21(6c).

If you advise NICNAS of introductions under these exemption categories you will be required to declare, on your annual reporting form, that the chemicals are not nanomaterials according to the NICNAS working definition.

These exemption categories will remain available for nano-forms of new chemicals:

- trans-shipment exemptions for which current conditions of introduction remain unchanged—section 21(6b)
- research and development exemptions—Section 21(6a)—with some amendments to annual reporting requirements. You must identify all nanomaterials introduced in volumes over 100g a year as nanomaterials and provide their full chemical name.

You must obtain a permit or certificate from NICNAS for any substances that meet the working definition of industrial nanomaterial currently introduced under exemption categories if their introduction is to continue after 1 January 2011. Contact NICNAS to determine the most appropriate notification category for your nanomaterial(s).

2.8.3 PERMIT CATEGORIES

All permit categories under Part 3 of the Act will remain available for use by introducers of nano-forms of new chemicals. These changes to notification forms and information requirements may apply:

- addition of a declaration by the notifier on the permit application form stating if the chemical is a nanomaterial
- morespecific information (such as particle size, shape and other specific information on properties) may be required under some conditions (Specified conditions for requesting additional data requirements).

To complement these changes NICNAS may stipulate permit conditions for conventional chemicals where it can be reasonably assumed that a nano-form may be introduced.

2.8.4 CERTIFICATE CATEGORIES

All certificate categories currently available—except for self-assessment categories—will be available for use by introducers of nano-forms of new chemicals. If you annually report introductions under self–assessed certificate categories you are required to declare that your chemicals are not nanomaterials, according to the NICNAS working definition (see above).

These changes to notification forms and information requirements may apply:

- addition of a declaration by the notifier on the certificate application form stating if the chemical is a nanomaterial
- morespecific information (such as particle size, shape and other specific information on properties) may be required under some conditions (see Specified conditions for requesting additional data requirements).

To complement these changes, NICNAS may stipulate specific Secondary Notification conditions to the assessment of conventional chemicals where a nano-form may be introduced.

2.8.5 SPECIFIED CONDITIONS FOR REQUESTING ADDITIONAL DATA REQUIREMENTS

As a minimum requirement, you need to provide particle size information (primary particle size and numberweighted size distribution) where:

- the chemical is an industrial nanomaterial
- it can be anticipated or there is uncertainty that the chemical could be a nanomaterial and exposure to human health or the environment is expected based on use scenarios
- the chemical is introduced as a solid or powder or as a dispersion and is insoluble^[1]. and/or known to be biopersistent.^[2]

NOTES:

- 1. If particle size information cannot be supplied for a chemical that meets certain conditions outlined immediately above (other than when declared as a nanomaterial), the chemical will be assumed to be an industrial nanomaterial for risk assessment and recommendation purposes.
- 2. These chemicals meet the conditions but may not be subject to additional data requirements.
- a) compounds that dissociate in water to form ions
- b) colloidal polymers
- c) micelles
- d) biological materials.

Contact NICNAS for advice on notification requirements for these chemicals.

You may also need to provide this additional data under certain circumstances (Figure G5). Specific guidance on physico-chemical characteristics and toxicity testing are provided below

- method of production
- medium identity
- medium conditions (identity and concentration of stabilizers, ionic strength and ionic composition)
- shape
- crystalline phase
- agglomeration/aggregation state
- composition(purity/impurities)
- surface area
- surface charge
- surface chemistry (such as coatings and modifications)
- toxicity data will be requested case-by-case.

NOTE:

These additional data requirements will be determined case-by-case and are subject to variation as new knowledge on toxicity of nanomaterials is developed.

[1] for example, water insolubility <1 mg/L); [2] the ability of a substance to remain in the body in spite of physiological clearance mechanisms

CONDITIONS FOR PROVISION OF PARTICLE SIZE INFORMATION AND ADDITIONAL DATA REQUIREMENTS FOR PERMIT AND CERTIFICATE CATEGORIES



2.8.6 GUIDANCE ON PROVIDING ADDITIONAL DATA REQUIREMENTS

This section gives guidance on the physico-chemical characterisation and reporting requirements for additional data requirements (above that normally required for the notification category).

The recommended test methods identified for the physico-chemical data are informed by the International Organization for Standardisation's (ISO) technical report (ISO/PDTR 13014) on Nanotechnologies—Guidance on physico-chemical characterisation for manufactured nano-objects submitted for toxicological testing^[1] and the Organisation for Economic Co-operation and Development (OECD) sponsorship program *Guidance manual for the testing of manufactured nanomaterials OECD's sponsorship programme*.^[2] Refer to these documents for further details and alternative methods.

Where NICNAS asks for specific physico-chemical data and/or test results but it is not feasible or not considered applicable to provide it, you must provide a scientific rationale for not doing so.

You need to supply physico-chemical data for the nanomaterial as manufactured (that is, at the point on completion of manufacture or as the sample is removed from the manufacturer's container) and, where data is available, in the end-use product formulation.

In general, all physico-chemical data should specify the:

grade of the nanomaterial tested, including its purity 214/323

- testing authority or organisation
- method of preparing the test sample
- physical conditions used for all test data (for example, agitation method (dispersing aids), pH, ionic strength, ionic composition, temperature or pressure).

You need to ensure that the standard of testing used to obtain data complies with the OECD Principles of Good Laboratory Practice.

Note:

The OECD Working Party on Manufactured Nanomaterials (WPMN) reviewed all 22 OECD test guidelines for physico-chemical properties for their applicability to the testing of nanomaterials.^[3] The review concluded that all but two of the current tests may provide information applicable to nanomaterials. The two tests not considered to provide useful information are TG 103 Boiling Point and TG 114 Viscosity of Liquids.

It was also recognised that some tests would only be applicable to a sub-set of nanomaterials depending on their physical form and chemical composition. For example, it was concluded that the three test guidelines for physico-chemical properties of polymers (OECD TG 118 to 120) would only apply to polymeric manufactured nanomaterials.

The key physico–chemical properties requiring characterisation when considering aquatic environmental exposure of chemicals are water solubility, water-soil and water-oil partitioning, hydrolysis and dissociation constants. All standard test guidelines for these properties potentially apply to nanomaterials. However, it is noted that this applicability depends in part on the presence of colloidal dispersions of nanomaterials in water which may complicate both the conduct and/or interpretation of studies.

Particle size and size distribution

You need to provide the mean primary particle size and number weighted primary particle size distribution with number fraction <100 nm. In addition, provide a representative microscopy image at a magnification capable of resolving features <100 nm, to validate the particle sizing method.

When measuring the particle size distribution, effort should be made to break down loose agglomerates, including those of fibres (for example, through sonication or the use of dispersing aids to fully disperse the nanomaterial). Report the method of dispersion and sample preparation.

Where you have not provided the size distribution and number weighted percentage of particles <100 nm, the chemical will be assumed to be a nanomaterial under the NICNAS definition if there is evidence of primary particles of <100 nm in the representative microscopy image.

Fibre-like nanomaterials

For fibre-like nanomaterials, such as carbon nanotubes, provide the aspect ratio (fibre length range and diameter range). For guidance on measurement refer to the OECD's technical guidance document No. 10—Particle Size Distribution/Fibre Length and Diameter Distributions^[4].

Recommended test methods are: Scanning electron microscopy (SEM), Transmission electron microscopy (TEM), Atomic force microscopy (AFM), Dynamic Light Scattering (DLS)*, Laser Diffraction, Disk centrifugation and Scanning Mobility Particle Sizer (SMPS).

*DLS, although suitable for monodisperse materials, should not be solely relied upon for measuring the primary particle size distribution of nanomaterials with broad size distributions as this method is strongly biased towards larger particles or aggregates which may obscure the presence of nanoparticles.

Method of production

You must describe the method of production, including the methods used for purification as these may affect key properties of the nanomaterial, including the type and level of impurities and surface chemistry.

Shape

You must describe in detail the physical shape of the nanomaterial, using terms such as spheres, fibres, tubes or plates.

Recommended test methods are: SEM and TEM.

Agglomeration/aggregation state

You must provide the agglomeration/aggregation state of a dispersion of the nanomaterial in an aqueous medium. NICNAS recommends that you do so using two techniques—a direct observational technique such as TEM or SEM, and a DLS technique.

The electron microscopic techniques provide information on the structure and size of primary nanoparticles whereas light scattering provides information on the average hydrodynamic radius of agglomerates and aggregates of nanoparticles dispersed in the water phase. The information derived from both techniques is complementary and important to fully characterise the state of nanomaterial aggregation in aqueous media used for environmental fate and effects testing.

You must also provide a qualitative assessment of the degree of aggregation and agglomeration in the enduser or finished product and, where feasible, a representative microscopy image.

Agglomerate (definition from the International Organization for Standardisation's ISO TS27687 2008 - www.iso.org/iso/catalogue_detail?csnumber=44278):

... collection of loosely bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components.

Notes:

- 1. The forces holding an agglomerate together are weak forces, for example van der Waals forces, as well as simple physical entanglement.
- 2. Agglomerates are also termed secondary particles.

Aggregate (definition from ISO TS27687 2008 - www.iso.org/iso/catalogue_detail?csnumber=44278):

... particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components.

Notes:

- 1. The forces holding an aggregate together are strong forces, for example covalent bonds, or those resulting from sintering or complex physical entanglement.
- 2. Aggregates are also termed secondary particles and the original source particles are termed primary particles.

Recommended test methods are: SEM, TEM and DLS.

Crystalline phase

Crystalline phase refers to the specific space group for a given crystal structure. In certain cases it is possible to have multiple crystalline phases, such as with silica (that is, amorphous and different crystalline forms) and titanium dioxide (that is, rutile phase and anatase phase).

You need to describe the average crystalline phase.Recommended test methods are: X-ray diffraction, electron diffraction and TEM.

Composition (purity/impurities)

You must provide the percentage purity of the nanomaterial and the identity and percentage of all impurities. 216/323
Impurities may arise from incomplete reactions, from reagents used for production (for example, catalysts) or from post-production handling (such as absorption of endotoxins).

Recommended test methods are:

- Metallic impurities: atomic absorption spectroscopy, Inductively coupled plasma mass spectroscopy and Inductively coupled plasma atomic emission spectroscopy.
- Organic impurities: UV/VIS (Ultraviolet-visible spectroscopy), GC-MS (Gas chromatography-mass spectrometry) or LC-MS (Liquid chromatography-mass spectrometry).

Surface area

You must provide the exposed surface area per unit mass of the nanomaterial presented as m^2/g .

The recommended test method is: BET^[5] gas-absorption method.

Surface charge

Due to their extremely high specific surface area, aqueous dispersions of nanoparticles can easily lose their colloidal stability as a result of changes in the chemistry of the dispersion medium (for example, ionic strength, pH, level of dissolved organic carbon). Agitation conditions and changes in concentration of the particles can also lead to agglomeration or aggregation.

An important predictor of colloidal stability is the surface charge of particles. The surface charge is usually characterised by measurements of the zeta potential. You must provide the measurement of this electrokinetic parameter over a wide range of pH and ionic strengths in water. This is valuable information on the tendency of particle size and size distribution to change with time and solution chemistry.

The zeta potential of the nanomaterial in aqueous dispersion should be measured over as wide a pH range as practicable, but measurements must span the environmentally relevant pH range of 4 to 9. You must fully describe the test methodology, including details of the dispersion medium (such as ionic strength and identity and concentration of any added electrolytes or stabilisers). You must submit a full plot of the measured zeta potential versus pH profile of the nanomaterial. You must also provide an estimate of the pH for the point of zero charge of the nanomaterial if there is no net charge on the particles in the measured pH range.

The recommended test method is: Measure electrophoretic mobility and calculate zeta potential.

Surface chemistry (for example, coating or modification)

Surface chemistry plays a key role in determining fate in natural aqueous systems, colloidal stability and exposure. For a given functionalisation or coating it will affect other physico-chemical properties such as agglomeration, surface charge, surface area and water solubility.

You must provide the chemical nature of the outermost layers of the nanomaterial, if different to the rest of the material, including the identity of any coatings or stabilisers and/or surfactants and intentional functionalisation. If the nanomaterial has a functionalised surface, you need to identify the treating agent. You must also identify, if feasible, the unintended functional groups on the surface, such as those induced by purification processes.

[1] ISO 2010, ISO/PDTR 13014, The International Organization for Standardization, <www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&development=on>, accessed 17 November 2010.

[2] OECD 2009a, first revision, ENV/JM/MONO(2009)20/REV. In: *OECD Environment, Health and Safety Publication,* series on the safety of manufactured nanomaterials, OECD Paris, Organisation for Economic Co-operation and Development, no. 25, p. 92, <www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1_00.html>, accessed 17 November 2010.

[3] OECD 2009b, 'Preliminary review of OECD test guidelines for their applicability to manufactured nanomaterials', *OECD Environment, Health and Safety Publication*, series on the safety of manufactured nanomaterials, no. 15, ENV/JM/MONO(2009)21,

OECD Paris, Organisation for Economic Co-operation and Development, p. 71, </br><www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1_00.html>, accessed 17 November 2010.

[4] See: tsar.jrc.ec.europa.eu/documents/Testing-Methods/Guidance_Document_on_Granulometry.pdf

[5] Method expounded by Stephen Brunauer, Paul Hugh Emmett, and Edward Teller.

2.8.7 GUIDANCE ON TESTING HEALTH EFFECTS OF NANOMATERIALS

The applicability of the OECD Test Guidelines for testing manufactured nanomaterials has been reviewed by the OECD WPMN.³ This review found that, in general, the guidelines are applicable for investigating the health effects of nanomaterials, although in some cases there is a need to further modify the guidelines—particularly with studies using the inhalation route and with toxicokinetic studies. The table below summarises the key points from the WPMN's review.

For each test, you must report an adequate characterisation of the nanomaterial tested out-of-the-bottle and describe the sample preparation. Where feasible, provide the characterisation of the nanomaterial in the dosing medium (that is, particle size distribution, agglomeration and aggregation state).

SUMMARY OF PRELIMINARY REVIEW OF OECD TEST GUIDELINES FOR THEIR APPLICABILITY TO MANUFACTURED NANOMATERIALS

OECD test guideline/s	Test	Notes
417	Toxicokinetics (Administration- Distribution-Metabolism- Excretion)	The guideline is very general. Although being updated at time of writing, it is questionable if modifications will be sufficient for investigating nanomaterials. It is likely that specific studies on the absorption and distribution of nanomaterials will need to be designed case-by-case. In particular, due to the likely property of nanoparticles to translocate whatever the exposure conditions, studies tracking the distribution of labelled nanomaterials <i>in vivo</i> at realistic exposure scenarios will be necessary. The main issues associated with absorption, distribution, metabolism and excretion studies with nanomaterials are ensuring the (product) label: (1) remains with the nanoparticles following route of entry into the body; and (2) does not alter the biological activity of the nanoparticle, particularly since the changes in surface chemistry of the nanoparticle can significantly influence its physicochemical properties and, as a consequence, its toxicity. Preliminary studies should therefore be undertaken to certify that both issues are covered before undertaking a toxicokinetic study.
427	Skin absorption in vivo	No comments.
428	Skin absorption <i>in vitro</i>	The use has been questioned for nanomaterials since it has been claimed that mechanical aspects such as flexing may be important and some further development of this assay may be needed for nanomaterials.

420, 423, 425	Acute oral	Would be appropriate for initial investigation. It should be recognised that the extent of pathology at autopsy is limited.
403	Acute inhalation	Includes only very limited histological examination at autopsy. Detailed examination of the respiratory tract would be appropriate with consideration of the addition of broncho-alveolar lavage and possibly pulmonary cell proliferation endpoints. The methodology for this test should not be confused with intratracheal instillation, commonly used to assess the pulmonary toxicity of nanomaterials. Intratracheal instillation in rats can cause misleading artefactual effects associated with doses that overload respiratory clearance mechanisms. This guideline is being updated, but the update is not taking into account nanomaterial assessment. Further revision should be planned or a separate guideline developed.
402	Acute dermal	Only requires minimal pathology; would be desirable to have enhanced pathology when investigating nanomaterials.
430, 431, 435	<i>In vitro</i> methods for investigating skin corrosion	May be used, but noting that measurement of cell viability using MTT (or other metabolically converted vital dye) may not be appropriate due to marker inactivation.
404, 405	Skin and eye irritation	Appropriate for investigating the irritancy of nanomaterials.
406	Skin sensitisation—guinea pig models	Should not be considered for nanomaterials. TG 429 is the preferred method.

429	Skin sensitisation—local lymph node assay	Appears to be the most appropriate method for investigating the skin sensitisation potential of nanomaterials. The test permits an estimation of the potency of the sensitisation reaction.
432	Phototoxicity—in vitro assay	Mainly used for cosmetics—ultra violet filters in sunscreens for phototoxicity.
407, 409	28-day and 90-day repeat dose oral studies	Appropriate for investigating the repeated dose toxicity of nanomaterials by the oral route. Consideration needs to be given to enhancing the ability of this method to detect adverse effects that are a particular concern with some nanoparticles (for example, cardiovascular effects with nanoparticles). Has been updated to enhance their ability to detect neurotoxic and immunotoxic effects and also effects on the reproductive system. TG 407 is being updated to give enhanced ability to detect effects on the endocrine system.
412 and 413	14 to 28-day and 90-day repeat dose inhalation	Both guidelines need to be enhanced with respect to neurotoxicity and immunotoxicity when investigating nanomaterials. TG 412 has very limited pathology. Detailed histological examination of the entire respiratory tract would be expected when investigating the effect of nanomaterials following repeated exposure by inhalation. Consideration needs to be given to enhancing the ability of these methods to detect adverse effects that are a particular concern with some nanoparticles.
		Little use for chemicals in general.

410, 411	21, 28 or 90-day repeat dose dermal studies	It is likely that any testing of nanomaterials by the dermal route would be limited to acute toxicity and investigation of the extent of absorption through skin.
471 473 476	<i>In vitro</i> genotoxicity tests Bacterial reverse mutation assay <i>In vitro</i> mammalian cell gene mutation test <i>In vitro</i> mammalian cell gene mutation assay, with the mouse lymphoma assay being the preferred assay	Appropriate for an initial investigation of the mutagenic potential of nanomaterials. However it has been recognised that treatment of mammalian cells <i>in vitro</i> with insoluble particles may lead to misleading results.
474, 475 or 486	In vivo genotoxicity tests	Positive results <i>in vitro</i> would need to be followed up <i>in vivo</i> if the bone marrow or liver were appropriate target organs, and this would depend on systemic availability.
477, 478, 479, 480, 481, 482, 483, 484, 485	Genotoxicity tests	Unlikely to be used when investigating the mutagenicity of nano materials.
451, 452, 453	Chronic toxicity and carcinogenicity	Unlikely to be used for nanomaterials, except in very exceptional circumstances.
421, 422, 415, 416	Reproductive toxicity	Appropriate for investigating the reproductive toxicity of
414	Developmental toxicity	Needs to be modified if exposure was by inhalation and needs careful consideration.

2.8.8 GUIDANCE ON TESTING THE ENVIRONMENTAL FATE AND EFFECTS OF NANOMATERIALS

The assessment of the environmental risks of nanomaterials in Australia will be conducted using the conventional risk assessment paradigm currently applied to all chemical substances, including industrial chemicals.

This risk assessment framework involves parallel evaluations of the environmental fate and effects of chemical substances according to harmonised international test guidelines, followed by a risk characterisation step^[1](Environment Protection and Heritage Council (EPHC), 2009).

The unique properties of nanomaterials may present new challenges, including technical issues to do with the applicability of harmonised test guidelines for chemicals.^[2]

However, coordinated global activities by the OECD WPMN have identified critical strengths and weaknesses in the current test guidelines as they may apply to testing of the environmental fate and effects of nanomaterials.

The results of the Working Party's review and supporting scientific data for the behaviour of nanomaterials in aquatic systems provides a basis for general guidance on appropriate approaches to characterising the environmental fate and effects of industrial nanomaterials.

Environmental fate

The OECD test guidelines for environmental fate endpoints have each undergone a preliminary review by the WPMN for applicability to testing nanomaterials.³ According to this preliminary review, several existing test guidelines are applicable for testing the environmental fate of nanomaterials. However, the applicability of individual test methods depends on the behaviour of the nanomaterials in the environment, which in turn depends on the physical and chemical properties of nanomaterials in environmental media.

Based on a detailed evaluation carried out by the WPMN on test guidelines related to abiotic and biotic degradation, available tests seem to be applicable to the same extent for nanomaterials as for the comparable bulk materials. However, fully inorganic nanomaterials will not require testing in any of the biotic degradation tests. The conclusions of the WPMN on the current OECD test guidelines for biodegradability to nanomaterials is summarised in Table 1.

The potential for bioaccumulation of nanomaterials in aquatic organisms to be assessed using *OECD TG 305 Bioconcentration: Flow-through Fish test* may have some critical limitations in sole testing of bioaccumulation of nanoparticles. For example, it is likely that in most cases the size of nanoparticulate materials (one critical dimension in the range 1 to 100 nm) limits the uptake of these particles through membranes in fish compared to standard molecular chemical substances. Nevertheless, this test provides a valuable starting point for assessing bioaccumulation potential in aquatic organisms.

TABLE 1: OECD INTERNATIONAL GUIDELINES FOR ASSESSING BIODEGRADABILITY— APPLICABILITY FOR NANOMATERIALS

OECD test guideline	Limitations	Applicability for nanomaterials
OECD 301A DOC die way	Test substance has to be soluble, non-volatile, not sorbed to vessel or sludge and non-toxic at test concentration	In principle not applicable as the nanomaterial has to be soluble.
OECD 301B CO ₂ evolution test	Test substance must be non- volatile and non-toxic at test concentration.	Applicable, but higher test material concentration needed— for example, compared to OECD 310 (2–40 mg C/L). Measures mineralisation.
OECD 301C Modified MITI Test	Test substance has to be non- toxic at test concentration, subject to interference from nitrification.	In principle applicable, but high conc. Needed.
OECD 301D Closed bottle test	Test substance has to be non- toxic at test concentration, subject to interference from nitrification.	In principle applicable.
OECD 301E Modified OECD screening test	Test substance has to be soluble, non-volatile, not sorbed to vessel or sludge and non-toxic at test concentration	In principle not applicable as the nanomaterial has to be soluble.
OECD 301F Manometric respirometry test	Test substance has to be non- toxic at test concentration, subject to interference from nitrification.	In principle applicable, high conc.
OECD 310 (Headspace test)	Test substance must be non- toxic at test concentration (pH 2 for analysis of CO ₂).	Applicable, test material need not be soluble; carriers can be used. Measures mineralisation.
Simulation tests for freshwater	(marine) and sediment systems	
	Simulates suspended sediment only. Test substance has to be	Applicable, but the bioavailability

OECD 308 Aerobic and anaerobic transformation in aquatic sediment systems	non-toxic, non-volatile and soluble. Site specific with respect to sediment. Sorption to sediment may be misleading if ¹⁴ C not used.	may limit degradation. Measures mineralisation from labelled particles.
OECD 309 Aerobic mineralisation in surface water	No comment	Applicable. Measures mineralisation from labelled particles.

Environmental effects

There are 13 OECD guidelines (see: www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-ofchemicals-section-2-effects-on-biotic-systems_20745761) for testing substances for adverse effects on various aquatic life, and these include tests for acute and chronic effects (Table 2). These guidelines have each been reviewed by the WPMN to evaluate their applicability to the testing of nanomaterials.³ In summary, it is likely that the ecotoxicity endpoints described in current test guidelines are applicable. These endpoints generally involve whole-organism responses that integrate many possible modes of toxicity and are thus also likely to be indicators of potential adverse effects of nanomaterials.

However, the WPMN review also highlighted a common challenge associated with applying these test guidelines to nanomaterials: that guidance on preparation, delivery, measurement, and metrology in all test guidelines is insufficient for the testing of nanomaterials. The OECD is coordinating efforts to refine and adapt this aspect of the test guidelines, in particular testing requirements for the environmental effects of nanomaterials. In the interim, it is recommended that the design and conduct of aquatic effects tests of nanomaterials be closely integrated with measurements of the physical and/or chemical properties of these materials. The particularly relevant properties that should be characterised relate to the colloidal stability and solubility of the nanomaterials under typical aquatic exposure conditions.

TABLE 2: LIST OF OECD GUIDELINE TESTS FOR AQUATIC ECOTOXICITY REVIEWED FOR APPLICATIONS TO NANOMATERIALS

OECD test guideline	Description of test
201	Alga, Growth Inhibition Test
202	Daphnia sp. Acute Immobilisation Test
203	Fish, Acute Toxicity Test
204	Fish, Prolonged Toxicity Test
209	Activated Sludge, Respiration Inhibition Test
210	Fish, Early-Life Stage Toxicity Test
211	Daphnia magna Reproduction Test
212	Fish, Short-term Toxicity Test on Embryo and Sac- Fry Stages Test
215	Fish, Juvenile Growth Test
218	Sediment-Water Chironomid Toxicity Using Spiked Sediment Test
219	Sediment-Water Chironomid Toxicity Using Spiked Water Test
221	Lemna sp. Growth Inhibition Test
224	Determination of the Inhibition of the Activity of Anaerobic Bacteria Test Reduction of Gas Production from Anaerobically Digesting (sewage) Sludge Test

[1] EPHC 2009, 'Environmental risk assessment guidance manual for industrial chemicals', Environment Protection and Heritage Council, Australia, p. 109, www.scew.gov.au/system/files/resources/bffdc9e9-7004-4de9-b94f-b758140dbc8c/files/cmgt-nchemeragm-industrial-chemicals-200902.pdf>, accessed 28 October 2010.

[2] Batley GE & McLaughlin MJ 2010, 'Fate of manufactured nanomaterials', *Australian environment*. Bangor, Centre for Environmental Contaminants Research, CSIRO Land and Water, p. 76 <www.environment.gov.au/settlements/biotechnology/publications/manufactured-nanomaterials.html>, accessed 11 November 2010.

2.9 APPENDIX I: EXPOSURE CRITERIA AND SCENARIOS FOR CONTROLLED USE PERMIT: ADDITIONAL INFORMATION

The information in this appendix should be read in conjunction with the information in Controlled use permit.

Sections of this appendix:

- Controlled use exposure criteria
- Controlled use exposure scenarios

2.9.1 CONTROLLED USE EXPOSURE CRITERIA

To be granted a Controlled Use Permit (CUP), the information in your application must demonstrate that you have met each criterion for occupational health and safety, public health and environmental exposure.

Note: You can only be issued with a CUP if you can supply the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) with details of the identity and practices of downstream user/s.

OCCUPATIONAL HEALTH AND SAFETY EXPOSURE CRITERIA

The principal criterion for occupational exposure is adequate protection as controlled by engineering controls, work practices and personal protective equipment.

Examples of adequate engineering controls and work practices are included in the two exposure scenarios in the next section of this appendix, which may be generally applied only to industrial circumstances.

Industry is encouraged to help NICNAS develop other exposure scenarios.

PUBLIC HEALTH EXPOSURE CRITERIA

The principal criterion for public exposure is that there be no exposure to the general public, including consumers, from proposed manufacturing, processing or using the substance.

The chemical must not be present in products available to the public, except in an article where the chemical or polymer is fixed into the article's matrix and is not available for exposure. If the chemical or breakdown product is released at a sufficient rate that it can accumulate in the environment (considering the environmental fate properties of the chemical or breakdown product) and result in potential exposure of humans to elevated levels, then the chemical would not meet CUP criteria.

Examples of the types of uses that fall outside the scope of the CUP are ink in ink-jet cartridges, detergents, personal care products and engine lubricants where 'do it yourself' use may occur.

ENVIRONMENTAL EXPOSURE CRITERIA

The criteria for environmental exposure are that there must be no:

- ambient release to surface water resulting in concentrations of the chemical above 1 μ g/L (1 ppb) 227/323

- ambient release to air above 1 μg/m3 average annual concentration
- release to land or landfill unless the chemical has negligible potential for migration to groundwater.

Release to surface water

This criterion covers all controlled point-source releases to surface water (marine and freshwater) throughout the lifecycle of the chemical in Australia.

The maximum Predicted Environmental Concentration in water (PECwater) after secondary or tertiary wastewater treatment arising from any controlled point-source release can be calculated using this formula:

PEC_{water} = (Q 1000) , F

Where:

 PEC_{water} = Predicted Environmental Concentration in water in μ g/L

Q = Daily Quantity of chemical released from site in kg/day, and

F = Daily receiving stream Flow in ML/day.

Non point-source (dispersive) releases of chemicals, such as those associated with release after use of detergents and personal care chemicals (shampoos, cosmetics etc.), are not considered to be controlled and therefore fall outside the scope of the CUP.

Release to air

This criterion covers all releases to air throughout the lifecycle of the chemical in Australia.

The maximum Annual Average Concentration in air (AACair) can be calculated using this formula:

$AAC_{air} = Q' N' 9.68' 10^{-6}$

Where:

 AAC_{air} = Annual Average Concentration in air in µg/m³

Q = Daily Quantity of chemical released from site in kg/day, and

N = Number of release days per year in days.

You must provide sufficient detail to demonstrate that significant releases to air will be restricted by proposed physical controls for chemicals that:

- are gases at any point in the chemical's lifecycle
- have a vapour pressure ≥ 0.01 Pa at $20 25^{\circ}$ C.

Releases to land or landfill

This criterion covers all releases to land, including landfill, throughout the lifecycle of the chemical in Australia. To meet it, the chemical must have negligible potential for migration to groundwater from releases to land or landfill.

You can assume negligible potential if these conditions are satisfied:

- no uncontrolled releases to land
- the chemical's log10 Adsorption/Desorption Coefficient (log10 $KOC^{[1]}$) ≥ 4
- migration to groundwater is precluded throughout the lifecycle of the chemical in Australia by the chemical's inherent properties or by management conditions.

Data for adsorption/desorption coefficient for the notified chemical or accepted close analogue can be measured or estimated by an appropriate, validated model.

'No uncontrolled release' precludes, for example, chemicals incorporated into rubber tyres, which—by the nature of their use—will be released to land in an uncontrolled manner. Similarly, uncontained drift from outdoor spray applications will fail this condition. Another example that falls outside the CUP scope is chemicals used as engine lubricants where do-it-yourself operations may occur, such as changing oil and filters.

Release of chemicals to land associated with biosolids (sludge removed from Sewerage Treatment Plants spill out) is considered to be a controlled release. However, the chemical must still meet the other associated conditions.

Finally, while release to regulated landfill, for the sake of this condition, is considered to be controlled, the chemical must still meet the other associated conditions (that is, the chemical could be disposed of to landfill but it must meet the second and third dot points above).

[1] Organic carbon coefficient

2.9.2 CONTROLLED USE EXPOSURE SCENARIOS

NICNAS has developed two controlled use exposure scenarios in consultation with industry. The control measures specified in the two exposure scenarios generally apply to industrial use.

Typically a chemical being used as described in these scenarios meets the exposure criteria set out in the previous section of this appendix.

Exceptions may occur where a chemical has particular physico-chemical characteristics (for example, highly volatile or persistent). Specific criteria (for example, calculation of releases to surface water) must comply with CUP requirements.

These exposure scenarios are set out as performance criteria:

- specificcontrols are discussed against each criteria where information is available to NICNAS
- listedcontrol measures are in bullet lists
- listedcontrol measures are considered to meet the performance criteria as suitable controls under the CUP category
- controlmeasures other than those listed may also meet the performance criteria, and the permit application must describe how each unlisted control does so.

Personal protective equipment is generally not specified as part of controls—granting a CUP normally depends on suitable engineering controls. However personal protective equipment must always be used as an additional protection measure, according to the Safe Work Australia Code of Practice, and you must specify use in your application. You must also describe the use of personal protective equipment for cleaning and maintenance tasks, including likely operational risks.

EXPOSURE SCENARIO 1—CONTAINMENT AND CONTROLLED REFORMULATION (REFORMULATION OF A PLASTIC ADDITIVE)

This scenario is for chemicals not manufactured in Australia. The only handling of the chemicals is to reformulate them into plastic articles, whether in a master batch or directly.

Chemicals added to the plastics normally have these functions: fillers, plasticisers, antioxidants, coupling agents, colourants, ultraviolet and other weathering stabilisers, polymeric impact modifiers, anti-static agents, flame retardants and preservatives. Processing additives, such as curing agents, blowing agents, heat stabilizers, slip promoters, lubricants, and viscosity aids, may also meet this scenario.

Occupational exposure

Occupational exposure can occur at several stages: transporting and storing; weighing and transferring to a mixing vessel; mixing and extrusion; handling the finished polymer or master batch; and disposing and cleaning. Exposure scenarios are mostly for dermal exposure or exposure to vapours or dusts.

The performance (handling) criteria for packaging, transporting and storing the chemical are the same as outlined under Public exposure above.

Handling criteria for the chemical must include:

- opening packaging to access the new chemical in designated areas by operators specifically trained in operational procedures, using precautions relating to the new chemical or to products containing it
- not liberating contents until the bag or container is opened to add the contents to a pre-mix container, hopper or low or high-speed mixer (automated unloading is expected for large containers)
- enclosing all dust or vapour generating processes, such as mixing, grinding and heating
- generally performing transfer processes under local exhaust ventilation
- enclosing mixing, grinding, extrusion and/or moulding operation; the possible volatilisation of the additive during extrusion must be addressed by keeping the vapour pressure low at the relevant temperature, or by detailing vapour control measures
- enclosing melting and extrusion or moulding operations
- controlling fumes and/or vapours with exhaust ventilation
- addressing dust exposure generated during transferring and weighing the chemical and disposing of packaging through an enclosed process with sufficient local exhaust ventilation, or using a non-dusting form such as master batch pellets or waxy solids
- using the chemical in non-dusting form or in a master batch
- using, for bulk quantities, mechanical systems for unloading and weighing (for example, in a weight feeder) and automating distribution through enclosed transfer systems
- weighing and adding to mixers under a suitably designed local exhaust ventilation system that has been properly installed, tested and is properly maintained
- using pre-cleaning (where the situation permits) and personal protective equipment for cleaning and maintenance
- handling finished articles or master batches is considered to be qualitatively the same process as use of the finished article by the public, and therefore does not require specific controls.

Public exposure

The only products available to the public are finished moulded plastic articles. The chemical is sufficiently immobilised by its incorporation into the plastic article and the criteria for public exposure met. The exception is if the chemical or breakdown product from the plastic article is released at a sufficient rate that leads to accumulation in the environment (considering the environmental fate properties of the chemical or breakdown product) and results in potential exposure of humans to elevated levels. The potential for public exposure is only possible if the chemical is released after a transport incident or inappropriate handling.

Packaging, transporting and storing criteria for the chemical must include:

- packaging in dangerous goods-approved packaging or in robust packaging suitable for protecting and retaining the contents
- transporting and storing additives in robust polyethylene-lined, heavy-duty woven polypropylene bags or flexible intermediate bulk containers
- transporting by road or rail as dangerous goods according to the Australian Code for Transport of Dangerous Goods by Road and Rail (if appropriate), or transporting by recognised industrial chemical transport operators.
- storing the chemical in dangerous goods stores approved under state and territory government legislation, or storing in general industrial chemicals stores controlled by experienced stores operators and in a

location preventing damage to packaging and release into drains, sewers or soil.

Environmental exposure

Overall, the new chemical cannot be intentionally released to the aquatic, air or terrestrial environmental compartments.

Environmental exposure may be possible in the event of release of the chemical after a transport incident. The performance criteria for packaging, transporting and storing the chemical are the same as outlined under Public exposure above

Handling criteria for the chemical must include:

- disposing residual chemical retained in packaging with the empty packaging to regulated landfill, while
 ensuring the chemical must have negligible potential for migrating to groundwater from releases to land or
 landfill
- ensuring waste chemical generated during setting of initial extrusion specifications, or from offspecification material and from cleaning and/or purging at the end of production runs extrusion processes, is a minor proportion of the introduced substance
- ensuring quantities of waste chemical arising from spillage before blending or when captured in a dust or vapour extraction filter or from waste extruded preparations, is not recycled
- recycling all production and cleaning waste, where possible, or collecting and consigning it to regulated landfill while ensuring the chemical has negligible potential for migrating to groundwater from releases to land or landfill
- recycling or releasing to regulated landfill sites moulded articles at the end of their life, while ensuring the chemical has negligible potential for migrating to groundwater from releases to land or landfill

EXPOSURE SCENARIO 2—SITE-LIMITED AND CLOSED SYSTEM (ENCLOSED USE AND COMPLETE CONSUMPTION)

This scenario is for the use of a chemical as a chemical industry feedstock resulting in conversion to a different chemical or polymer before being released from the industrial environment. It is specific for importation, but also relevant for onsite production of an intermediate.

This scenario does not address the chemical or polymer produced from the feedstock or intermediate. This is subject to other NICNAS requirements.

Occupational exposure

Occupational exposure is limited by the use of an enclosed process, which accounts for weighing and transferring to a reaction vessel, at which point the chemical ceases to exist.

Exposure scenarios are mostly for dermal exposure or exposure to vapours or dusts during transfer from imported containers to the enclosed pipe work system attached to the reactor, and also maintenance and cleaning.

Overall handling criteria for the chemical must include:

- opening packaging to access the new chemical in designated areas by operators specifically trained in operational procedures, using precautions relating to the new chemical or to products containing it
- ensuring the chemical remain in an enclosed pipe work system for its entire lifecycle within a factory, with weighing by load cell or volumetric metering
- limiting potential exposure, apart from maintenance and cleaning, to transfer operations, conducting these operations using protective transfer mechanisms, particularly low dead volume couplings
- demonstrating, if drum spears are used, suitable control of exposure during drum changing.

Liquids

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Criteria for transferring liquids include:

- emptying into a calibrated vessel
- emptying through volumetric meters
- running drain lines to installed scales.

In addition, when transferring liquids, handling criteria to prevent hazardous substances in the gas phase includes:

- transferring in enclosed systems or in systems that can be equalised
- using gas displacement devices for pumping
- extracting vapours at the point of escape
- providing good general ventilation

To avoid liquid escaping during transfer, chemical pumps must conform to appropriate international standards and piping connections must employ dry break couplings. Design considerations must take account of shortening the distance of transfer to and from storage containers.

Solids

When transferring solids, ensure enclosure of process through engineering controls. Manual unloading under Local Exhaust Ventilation does not meet NICNAS's requirements.

Criteria for transferring solids to the reactor include:

- ensuring manual unloading is not used
- ensuring a low dust or no dust form of the solid is used
- enclosing reactors
- ensuring the action of pressure relief devices does not threaten personnel
- ensuring splash deflectors are used
- conducting, because of the quantity and nature of the substances present, releases to the atmosphere or providing scrubbers, flare systems or blowdown tanks
- installing seal systems on shafts of pumps, drives, mixers and stirrers to accord with the reaction mix
- testing seal systems regularly
- fixing leaks
- designing sampling systems to minimise exposure.

Design systems for sampling of the reactor using these procedures:

- withdraw the sample at a point in the plant where the pressure and temperature are as low as possible
- ensure the cross-sectional area of the sampling device is as low as possible
- design sampling devices so a malfunction does not result in the release of large quantities of reactor contents
- return the inevitable pre-sample liquid to the closed system.

Transfer the sample into the sample container by:

- preventing splashing, vapourising, dripping, overflowing and escaping of hot liquids
- taking steps to prevent static charging
- using a vacuum (or other means) to take samples with no pre-sample flow.

Pre-cleaning (where the situation permits) and personal protective equipment must be prescribed for cleaning and maintenance.

The criteria for transporting and storing the chemical are the same as outlined under Public exposure above.

Environmental exposure

Overall, the new chemical cannot be intentionally released to the aquatic, air or terrestrial environmental compartments.

Handling criteria for the chemical must include:

- disposing of residual chemical retained in packaging by taking empty packaging to regulated landfill, ensuring the chemical has negligible potential for migrating to groundwater from releases to land or landfill
- collecting quantities of the new chemical spilled or remaining from batch production and placing it into sealable containers for reusing or disposing
- ensuring the new chemical is totally consumed during production
- sending production and cleaning waste to a regulated landfill, ensuring the chemical has negligible potential for migrating to groundwater from releases to land or landfill.

Additional scenarios

NICNAS is interested in developing additional scenarios for use by industry.

If you would like NICNAS to consider developing a new scenario with your company, send a written request detailing:

- 1. your proposed scenario
- 2. how you would arrange for NICNAS to visit your site/s.

2.10 APPENDIX J: STRUCTURAL ALERTS FOR PERMIT CATEGORIES

The structural alerts are classes of chemicals, functional groups or substructures that are linked to a particular endpoint. The absence of a structural alert does not mean that a chemical is non-hazardous or is not of concern for a particular end-point (unless defined by an exclusion/boundary).

Chemicals with a structural alert for corrosion are considered to have the potential to cause both skin and eye irritation.

Sections (in the form of tables) in this appendix:

The structural alerts have been compiled from references used internationally e.g. the US Environmental Protection Agency (US EPA) categories of concern and those commonly used by NICNAS. These alerts have been grouped as follows:

С	Structure contains only C, H, (O)	Structural alert table 1
CHal	Structure contains only C, H, (O) and Halogen atoms	Structural alert table 2
CN	Structure contains only C, H, (O) and N atoms	Structural alert table 3
CNHal	Structure contains only C, H, (O), N and Halogen atoms	Structural alert table 4
CNS and CNSHal	Structure contains only C, H, (O), N and S atoms or Structure contains only C, H, (O), N, S and Halogen atoms	Structural alert table 5
CS and CSHal	Structure contains only C, H, (O), and S atoms or Structure contains only C, H, (O), S and Halogen atoms	Structural alert table 6
CSi and CSiHal	Structure contains only C, H, (O), and Si atoms or Structure contains only C, H, (O), Si and Halogen atoms	Structural alert table 7
Other	Structure contains atoms other than C, H, N, O, S, Si and Halogen atoms	Structural alert table 8

In determining whether a chemical contains a structural alert, it may be necessary to consult more than one table, if different substructures of the chemical would be covered by different tables.

Boundaries and exclusions for the structural alerts have been included in the tables. Specific physicochemical exclusion rules for corrosion and skin/eye irritation have been included at the end of each table. These have been externally developed and validated. Those shown during validation to have limited predictive value or found to be not properly defined have not been included.

2.10.1 STRUCTURAL ALERT TABLE 1 - C - STRUCTURE CONTAINS ONLY C, H, (O)

-C

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Category	Structure	Boundaries	Endpoints	Comment	Reference
(meth)acrylic acids	$R = H \text{ or } Ch_3$	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion		2
Acid anhydrides	$ \begin{array}{c} 0 \\ R = any \end{array} $	Structures with a carboxylic acid anhydride equivalent weight of ≥5,000 are presumed not to pose a hazard under any conditions. Typically, concerns for health effects are confined to those species with molecular weights <1,000. Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation, Sensitisation, Reproductive and Developmenta I toxicity	concern for potential pulmonary sensitisation	1, 2, 3, 6
Aliphatic acids	R = aliphatic chain no other subgroups	C1-C7 – Corrosion C7-C14 eye irritation >C20 – only slight eye irritant Physicochemi cal exclusion rules apply for corrosion/irrita tion	Corrosion, eye irritation		2,5

Alpha-, beta- unsaturated esters and precursors	R_{2} R_{1} $R = O(not OH)$ $R_{1} = not a$ heteroatom $R_{2} = not aryl$ (unless R = H) $H = good$ leaving group	For Carcinogenicit y R2 not C>5 or aromatic	Carcinogenicit y Sensitisation	See also esters	3,4
Diacyl peroxides	R = any	Physicochemi cal exclusion rules apply for corrosion/irrita tion	Corrosion/Ski n irritation, Sensitisation, potential carcinogenicit y		2, 3, 6
Esters (incl. Acrylic and methacrylic esters)	R_{1} CH_{2} CH_{2} R $R and R_{1} = alkyl, aryalkyl or aryl group$	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin irritation		2
Aliphatic alpha hydroxyesters	$R_{R_{1}} = H \text{ or }$	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Eye irritation		5

Phenyl esters	R = alkyl, aryl R ₁ = any	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin irritation, Sensitisation	2, 3
Coumarins and Furocoumarin s			Carcinogenicit y	4
Phenyl carbonates	R = any R ₁ = alky, aryl		Sensitisation	3
Lactones	$R, R_1 = H,$ alkyl, arylalkyl or aryl group	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation	2
Propiolactone	0.	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Carcinogenicit y, Corrosion/Ski n irritation	2,4
Phenolphthale ins			Carcinogenicit y	6

(RCOO-).

-----C____OH and -----C____O___C-----

Category	Structure	Boundaries	Endpoints	Comment	Reference
Aliphatic glycerol monoethers	R = aliphatic chain	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	serious eye damage		5
Alpha, beta- unsaturated aliphatic alkoxy group	R_1 R_1 = any aliphatic carbon R_2 = aliphatic or aromatic carbon		Carcinogenicit y		4
Ethylene glycol ethers	$R - (-0 - CH_2 - CH_2 -)_n^R'$ $n = 1,2,3 R =$ Alkyl C7 or less or phenol or alkyl substituted phenyl R' = H or alkyl C7 or less or any group that can be chemically or metabolically removed to yield a glycol ether	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin irritation, systemic toxicity, developmental /reproductive toxicity	Concern for hemolysis, bone-marrow damage, and leukopenia of both lymphocytes and granulocytes; direct and indirect kidney damage; liver damage, immunotoxicit y, and central nervous system (CNS) depression.	2, 6
precursors of aldehydes and ketones	$R_{2} \xrightarrow{0} C_{R_{1}} \xrightarrow{0} R_{2}$ $R, R_{1} = alkyl, aryl$ $R_{2} = any$		Sensitisation		3
	$R_3 \longrightarrow 0 \longrightarrow R_3$ $R_2 \longrightarrow R_1$				

Precursors of alpha, beta- unsaturated aldehydes, esters and ketones	R = H, C, O R ₁ = not a heteroatom R ₂ = not aryl (unless R = H) R ₃ = any	For Carcinogenicit y, R1 and R2 not C>5 or aromatic	Carcinogenicit y, Sensitisation	3,4
Enol precursors of aldehydes and ketones	R_2 R_2 R_1 $R_1 = not a$ heteroatom		Sensitisation	3
Epoxides	$R \xrightarrow{O} R$ For sensitisation and corrosion / irritation R = H, alkyl, aryl, akyl else R = any	Structures with epoxy equivalent weights of ≥5000 are presumed not to pose a hazard under any conditions. Carcinogenicit y and reproductive toxicity concerns are confined to those species with molecular weights <1,000. Carcinogenicit y and reproductive toxicity concerns are restricted to species with molecular weights <500 if exposure is limited to the dermal route.	Carcinogenicit y, Reproductive toxicity, Corrosion/Ski n irritation, Sensitisation	1,2,3,4,6

		corrosion/irrita tion.		
Catechols and o-alkyl precursors	R = any R ₁ = H, alkyl	For sensitisation: CN at ortho or para removes activity, R groups on both oxygens remove activity	Carcinogenicit y, Sensitisation	1,3,9
resorcinols and o-alkyl precursors	$R_{1}, R_{2}, = H,$ $R_{1}, R_{2}, = H,$ OH, any $carbon or O$ $alkyl.$ $One R_{1} must$ $be H. R = H,$ $methyl, ethyl$	CN at ortho or para removes activity, R groups on both oxygens remove activity	Sensitisation	1
hydroquinones and O-alkyl precursors	$R = any$ $R_1 = H, alkyl$	CN at ortho or para removes activity, R groups on both oxygens remove activity	Sensitisation	1,3
Phenols	R	Physicochemi cal exclusion rules apply for corrosion/irrita tion	Corrosion/Ski n irritation	2
Aliphatic monoalcohols	$R \xrightarrow{R_{1}} C \xrightarrow{R_{1}} OH$ $R \xrightarrow{R_{2}} R = aliphatic$	C3-C11 – serious damage to eyes C12-14 – eye irritation >C15 – only slight eye	Eye irritation/serio us eye	5

chain	irritation	uamage	
R _{1,2} = H or aliphatic chain	Physicochemi cal exclusion rules apply for corrosion/irrita tion		



Category	Structure	Boundaries	Endpoints	Comment	Reference
1,2- Dicarbonyls	$R = alkyl, aryl$ $R_1 = H, alkyl, aryl$ $R_1 = H, alkyl, aryl$		Sensitisation	See also aldehydes and ketones	3
1,3-diketones	R = alkyl, aryl		Sensitisation		3
Ketones	$R_{R_{1}} = alkyl, aryl$	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin irritation, sensitisation		2,3
Benzanthrone derivatives	$ \begin{array}{c} $	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin irritation	These dyes may be irritants. Lipophilic dyes containing different functional groups e.g. halogens, amino, imino, phenolic, thiol, make the molecule more electrophilic, leading to higher reactivity.	2

Aldehydes	R = any type of carbon atom linked to any other atom	Physicochemi cal exclusion rules apply for corrosion /irritation	Carcinogenicit y, Corrosion /Skin irritation, sensitisation	1, 2,3,4
Alpha-, beta- unsaturated aldehydes and ketones	R_{2} R_{2} R_{1} $R = H, C$ $R_{1} = not a$ heteroatom $R_{2} = not aryl$ (unless R = H)	For Carcinogenicit y, R2 not C>5 or aromatic	Carcinogenicit y, Sensitisation	3,4
Precursors of alpha, beta- unsaturated aldehydes and ketones	R_{2} R_{2} R_{2} R_{2} R_{1} $R = H, C$ $R_{1} = not a$ heteroatom $R_{2} = not aryl$ (unless R = H) $X = good$ leaving group	For Carcinogenicit y, R2 not C>5 or aromatic	Carcinogenicit y, Sensitisation	3,4
	R_1 R_1 R_1 R_1 R_1	For sensitisation		

Ortho- quinones and paraquinones $R_{1}, R_{2} = H,$ OH, any carbon or O- alkyl. One R_{1} position must be H	Corrosion: CN at ortho or para removes sensitisation/ir ritation activity Physicochemi cal exclusion rules apply for corrosion/irrita tion	Carcinogenicit y, Corrosion/ Skin Irritation, Sensitisation		1, 2, 3,4
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Miscellaneous

Category	Structure	Boundaries	Endpoints	Comment	Reference
Alpha alkyne	CHEC CHEC R can be any kind of group	Physicochemi cal exclusion rules apply for corrosion/irrita tion	Skin irritation		2
peroxide (hydro/alkyl)	R_1 O - O R R = H or alkyl chain $R_1 = C$ -any	Physicochemi cal exclusion rules apply for corrosion/irrita tion	Skin irritation, potential carcinogenicit y		2, 6
Polycyclic aromatic hydrocarbons	Three or more fused rings, not heteroaromati c e.g. pyrene, tetracene.		Carcinogenicit y		4

Physicochemical exclusion rules for corrosion and skin/eye irritation for C chemicals^{7,8}

If molecular weight >350, then not classified as R34, R35,

If molecular weight >380, then not classified as R34, R35, R41 or R36 $\,$

If log Kow < -3.1, then not classified as R34, R35 or R38



If aqueous solubility <0.0001 g/L, then not classified as R34, R35, R41 or R36

2.10.2 STRUCTURAL ALERT TABLE 2 - CHAL -STRUCTURE CONTAINS ONLY C, H, (O) AND HALOGEN ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
Acyl halides	R Hal	Irritation/corro sion: R = alkyl, arylalkyl, or aryl Sensitisation: R = any Hal = F, Cl, Br Carcinogenicit y: R = any group except OH, SH Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n Irritation, Sensitisation, Carcinogenicit y		1,2,3,4
Aliphatic alpha-halogen esters	$R_1 \longrightarrow 0$ $R_2 \longrightarrow 0$ $R_1, R_2 = any,$ but not containing N atoms	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Skin Irritation		2
Aliphatic esters of chloro formic acid	CI O R R = aliphatic chain	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Serious eye damage		5
Aliphatic halogenated saturated acids	R = aliphatic chain Hal = Cl, Br	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n Irritation		2

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alpha- Carbonyl halogen compounds (alpha- halocarbonyls)	Hai = CI, Br $Hai = CI, Br$ $Hai = CI, Br$ $Hai = CI, Br$ $Hai = CI, Br$		Sensitisation	Primary halides are more reactive than secondary halides. Bromides are more reactive than chlorides.	1
Alpha- halogenated aldehydes/ket ones	R_{1} R_{2} $R_{1}, R_{2} = H,$ $R_{2}, R_{2} = H,$ $R_{1}, R_{2} = H,$ $R_{2}, R_{2} = H,$ $R_{1}, R_{2} = H,$ $R_{2}, R_{3} = H,$ $R_{1}, R_{2} = H,$ $R_{2}, R_{3} = H,$ $R_{1}, R_{2} = H,$ $R_{2}, R_{3} = H,$ $R_{2}, R_{3} = H,$ R_{3}, R	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n Irritation		2
Substituted benzoic acid halogenides	Hal = CI, F R ₁ - R ₄ = any	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion	Some benzoic acid halogenides hydrolyse immediately when getting in contact with water, the resulting acid may cause only mild skin irritation	2, 5
Substituted di- halogen- benzoic acids	Hal Hal R_1 R_2 R_3 $R_{1,2,3} = alkyl$	Physicochemi cal exclusion rules apply for corrosion/irrita	Skin Irritation, serious eye damage		2,5

(aliphatic chain) or Halogen	tion.			
R ₁ ,2,3,4 = H, aliphatic chain	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Serious eye damage		5
R ₁ = H or halogen R ₂ = aliphatic chain Hal = F, Cl or Br	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Serious eye damage		5
$R_{1} - R4 = H,$ $R_{1} - R4 = H,$ alkyl, arylakyl or aryl Hal = F, Cl or Br	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n Irritation		2
R_{2} R_{3} $R_{1}, R_{2} (or R_{3})$ $= H or alkyl$ $R_{3} (or R_{2}) =$ any atom / group (except halogens)		Carcinogenicit y		4
R — Hal For sensitisation: R = alkyl, aryl Hal = CI,Br,I				
	(aliphatic chain) or Halogen I = I = I = I = I = I = I = I = I = I =	(aliphatic chain) or Halogention.Image: Relation of the second	(aliphatic chain) or Halogention.I $i = (1, 1, 2, 3, 4]$ IPhysicochemi cal exclusion rules apply for corrosion/irritaSerious eye damage $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaSerious eye damage $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaSerious eye damage $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaSerious eye damage $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi cal exclusion rules apply for corrosion/irritaCorrosion/Ski n Irritation $i = (1, 2, 3, 4]$ Physicochemi corrosion/irritaCorrosion/irrita sensitisation: R = alkyl, aryl Hal = Cl, Br, IExclusion rulesPhysicochemi cal exclusion rulesPhysicochemi corrosion	(aliphatic chain) or Halogention.Ion.* + (Logention.Serious eye damage* * + (LogenPhysicochemi cal exclusion rules apply for ion.Serious eye damage * - (LogenPhysicochemi cal exclusion rules apply for corrosion/irritaSerious eye damage *

alpha- haloalkanes; halogenated alkanes	R = aliphatic Hal = F, Cl, Br For carcinogenicit y: R = any atom / group Hal = Cl, Br, I	cal exclusion rules apply for corrosion/irrita tion.	Carcinogenicit y, Sensitisation, Skin Irritation		1, 2, 3,4
(Poly)Halogen ated Cycloalkanes	Any cycloalkane skeleton with three or more halogens directly bound to the same ring		Carcinogenicit y	Non-genotoxic	4
Benzyl halides	R = alkyl, arylalkyl or aryl group X = halogen	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n Irritation		2
Halogenated benzene	Hal	Chemicals with two halogens in ortho or meta are excluded Chemicals with three or more hydroxyl groups are excluded	Carcinogenicit y	Non-genotoxic	4
Halogenated PAH	Ar — Hal Ar = napthalene, biphenyl, diphenyl		Carcinogenicit y	Non-genotoxic	4

2.10.3 STRUCTURAL ALERT TABLE 3 - CN - STRUCTURE CONTAINS ONLY C, H, (O) AND N ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
1,2-Diamines	R = H or alkyl	Up to three R groups can be alkyl, but with four alkyl groups the chemical is inactive.	Sensitisation	See also primary, secondary, tertiary aliphatic amines.	1,3
Alkylalkanol- amines	$R - R_2$ are small CH chains	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion		2
N-methylol derivatives	$CH_2 - N$ R = any		Carcinogenicit y		4
Aromatic hydroxyl amine and its derived esters	H = Ar = Ary $Ar = Ary$ $Ar = any$	Chemicals with ortho- disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the amino group are excluded.	Carcinogenici ty		4
Primary and secondary aliphatic amines	R_1 R_2 N R_2 N R_2 R_1 and R_2 R_1 R_1 R_1 R_1 R_1 R_2 R_1 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_1 R_2 R_1 R_3 R_1 R_1 R_2 R_1 R_3 R_1 R_2 R_1 R_1 R_2 R_1 R_3 R_2 R_1 R_3 R_2 R_1 R_3 R_2 R_3	Physicochemi cal exclusion rules apply for corrosion /irritation.	Corrosion	2	
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Tertiary aliphatic amines	R_{1} R_{2} $R_{1} - R_{3} =$ aliphatic chain and one of them needs to be small	Physicochemi cal exclusion rules apply for corrosion /irritation.	Corrosion/Ski n irritation	2	
		For Carcinogenicit y: R=H, methyl, ethyl Ar = any aromatic /heteroaromati c ring For carcinogenicit y: Chemicals with ortho- disubstitution, or with an ortho carboxylic acid substituent are excluded For carcinogenicit y: Chemicals with a sulfonic			

Aromatic primary and secondary amines	R	acid group on the same ring of the amino group are excluded. For irritation: Ar = sub/unsubstitu ted benzene ring R = H or aliphatic chain For sensitisation: Ar = sub/unsubstitu ted benzene ring R = H, alkyl, or aryl Physicochemi cal exclusion rules apply for corrosion /irritation.	Carcinogenicit y, Skin irritation, Sensitisation	2,3,4
Precursor aromatic amine	H_{2} N_{Ar} $Ar = any$ $aromatic /$ $heteroaromati$ $c ring$		Carcinogenicit y	4
		For carcinogenicit y R1= methyl, ethyl R2=methyl, ethyl Ar = any		

Tertiary aromatic amine	R_1 R_2 A_r	aromatic /heteroaromati c ring Chemicals with ortho- disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the amino group are excluded. For irritation: Ar = sub/unsubstitu ted benzene ring R = H or aliphatic chain	Skin Irritation, Carcinogenicit y		2,4
Derivatives of alpha amino benzene	$R_1 = H \text{ or}$ aliphatic chain $R_{2,3} = any$	Physicochemi cal exclusion rules apply for corrosion /irritation.	Serious damage to eyes		5
Hindered amines	Not well defined, though typically it will contain two or more hindered amine functional groups. An example structure is shown below:		Systemic Toxicity	Concerns for the immune system, liver, blood, the male reproductive system, and the G.I. tract. Where dermal uptake is limited due to MW these are mainly of concern if	6

	HZ			there is significant inhalation exposure. Also see primary and secondary amines	
Dianilines	$x = C, N, O \text{ or } S$ $n \ge 0$	The chemical must have at least two phenyl rings with a bridging carbon, oxygen, nitrogen, or sulfur Each terminal phenyl ring must have a primary amino group (or a group that can be readily metabolized to a primary amino group) either meta- or para- to the bridging atom Compounds with one or more additional phenyl ring(s), with or without ring substituents, and one or more bridging atoms are also included in the category.	Carcinogenicit y, Systemic toxicity	Systemic toxicity concern regarding retinopathy and reproductive organs. The compounds of greatest concern are those having X = C, N, or O and n = 0 or 1.	6
Quaternary organic ammonium compounds	RR RR	For corrosion, R = any, however one R group should be small. For sensitisation,	Corrosion, Sensitisation		2,3,5

		R = aryl or alkyl.		
Quaternary aromatic ammonium salts	R, R ₃ = any R _{1,2} = H or aliphatic chain		Serious damage to eyes/Eye irritation	5
Aziridines	R For carcinogenicit y, R = any atom / group R R For irritation / corrosion, R = H or alkyl	Physicochemi cal exclusion rules apply for corrosion /irritation.	Carcinogenicit y, Corrosion/Ski n irritation	2,4
Formaldehyde donors	$\begin{array}{c} R \\ H \\ H \\ H \\$		Sensitisation	3

Substituted indoles	$R_1 = H \text{ or } OH$ $R_2 = H \text{ or }$ aliphatic ketone $R_3 = any$	Physicochemi cal exclusion rules apply for corrosion /irritation.	Serious damage to eyes	5
Substituted pyrazole	$R = H, NH_2 \text{ or aliphatic chain}$ $R_1 = any$	Physicochemi cal exclusion rules apply for corrosion /irritation.	Serious damage to eyes	5
Heterocyclic polycyclic aromatic hydrocarbons	Three or more fused rings, heteroaromati c		Carcinogenicit y	4
Triarylmethan e pigments	R = CH3, $C2H5$ $f(0) = (0, 0) = 0$ $f(0) = (0, 0) = 0$	Dyes substituted with solubilizing groups such as carboxylic acid, sulfonic acid, or halogens, are not included. Pigments that have essentially negligible	Carcinogenicit y, reproductive and developmental toxicity	6

	R = CH3, C2H5	water solubility (<1ppb) and therefore, little or no bioavailability, are also not included.		
Activated N- heterocycles	$R = any$ $R_{1} = CN$		Sensitisation	1
Alpha-lactams	R = C-any		Sensitisation	1
Beta-lactams	R = any		Sensitisation	3
Acrylamides	$R_1 = H \text{ or } CH_3$ $R_2 = any$	Structures with an acrylamide equivalent weight of ≥5,000 are presumed not to pose a hazard under any conditions. Typically, concerns are confined to those species with molecular weights <1,000 whenever inhalation (or environmental) exposure is	Carcinogenicit y, Mutagenicity, reproductive and developmental toxicity	6

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		expected, and to species <500 when dermal, but not inhalation, exposure to humans is expected.		
Aromatic N- acyl amide		Chemicals with ortho- disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the nitro group are excluded.	Carcinogenicit y	4
Acid imides	R ₁ = any but not part of aromatic ring R ₂ = H or any carbon		Sensitisation	1
Pyrrolidones	R = H or aliphatic chain	Physicochemi cal exclusion rules apply for corrosion /irritation.	Serious damage to eyes	5
Alpha-, beta- unsaturated amides and	Precursors R = N	For Carcinogenicit y (not precursors),	Carcinogenicit y Sensitisation	3,4

precursors	R ₁ = not a heteroatom R ₂ = not aryl R ₃ = any X = good leaving group	C>5 or aromatic			
Alkyl carbamate	R = aliphatic carbon or hydrogen R1 = aliphatic carbon		Carcinogenicit y		4
Acid azides	R = any		Carcinogenicit y, Sensitisation		3,4
Azides and triazenes	R = any		Carcinogenicit y		4
Benzotriazole- hindered phenols	Any molecular structure containing this substructure		Systemic toxicity, Reproductive toxicity, Sensitisation	Concerns regarding haematology; weight and histopathology of lymphoid organs (spleen, thymus, and bone marrow); cellularity of the bone marrow, thymus, and spleen; and histopathology of the liver, kidney, heart, and all endocrine glands.	6

				Health effects may vary depending on the nature of the ring substituents.	
Hydrazines, hydrazonium salts and precursors	Not as part of a ring Hydrazone Hydrazide Semi carbazide	Physicochemi cal exclusion rules apply for corrosion /irritation. For irritation /corrosion sensitisation, R = H or any type of carbon atom linked to any other atom, except that R is not – C(=O)-R. R1 = any. For semicarbazid e and irritation /corrosion, R = H, alkyl, arylalkyl or aryl	Corrosion/Ski n irritation, sensitisation, carcinogenicit y, systemic toxicity	Concerns for carcinogenicit y and chronic effects to liver, kidney, and blood	1,2,4,6
Aromatic azo compound	For carcinogenicit y Ar = any aromatic / heteroaromati c For sensitisation R = aryl $R_1 \text{ or } R_2 =$ electron donating	For carcinogenicit y: Chemicals with a sulfonic acid group on both rings linked to the diazo group are excluded	Sensitisation, Carcinogenicit y		3,4

Aliphatic azo and azoxy	R ₁ = aliphatic carbon or hydrogen R _{2,3} = any atom / group R ₄ = aliphatic carbon		Carcinogenicit y		4
lsocyanates		For corrosion: R = aliphatic	Carcinogenicit y, Corrosion, Sensitisation	Concern for skin and respiratory sensitisation	1,2,3,4
Alkyl nitrite	90-Alkyl-nitrite R = any		Carcinogenicit y		4
Alkyl and aryl N-nitroso	R ₁ = aliphatic or aromatic carbon R ₂ = any atom / group		Carcinogenicit y		4
Aliphatic N- nitro	R = aliphatic carbon or hydrogen		Carcinogenicit y		4
Aromatic nitroso	Ar = any aromatic / heteroaromati c ring		Carcinogenicit y		4

Nitro-aromatic	Ar = any aromatic / heteroaromati c ring	Chemicals with ortho- disubstitution, or with an ortho carboxylic acid substituent are excluded Chemicals with a sulfonic acid group on the same ring of the nitro group are excluded.	Carcinogenicit y	4
Aromatic ring N-oxide			Carcinogenicit y	4

Physicochemical exclusion rules for corrosion and skin/eye irritation for CN chemicals^{7,8}

If molecular weight > 290, then not classified as R34, R35

If molecular weight > 540, then not classified as R34, R35 or R38

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 4.5, then not classified as R34, R35

If log Kow > 5.5, then not classified as R34, R35 or R38

If log Kow > 9, then not classified as R34, R35, R41, R38 or R36

If aqueous solubility < 0.01g/L, then not classified as R34 or R35

If aqueous solubility < 0.0001 g/L then not classified as R34, R35 or R38

2.10.4 STRUCTURAL ALERT TABLE 4 - CNHAL -STRUCTURE CONTAINS ONLY C, H, (O), N AND HALOGEN ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
Activated N- heterocycles	R = any R ₁ = F, CI	Physicochemi cal exclusion rules apply for corrosion / irritation.	Corrosion / Skin irritation, Sensitisation		1,2,3
Activated halo-pyridines, quinolines, and isoquinolines	R, R ₁ = withdrawing group X = F, CI		Sensitisation		3
Alpha- carbamoyl halogen compounds (a-halo- carbomoyl)		Physicochemi cal exclusion rules apply for corrosion /irritation.	Corrosion / Skin irritation		2
alpha- Carbonyl halogen compounds (alpha- halocarbonyls)	R = alklyl, aryl R ₁ = C-any Hal = Cl, Br		Sensitisation		1
N-Haloimides	R = any X = Cl, Br		Sensitisation		3
N- trihalomethyl imides	R = any X = Cl, Br, I		Sensitisation		3
Formaldehyde					

donors	R = any X = halogen	Sensitisation		3
N mustard	R = any X = F, Cl, Br, I	Carcinogenicit y		4
Halonitrobenz enes	R = any X = F, CI, Br OR X = F, CI, R = F, Ci, NO ₂ , CN, - C(=O)-R ₁ , or - C(=O)- OR ₁ (where R ₁ = alkyl)	Sensitisation	There may be additional R groups which are activating.	1, 3
Dichlorobenzi dine based pigments	(any diazo pigment containing dichlorobenzid ine coupled with acetoacetanili de)	Carcinogenicit y	There are oncogenicity / mutagenicity concerns for dichlorobenzid ine - based pigments based on the potential release of 3,3' - dichlorobenzid ine and on the presence of residual (unbound) dichlorobenzid ine. Concern for the intact pigment is restricted to uses at temperatures exceeding	6

Physicochemical exclusion rules for corrosion and skin/eye irritation for CNHal chemicals^{7,8}

If molecular weight >380, then not classified as R34, R35 or R38

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 3.8, then not classified as R34, R35, R38 or R41

If log Kow > 9, then not classified as R34, R35, R38, R41 or R36

If aqueous solubility < 0.1 g/L, then not classified as R34, R35

If aqueous solubility < 0.004 g/L, then not classified as R34, R35 or R41

If aqueous solubility < 0.001 g/L, then not classified as R34, R35, R41 or R38

2.10.5 STRUCTURAL ALERT TABLE 5 - CNS/CNSHAL -STRUCTURE CONTAINS ONLY C, H, (O), N AND S ATOMS OR STRUCTURE CONTAINS ONLY C, H, (O), N, S AND HAL ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
B- Naphthylamin es, sulfonated	R ₁ = H, OH, NH ₂ R ₂ = OH, HO ₃ S-CH ₂ - CH ₂	Included in the category are azo dyes which release a sulfonated ß-naphthylamine upon reduction of azo bonds. Also included in the category are N-acetylated sulfonated ß-naphthylamine s. Concern is restricted to sulfonated ß-naphthylamine s where not more than two sulfonate or sulfatoethylsulf one group(s) are on the ring distal to the ß-amino group.	Carcinogenicit y		6
Dionilinoo		The chemical must have at least two phenyl rings with a bridging carbon, oxygen, nitrogen, or sulfur Each terminal phenyl ring must have a primary amino group (or a group that can be readily metabolized to a primary	Carcinogenicit	Systemic toxicity concern regarding retinopathy and reproductive organs.	6
Diannines	X= C,N, O or S	amino group) either meta- or	y, Systemic toxicity	The	0

	n ≥ 0	para- to the bridging atom Compounds with one or more additional phenyl ring(s), with or without ring substituents, and one or more bridging atoms are also included in the category.		compounds of greatest concern are those having X = C, N, or O and n = 0 or 1.	
Sulphonyl azides			Sensitisation		3
lsothiocyanate s		For corrosion: R = aliphatic, else R = any. Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Carcinogenicit y, Corrosion, Sensitisation		1,2,3,4
(Benzo)isothia zolinones	R = H or C- R ₁ = H, alkyl or part of an aromatic ring	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Serious damage to eyes, Sensitisation		1, 3, 5
Thiazoles and thiazolidines	$R_1 = H \text{ or } C$ - any $R_2 = H \text{ or}$ aliphatic chain	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Serious damage to eyes		5

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Aminobenzoth iazole azo dyes		The boundaries are not strictly defined. For a typical member of the category, R_1 = N- and/or ring substituted p- aminophenyl groups, and R_2 = halogens or nitro groups.	Systemic toxicity, Carcinogenicit y	Concern for thyroid and liver	6
Alkylthiocarba mate	R = aliphatic carbon or hydrogen R1 = aliphatic carbon		Carcinogenicit y		4
Thiocarbonyl	R ₃ = any except OH, SH, O ⁻ , S ⁻		Carcinogenicit y	Non-genotoxic	4
N-Chloro- sulfonamides			Sensitisation		3
Alpha- carbamoyl halogen compounds (a-halo- carbomoyl)	R = alkyl, aryl	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation		2
Heterocyclic polycyclic aromatic hydrocarbons	Three or more fused rings, heteroaromati c		Carcinogenicit y		4

Physicochemical exclusion rules for corrosion and skin/eye irritation for CNS chemicals^{7,8}

If molecular weight > 620, then not classified as R34, R35

If log Kow < -2, then not classified as R34, R35 or R38

If log Kow > 3.6, then not classified as R41*, R36

If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.006 g/L, then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

Physicochemical exclusion rules for corrosion and skin/eye irritation for CNSHal chemicals^{7,8}

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*

If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

2.10.6 STRUCTURAL ALERT TABLE 6 - CS/CSHAL -STRUCTURE CONTAINS ONLY C, H, (O) AND S ATOMS OR STRUCTURE CONTAINS ONLY C, H, (O), S AND HAL ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
Allyl sulfates	R ₁ , R ₂ , R ₃ , R ₄ = H, alkyl, arylalkyl or aryl group R ⁵ = alkyl, arylalkyl or aryl group	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation		2
Dialkylsulfates	R = alkyl, aryl		Sensitisation		3
Dialkylsulfonat es	R = alkyl, aryl	For Carcinogenicit y: R=alkyl with C<5 (also substituted with halogens) or benzyl.	Carcinogenicit y, Sensitisation		3,4
Benzyl sulfonate	R = alkyl, arylalkyl or aryl	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation		2
Sulfonic salts	cation ⁺	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion		2, 5
	Sulfuric Esters R can be aromatic ring				

Esters of organic sulfonic or sulfuric esters	or aliphatic chain. R = aromatic ring than sulfonic salts Na/S0 ₃ seem to be non- irratants for 8/10, except when amine is attached Cyclic sulfonic esters Cyclic sulfonic esters	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion	2
Propiosultone s		Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Carcinogenicit y, Corrosion	2,4
Aromatic sulphinic acids and salts	R = any		Sensitisation	1
Vinyl sulfones	or		Carcinogenicit y	6
Thioesters	R = any		Sensitisation	3

Disulfides		For sensitisation R = alkyl, aryl For corrosion R = alkyl Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation, Sensitisation	2, 3
S mustard			Carcinogenicit y	4
Alpha- halogenated thioaldehydes, thioketones	R ₁ , R ₂ = H, alkyl, arylalkyl or aryl group	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion/Ski n irritation	2
Sulphonyl halides	R = alkyl, aryl X = Cl, Br		Sensitisation	3

Physicochemical exclusion rules for corrosion and skin/eye irritation for CS and CSHal chemicals^{7,8}

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*

If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

2.10.7 STRUCTURAL ALERT TABLE 7 - CSI AND CSIHAL - STRUCTURE CONTAINS ONLY C, H, (O), AND SI ATOMS OR STRUCTURE CONTAINS ONLY C, H, (O), SI AND HALOGEN ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
Silicon ethers with alpha ketone groups	R ₁ , R ₂ = any	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion		2
Alkoxy silane	R = any R1 = alky1	Methoxy- and ethoxysilanes are presumed not to pose a hazard under any conditions if the equivalent weight is 5,000 and no more than 25% of species have molecular weights less than 1,000 and no more than 10% of species have molecular weights less than 500. For alkoxysilanes with alkyl substituents larger than propyl groups, the equivalent weight cutoff is 1,000. The degree of concern depends on the relative abundance of lower molecular weight species, but there is no molecular weight threshold above which there would be no concern.	Systemic toxicity, skin irritation	Concern for lung toxicity from inhalation of vapors or aerosols	2, 6

		Physicochemi cal exclusion rules apply for corrosion/irrita tion.		
Mixed Oxy- Carboxysilane s	R ₁ , R ₂ = any	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Corrosion	2
Organic silicon halides	R, R ₁ , R ₂ = any X = F, CI , Br,	Physicochemi cal exclusion rules apply for corrosion / irritation.	Corrosion	2

Physicochemical exclusion rules for corrosion and skin/eye irritation for CSi and CSiHal chemicals^{7,8}

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41*

If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

2.10.8 STRUCTURAL ALERT TABLE 8 - OTHER -STRUCTURE CONTAINS ATOMS OTHER THAN C, H, N, O, S, SI AND HALOGEN ATOMS

Category	Structure	Boundaries	Endpoints	Comment	Reference
Nickel compounds	Inorganic and organic compounds of nickel in which there is the potential for uptake of either Ni ²⁺ or organonickel.		Systemic toxicity, carcinogenicit y		6
Boron compounds	Includes borates, organoborate s, borate esters, boron hydrides, boranes, boroxines.		Systemic toxicity, reproductive toxicity	Concerns for blood and neurotoxicity	6
Organotins	Includes all mono-, di-, tri- and tetra-alkyl or phenyl organotin compounds, including organotin esters/oxides.	Physicochemi cal exclusion rules apply for corrosion/irrita tion.	Systemic toxicity, Corrosion / Skin irritation	Concerns for neurotoxicity and immunotoxicit y	6
Alkyl or benzyl ester of phosphinic acid	R = Alkyl with C < 5 (also substituted with halogens), or benzyl R_1 = any atom/group except OH, SO O ⁻ , S ⁻	R=alkyl with C<5 (also substituted with halogens) or benzyl.	Carcinogenicit y		4
Triphenylphos phonium salts	R = any	Physicochemi cal exclusion rules apply for corrosion / irritation.	Serious damage to eyes		5

Organic phosphinic acids and their derivatives	R = aryl or liphatic chain	Physicochemi cal exclusion rules apply for corrosion / irritation.	Serious damage to eyes		5
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Physicochemical exclusion rules for corrosion and skin/eye irritation for chemicals containing atoms other than C, H, N, O, S, Si and Halogen atoms ^{7,8}

If log Kow < -3.1, then not classified as R34, R35 or R38

If log Kow > 9, then not classified as R34, R35, R41 or R36

If aqueous solubility < 0.00002 g/L, then not classified as R41 *

If aqueous solubility < 0.000005 g/L then not classified as R41* or R36

* chemical would be considered to cause serious damage to eyes if classified as R34 or R35

References:

1) Gerner, I., Barratt, M.D., Zinke, S., Schlegel, K., Schlede, E. (2004) Development and Prevalidation of a List of Structure-Activity Relationship Rules to be Used in Expert Systems for Prediction of the Skin-sensitising Properties of Chemicals. Alternatives to Laboratory Animals . 32: 487-509

2) Hulzebos, E., Walker, J.D., Gerner, I. and Schlegel, K. (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. QSAR Combinatorial Science. 24:332-342

3) Barratt, M.D., Basketter, D.A., Chamberlain, M., Payne, M.P., Admans, G.D., Langowski, J.J. (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839

4) Benigni R, Bossa C, Jeliazkova N, Netzeva T, Worth A (2008) The Benigni / Bossa rulebase for mutagenicity and carcinogenicity - a module of Toxtree. EUR 23241 EN. Luxenbourg, Office for the Official Publications of the European Communities. EUR - Scientific and Technical Report Series. download: http://ecb.jrc.it/documents/QSAR/EUR_23241_EN.pdf

5) Tsakovska, I., Saliner Gallegos, A., Netzeva, T., Pavan, M. and Worth, A.P. (2007) Evaluation of SARs for the prediction of eye irritation/corrosion potential - structural inclusion rules in the BfR decision support system. SAR and QSAR in Environmental Research. 18: 221-235

6) US EPA (2002) TSCA New Chemicals Program (NCP) Chemical Categories. Washington. http://www.epa.gov/opptintr/newchems/pubs/cat02.pdf

7) Rorije E, Hulzebos EM (2005) Evaluation of (Q)SARs for the prediction of Skin Irritation/Corrosion Potential. Physico-chemical exclusion rules. Report submitted by the National Institute of Public Health and Environment (RIVM) to the European Chemicals Bureau (ECB). Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.

8) Tsakovska I, Netzeva T & Worth AP (2005). Evaluation of (Q)SARs for the Prediction of Eye Irritation/Corrosion Potential -Physicochemical Exclusion Rules. EUR 21897 EN. Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.

9) http://www.inchem.org/documents/iarc/vol71/012-catechol.html

2.11 APPENDIX K: ASSESSMENT METHODOLOGIES

The methodologies NICNAS uses to assess Existing or New Chemicals may be relied on for further guidance when, as a notifier, you are preparing your application.

This appendix details how NICNAS considers the various aspects of a chemical's toxicology, and its effects on occupational health and safety, public health and the environment, during an assessment.

Sections of this appendix:

- Risk assessment of chemicals: assessment of exposure from all sources
- Human health hazard assessment •
- Occupational health and safety assessment
- Public health assessment
- Environmental assessment •
- References

For further information on methodologies used for other assessments - such as those which use the IMAP framework (below) - refer to the IMAP webpages.



2.11.1 RISK ASSESSMENT OF CHEMICALS: ASSESSMENT OF EXPOSURE FROM ALL SOURCES

The prime aim of the Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth) is to provide a national system of notification and assessment of industrial chemicals to protect the Australian people and the environment by establishing the risks that could be associated with importing, manufacturing or using industrial chemicals.

NICNAS assesses the risks to occupational health and safety, public health and the environment from industrial chemicals by using well established, internationally accepted methodology (International Programme on Chemical Safety, 1999; European Commission, 2003).

Department of Health officers carry out occupational health and safety and public health assessments. Department of the Environment officers conduct environmental assessments for NICNAS under a service agreement.

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The type and degree of risk assessment varies depending on the type of New Chemical notification (that is, certificate or permit) or existing chemical assessment product. Most assessments cover some or all of these elements:

- hazard identification
- hazard assessment, incorporating the dose-response relationship
- exposure assessment
- risk characterisation, where hazard and exposure assessments are integrated.

For some chemicals declared as Priority Existing Chemicals (PECs), because of specific concerns about their potential effects on health and environment, assessments may be limited to a hazard and/or exposure assessment.

Assessments are conducted case-by-case and are based on a weight-of-evidence approach, taking into account scientific judgment, knowledge of the mechanism of action of effects, and recognition of the inherent uncertainty in extrapolating animal data to humans.

With risk assessments, recommendations are formulated to manage risk, taking into account existing risk management strategies.

Hazard assessment

Hazard assessment establishes the toxicity of a chemical and identifies the set of inherent properties that makes it capable of causing adverse effects. It identifies the types of hazards that might occur in acute or repeated exposure situations through different exposure routes. See Appendix K2 for more information.

Exposure assessment

A major variable in risk characterisation is estimating exposure—identifying the extent of exposure to a particular chemical, and determining the frequency and duration of that exposure and all the routes by which exposure occurs over the chemical's lifecycle.

For most chemicals, establishing exposure is probably the most variable aspect of risk assessment. It reflects various contributing factors such as differing and/or unique exposure and use patterns of chemicals across a range of industrial uses, the unique nature of ecosystems, fauna and flora, and differing methodologies for exposure assessment.

The exposure assessment is a critical element of the risk assessment and can comprise direct exposure (for example, workers carrying out manufacture or consumer use of household products), and indirect exposure through the environment (for example, through drinking water).

The assessment of direct and indirect exposures to a chemical is important for determining risk, particularly for public health and environmental aspects where exposure may arise from several sources—the raw chemical itself, a preparation or mixture, finished goods containing the chemical (such as treated fabrics and carpet) or contamination of the environment (for example, by lead and other chemicals in household dust and air).

Where exposure of the population to a chemical is likely or suspected (through biomonitoring data or known chemical properties such as leaching) the risk assessment is extended to include all sources of exposure.

The release of chemicals into the environment (for example, from leaching, exudation and/or surface abrasion) may occur at any time in the article's lifecycle, including through using, handling, disposing or storing.

Hence, NICNAS's risk assessment, while concentrating on regulating chemical use, may also consider the use of a chemical in the production of and release from a finished article.

Information about the possible release of a chemical from an article may therefore be required so NICNAS can fully assess risk.

Risk characterisation

Risk characterisation involves integrating hazard identification, hazard characterisation and exposure assessments.

Interpreting and integrating the information on hazard and exposure to estimate risk is complex and can involve determining what risk is acceptable and how risk should be managed.

2.11.2 HUMAN HEALTH HAZARD ASSESSMENT

Human health hazard assessment establishes the toxicity of the chemical and identifies the set of inherent properties that make it capable of causing adverse health effects.

For chemicals with unknown toxicity (for example, New Chemicals), this involves a series of animal studies investigating major biological systems, including studies on acute toxicity, repeat dose toxicity, genotoxicity and other specific endpoints such as irritation and sensitisation.

For existing chemicals, in addition to animal data, human health effects data may be available.

NICNAS assesses both human and animal data in accordance with international guidelines to identify the critical health effects of the chemical and determine the dose–response relationship, with No Observed Adverse Effect Levels (NOAELs) established wherever possible.

NICNAS prefers to use good quality human data for risk assessment. NICNAS classifies the chemical's health hazards in accordance with the Approved Criteria for Classifying Hazardous Substances and the Globally Harmonised System of Classification and Labelling of Chemicals.

The toxicological data may consist of studies performed with a structural analogue of the chemical, or with a formulation containing the chemical.

NICNAS takes data adequacy and applicability into account when assessing available data (for example, concentrations tested in toxicological studies).

Where data gaps exist, or the notification does not require toxicology data (as with some classes of polymer), NICNAS may be able to predict the toxicological hazard from the chemical's physical properties or the characteristics of structurally related chemicals, given that factors such as volatility, water solubility and molecular weight can indicate the likely extent of absorption across biological membranes.

For existing chemicals, structurally similar chemicals may be grouped into a category based on structure and physical chemical properties, and a read across methodology applied where data from one chemical is used for a data-poor chemical in the category.

Quality of data

To ensure data are of sufficient quality for use in risk assessment, NICNAS requires that all new testing must be conducted according to internationally recognised methods, for example, the Organisation for Economic Co-operation and Development's Test Guidelines and Good Laboratory Practice standards.

For many existing chemicals, data will have been generated before these guidelines and standards were created, and may be able to be sourced from academic publications using non-standard methodology. These data can still be used for assessment if valid conclusions can be drawn from them.

Evaluation and assessment requires expert judgment, and determining validity has to be both justified and transparent. In determining the quality and validity of data, matters such as completeness and scientific detail in test reports must be considered.

Relevance of data

When assessing chemicals, NICNAS considers the relevance of test data by, for example, judging if the appropriate route of exposure was used, if the most suitable species was studied and if the substance tested

represented the chemical being assessed. NICNAS also considers the relevance of animal and *in vitro* test data for humans.

The NICNAS assessment also considers toxicokinetic and metabolism data for the chemical, in animals and humans, if available. Information on the physicochemical properties and chemical structure can be used to make predictions on the absorption, distribution, metabolism and excretion of substances. For example, physico-chemical parameters can inform the potential to cross biological membranes.

Generally, NICNAS assumes that effects observed in animals occur in humans unless there is clear, welldocumented evidence for a species-specific effect that would justify concluding that the effect could not occur in humans or is of little relevance.

NICNAS accepts non-animal alternative test methods if they are included in the OECD Test Guidelines and are scientifically validated and have received regulatory acceptance (for example, EpiDerm or Episkin skin corrosivity test, Bovine Corneal Opacity and Permeability test, Isolated Chicken Eye test).

In vitro data alone are generally not directly predictive for effects on humans. However, highly electrophilic substances, which give positive results in genotoxicity studies *in vitro*, may be of concern for their potential to be mutagenic in humans at the initial site of contact (for example, the skin or respiratory tract).

Evaluation of human data

The evaluation of human data generally requires more critical appraisal of data validity.

The main types of human data are epidemiological studies, controlled studies in volunteer case reports and, in the case of sensitisation, multi-clinic data.

The strength of epidemiological evidence for specific health effects depends on matters such as the type of analysis and the magnitude and specificity of response.

NICNAS confidence in findings is increased when comparable results are obtained from at least two independent studies on populations exposed to the same chemical under different conditions.

Criteria for assessing the adequacy of epidemiological studies include the proper selection and characterisation of the exposed and control groups, adequate characterisation of effect and exposure, sufficient length of follow up for disease occurrence, adequate control for confounding factors and proper statistical analysis.

Controlled human studies can be used by NICNAS in determining exposure levels associated with acute effects such as skin irritation. Human patch tests for skin sensitising effects can also be conducted.

Criteria for a well-designed study include using a double blind study design, including a matched control group, using a sufficient number of subjects to detect an effect and taking confounders and bias into account.

Epidemiological studies with negative results cannot prove the absence of a particular toxic effect of the chemical in humans, but good quality controlled human studies that are negative may be useful in assessing risk. Negative human data for skin-sensitising effects cannot normally be used to negate positive results from animal studies.

Evaluation of animal and in vitro studies

Most health effects information required for risk assessment will be derived from controlled studies in experimental animals and *in vitro* test systems.

NICNAS needs to identify the adverse effects of the chemical in these studies, and judge how well the studies identify particular effects.

Generally, NICNAS needs to judge if a study establishes a dose or exposure level at which the critical effect is not observed. For repeated dose studies, a NOAEL should be established or, where this is not possible, a Lowest Observed Adverse Effect Level (LOAEL) stated.

For each study, it is important for NICNAS to evaluate the study design and how the study was carried out, 282/323

considering matters such as frequency and duration of exposure, appropriateness of species and strain of animals used, route of exposure and choice of doses.

When evaluating data in each study, NICNAS considers matter such as the effects in treated animals compared to control animals, causes of mortality, clinical observations during exposure, organ and body weight changes, biochemical changes, mode of action and relevance of effects on humans.

Dose response assessment

The international community generally agrees that there is a threshold dose or concentration for many adverse health effects caused by chemicals.

The threshold dose may vary considerably for routes of exposure and for different species because of differences in toxicokinetics and possibly mechanisms of action.

The observed threshold dose in a toxicity test is influenced by the sensitivity of the test system, that is, it depends on exposure concentrations and durations used in the study.

For genotoxic carcinogens, it is generally a given that thresholds cannot be identified, unless a threshold mechanism is demonstrated.

When a reliable dose–response relationship is identified, then the slope of the curve is taken into account. For a steep curve, the NOAEL is more reliable, as the greater the slope the greater the reduction in response to reduced doses.

For a shallow curve, the uncertainty in the NOAEL may be higher and must be allowed for when assessing risk.

2.11.3 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

The aim of occupational health and safety assessments is to determine the potential risk to the health and safety of workers. This is achieved by assessing the health hazards and physico-chemical properties of the chemical, estimating exposure and characterising risk.

For new industrial chemicals, the occupational health and safety risk assessment is conducted based on hazards of the chemical and possible exposure scenarios. For existing chemicals atmospheric monitoring or biomonitoring data may be available for use in characterising exposure.

Some types of PEC preliminary assessments may be limited to a characterisation of use or an assessment of exposure. Where possible, peer-reviewed international reviews are used.

Exposure assessment

An exposure assessment is conducted by establishing the use pattern of the chemical and identifying the sources of occupational exposure.

Exposure is then estimated by taking into account the routes of exposure, the frequency and duration of exposure, and measured worker data (for example, atmospheric and/or biological monitoring results). Information is needed for each situation in which workers are potentially exposed.

NICNAS considers the reliability of the measured data, and its ability to be representative, when assessing. If insufficient measured data are available, then model calculations are used to estimate typical and reasonable worst case exposure levels. Where necessary, default values are used for certain input parameters in the model calculations (for example, inhalation rate, body weight and skin surface area).

Internationally accepted methods are also used to estimate exposure (for example, a modified United Kingdom Estimation and Assessment of Substance Exposure model—see: www.hse.gov.uk/research/rrhtm/rr136.htm for more information).

Where exposure levels have been determined from measured and modeled data, NICNAS prefers measured 283/323

data, provided they are reliable and representative.

For New Chemicals, the occupational exposure assessment is usually qualitative, as measured data are unlikely to be available and there is insufficient information to predict reliable quantitative estimates. Where quantitative assessment is required to determine risk, realistic worst case assumptions are used in the absence of data.

Risk characterisation

The health risk of the chemical to workers is characterised by integrating exposure and potential hazards.

For brief or short-term exposures, human data and information from acute toxicity studies in animals are taken into account to determine the risk of adverse health effects such as acute respiratory effects and skin irritation.

For repeated, longer-term exposures, the health risk is first characterised by comparing exposure estimates with NOAELs to give a margin of exposure, and then deciding whether there is cause for concern.

Matters taken into account when characterising the risk include the uncertainty arising from the variability in the experimental data and inter- and intra-species variation, the nature and severity of the health effect and its relevance to humans, and the reliability of the exposure estimates.

Where an exposure estimate is higher than, or equal to, the NOAEL, NICNAS considers the chemical to be of concern.

Where the exposure estimate is lower than the NOAEL, matters—such as those mentioned earlier in this section—are taken into account before deciding if the chemical is of concern. For example, the margin of exposure may be based on a human NOAEL, leading to greater certainty in risk characterisation.

Conversely, if a LOAEL is used in the absence of a NOAEL, the degree of uncertainty would be higher and a higher margin of exposure would be required. Expert judgment is required to weigh these individual parameters case-by-case, and the approach needs to be transparent and justifiable.

Where it is not possible to determine a NOAEL or LOAEL—for example, where there is not enough suitable data—risk is evaluated on the basis of qualitative or quantitative exposure relevant to the human population under consideration.

Where effects are deemed to pose greater risk to certain sensitive populations in the work force—for example pregnant women—an additional safety factor may be introduced.

For New Chemicals, a more qualitative characterisation takes place as exposures are often unknown or more difficult to predict.

Risk management

NICNAS assesses current risk-reduction strategies and, if the risk characterisation shows cause for concern, further control measures are recommended. Both regulatory and non-regulatory controls may be recommended.

The hierarchy of controls is used to formulate measures that can be applied directly to the workplace to reduce adverse health risks. Where regulatory controls may be required, current controls (for example, exposure standards) are appraised for adequacy.

The standard of hazard communication is often addressed when considering risk management strategies. Information on (Material) Safety Data Sheets and labels are assessed against respective codes of practice.

2.11.4 PUBLIC HEALTH ASSESSMENT

In broad terms, public health assessment aims to establish if there is potential for the chemical to adversely affect public health. This is influenced by two main factors: the nature and extent of public exposure to the chemical; and the chemical's toxicological properties.

Public exposure assessment

When assessing exposure, NICNAS begins by identifying the chemical, together with its estimated production or import volume and proposed use—examining its life history and considering the potential for the public to become exposed to it at each phase of its lifecycle.

This normally begins by assessing importation or synthesis and transport within the country. The assessment proceeds through to reformulation or use in industrial processes and possible use in consumer or industrial goods, and ends with the eventual disposal of the chemical (or products containing it).

Public exposure to notified chemicals most often occurs when they are sold in consumer products, or when products containing them enter the public domain.

The extent of public exposure depends on the concentration of the chemical in products, sales volume, pattern of use and other factors, including the physical state of the notified chemical.

NICNAs differentiates between the number of people likely to be exposed and the likely dose (amount of chemical) to which each person is exposed from the product's intended use.

Most members of the public will be exposed to a chemical constituent of a widely used product (for example, an additive to motor oil) but the amount of exposure may be minimised by the short time they are exposed to it and/or low frequency of contact.

Conversely, small numbers of people (for example, users of an exclusive small volume cosmetic or perfume), may be exposed to comparatively greater amounts of a chemical, with exposure increasing by prolonged or frequent contact.

Some products, such as ink cartridges, are packaged to reduce contact with the notified chemical during normal handling. Others may come into contact with the public without causing exposure. Polymers or dyes used in plastic or fibre, for example, may enter the public domain in an encapsulated, bonded or cured state from which they cannot be absorbed or otherwise become bio-available. Here, even extensive or prolonged contact would lead to negligible exposure.

NICNAS must take into account the possibility of public exposure arising from chemical release into the environment during transport, manufacture, reformulation and end-use.

Among the most important factors here is the amount of chemical which may be released, the location of possible discharges or spills, the chemical's physical state when it enters the environment and the chemicals persistence and ability to bioaccumulate. These factors influence the probability of public contact with the chemical at the release site, or the chemical exhibiting mobility in the air, soil or water, which will, in turn, determine if it may be inhaled or enter the potable water supply or food chain.

Emergency containment, cleanup and disposal procedures in the Safety Data Sheets could play a significant part in mitigating the effects of an accidental release, and will be noted by NICNAS.

Similarly, the notified chemical may enter the environment following its disposal, or disposal of products containing it. The assessment report will include this likelihood.

Toxicological properties assessment

Where toxicology data have been provided, NICNAS will assess toxicology for the nature and severity of hazards.

Irrespective of the class of notification of a new chemical, the identity and concentration of hazardous impurities or residual monomers will be examined, and NICNAS will comment on the likely toxicological significance at the levels present in products entering the public domain.

Implications for public health

Using the above information, NICNAS will assess if the chemical is likely to pose significant risks to public health. The use, concentration and physical state of the chemical when it reaches the public domain are

important for this part of the assessment.

Many notified chemicals have no adverse effect on public health, due to low potential for exposure and/or low toxicological hazard. However, where frequent or prolonged public exposure to the chemical is anticipated due to its presence in consumer goods (for example, in cosmetics and personal care products), NICNAS may make a quantitative estimate of the user's exposure and systemic intake through repeated use.

Some applicants may supply exposure information but, alternatively, NICNAS may apply an algorithm or default values based on those described in the European Commission's Risk Assessment of Existing Substances—Technical Guidance Document 2003 – see: http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd/tgdpart3_2ed.pdf. Other sources of default values include those used by the Scientific Committee on Consumer Products.

The software package ConsExpo (Consumer Exposure and Uptake Models), developed by the National Institute for Public Health and the Environment (RIVM) in the Netherlands—and also included in the European Union System for Evaluation of Substances software—is based on the basic algorithms from the Technical Guidance Document. The default values contained in ConsExpo were mainly derived from European studies. This software package may alternatively be used for estimating consumer exposures.

In the absence of dermal absorption data for the notified chemical, a default dermal absorption value will be used to estimate systemic exposure, based on physicochemical properties.

The estimated systemic exposure is then compared with the NOAEL established in a relevant repeat dose toxicity study for the notified chemical to determine the margin of exposure between the anticipated consumer use and doses causing toxicologically significant effects in animals.

Finally, NICNAS will recommend whether special conditions are required to protect public health, such as placing warning statements on labels or establishing an upper limit to the concentration at which the notified chemical may be used in certain products.

Methods for Priority Existing Chemicals

Public health assessment methods for PECs are similar to those for new chemical notifications, but the assessment report may be larger and more complex, depending on the amount of information available on use and the extent of animal and human toxicological data.

If a survey of the PECs use in industrial and consumer products has been performed, NICNAS will use these results during assessment.

Where a PEC has been subjected to poisons scheduling (SUSMP), NICNAS may examine consumer product labels to verify compliance with the requirements of the schedule with regard to signal headings, first aid instructions and safety directions. Otherwise, NICNAS will comment on the general suitability of label directions and other statements.

If there is indication of potentially significant public exposure to the PEC, either from environmental sources or its use in, or contamination of, consumer products, NICNAS will assess the level of risk to the public. The approach taken will vary with the extent of data on exposure levels and toxicology, and with the nature of any hazard the PEC poses. A margin of exposure will then be calculated. Alternatively, the level of risk to the public may be determined from the extent of public exposure and epidemiological evidence of health effects in persons exposed occupationally.

Whenever there appears to be significant risk to public health, NICNAS makes recommendations to reduce public exposure to the PEC.

Where public exposure arises from environmental contamination, NICNAS may recommend that measures be taken to reduce PEC emissions.

If the primary source of public exposure is from consumer products, NICNAS may recommend that the poisons scheduling status of the PEC be reviewed, or that label instructions for use, first aid instructions and/or safety directions be revised.

Where the nature of the hazard or the level of risk requires it, NICNAS may recommend an upper limit to PEC concentration in consumer products, or even that PEC use in consumer products must stop.

Where there are concerns based on toxicological findings, but insufficient information on which to base realistic estimates of public exposure and risk, NICNAS may recommend that further data be obtained to enable a more adequate assessment.

2.11.5 ENVIRONMENTAL ASSESSMENT

The Department of the Environment undertakes environmental risk assessments for NICNAS to consider in its overall assessment.

The guidance manual the Department of the Environment uses for environmental risk assessment of industrial chemicals is available at the Environment Protection and Heritage Council webpage: www.ephc.gov.au/sites/default/files/CMgt_NChEM_ERAGM_for_Industrial_Chemicals_200902.pdf>.

The guidance manual provides an overview of:

- the steps taken to carry out an environmental risk assessment on industrial chemicals, including lifestyle considerations
- what data are needed and how they are used
- nationally adopted criteria, such as for persistence, bioaccumulation and toxicity
- how international considerations are taken into account
- how risk assessors come to their recommendations about environmental risk management actions.

2.11.6 REFERENCES

The following references are very useful:

European Commission 2003, Technical Guidance Document on Risk Assessment, Part 1, Institute for Health and Consumer Protection, European Chemicals Bureau, EUR 20418 EN/1.(see: http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd/tgdpart3_2ed.pdf)

Industrial Chemicals (Notification and Assessment) Act 1989(Cwlth), Australian Government, Canberra. (see: www.comlaw.gov.au/Series/C2004A03939)

International Programme on Chemical Safety 1999, Environmental Health Criteria 2010, Principles for the Assessment of Risks to Human Health from Exposure to Chemicals, World Health Organization, Geneva. (see: www.who.int/ipcs/publications/ehc/en/index.html)

2.12 APPENDIX L: FORMS AND PAPERWORK NOTIFIERS MUST COMPLETE TO SUPPORT AN APPLICATION; FEES AND CHARGES PAYABLE

This section contains a listing of all NICNAS forms.

Note: You can download a range of forms and other paperwork you need to complete your application and pay fees and charges from the forms webpage.

There are also individual webpages for each of the following types of forms:

- New Chemicals forms
- Exisiting Chemicals forms

- NICNAS Registration forms
- NICNAS Compliance forms
- Rotterdam Convention forms
- Australian Inventory of Chemical Substances (AICS) forms

Information about all fees and charges is also available on the NICNAS website:

- New Chemicals notification fees and charges
- NICNAS Registration fees and charges
- AICS fees and charges
- Prior Informed Consent (Rotterdam Convention) fees and charges

The following tables provides an overview of the types of forms and guidance information that is available:
CERTIFICATES

Standard and Limited notifications		
	Mandatory forms	
	STD/LTD Form-Template	
	Modular/Foreign Scheme Attachment (if applicable)	
	UV Filter Attachment (if applicable)	
	Guidance Documents:1 Template2 Template Appendices	
	Other forms	
	Form 4 - Variation of Assessment Report	
	Form 5 - Third Party Information Lodgment	
Polymer of low concern		
	Mandatory forms	
	Form PLC-1	
	Modular/Foreign Scheme Attachment (if applicable)	

	Guidance document for Form PLC-1
	Other forms
	Form 4 - Variation of Assessment Report
	Form 5 - Third Party Information Lodgment
Extension application	
	Mandatory forms
	Form EXT 1 - Extension of an Original Assessment Certificate
	Form 14 - Agreement to Extension of Original Assessment Certificate
	Other forms
	Form 3 - Exemption Information
	Form 4 - Variation of Assessment Report
	Form 5 - Third Party Information Lodgment
Secondary notification	
	Mandatory forms
	Form SN 1 - Secondary Notification
	Other forms
	Form 3 - Exemption Information

	Form 4 - Variation of Assessment Report	
	Form 5 - Third Party Information Lodgment	
Self assessment		
	Mandatory forms for polymer of low concern (PLC)	
	Form 1 - PLC Self Assessment	
	Guidance Document	
	Example Notification	
	Mandatory forms for Non PLC	
	Form 1 - Non PLC Self Assessment	
	Guidance Document	
	Other forms	
	Form 3 - Exemption Information	
Agreement to transfer an assessment certificate		
	Form 73	
PERMITS		
Commercial evaluation permit (CEC)		
	Mandatory forms	

	Form CEC-1 - Commercial Evaluation Permit	
	CEC template	
	Checklist (Commercial Evaluation Permit Notification)	
	Form CEC-1R - Commercial Evaluation Permit RENEWAL	
	Form 8 - Commercial Evaluation Permit AGREEMENT	
	Other forms	
	Form 5 - Third Party Information Lodgment	
Low volume chemical permit (LVC)		
	Mandatory forms	
	Form LVC-1	
	Form LVC-1R - Low Volume Chemical Permit RENEWAL	
	Other forms	
	Form 5 - Third Party Information Lodgment	
Early introduction permit (EIP)		
	Form EIP-1 - Early Introduction Permit in conjunction with a STD/LTD notification	
	Guidance for Form EIP-1	

Export only permit (EOP)		
	Mandatory Forms	
	Form EOP-1 - Export Only Permit	
	Other forms	
	Form 5 - Third Party Information Lodgment	
Controlled use permit (CUP)		
	Mandatory forms	
	Form CUP-1	
	Other forms	
	Form 5 - Third Party Information Lodgment	
Exemptions		
	Form 6 - Advice of Introduction of a New Chemical for Site Limited Research and Development	
	Form 15 - Advice of introduction of a new chemical for cosmetics use and introduced at 10 kg to 100 kg per 12-month period	
	Form NCE-1 (replaces Form 21-4a) - For introducers of new chemicals under non-cosmetic exemption provisions. Form NCE-1	

EXISTING CHEMICALS

	Form 1- PEC - Assessment of a Priority Existing Chemical
	Form 1A - SN - Secondary Notification Assessment for an Existing Chemical
	Form 4A - PEC - Application for Variation of Report
	Priority Existing Chemicals Nominations Form
	FORM 3 (Exempt Information)
Registration	
	New Registration
	NR-1A - Application form for new registration
	Non-Registration
	NR-1B - Notice of Non-Registration
	Renewal / Notice of Non-renewal
	NR-2 - Application form for renewal of registration/Notice of non-renewal (incorporating renewal payment advice form)
	Final Statement
	NR-3 Final statement of introduction

Compliance		
	Report of Non-compliance with NICNAS requirements Form TPA-1	
Rotterdam Convention (PIC)		
	Annual Authorisation Application Form for Export Form AA/EXP-1	
	Annual Authorisation Application Form for Import Form AA/IMP-1	
Australian inventory of chemical substances (AICS)		
	Application Forms	
	Form AICS 1 - Application for a Chemical to be Listed/Re-listed in the Confidential Section of the Australian Inventory of Chemical Substances (AICS)	
	Form AICS 2 - Request for early listing on the non- confidential section of the Australian Inventory of Chemical Substances (AICS)	
	Form AICS 3 - Application for Status of Holder of Confidence in respect of a Chemical Listed in the Confidential Section of the Australian Inventory of Chemical Substances (AICS)	
	Search Forms	
	Form AICS 4C - Non-Confidential AICS Search	
	Form AICS 5C - Confidential AICS Search	

Payment Options		
	Payment Options Form	
Annual reporting		
	Annual Reporting Template - Exempt Chemicals	
	Annual Reporting Template - Permits/Certificates	

2.13 APPENDIX M: CONFIDENTIALITY

This appendix describes the steps required to ensure confidentiality for details of a New Chemical assessment.

For details of confidential listing of chemicals on the Australian Inventory of Chemical Substances (AICS), refer to Listing of chemicals on the AICS.

Sections of this appendix:

- Initial notification (first five years)
- Initial confidential Australian Inventory of Chemical Substances listing
- Re-listing a chemical on the Australian Inventory of Chemical Substances confidential section

2.13.1 INITIAL NOTIFICATION (FIRST FIVE YEARS)

For all notification categories, including submission of additional information, you can—as an applicant or notifier—claim certain data items to be regarded as confidential and therefore not to be published by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). You may, for example, consider certain data items required in your assessment or notification statement to be commercially harmful if disclosed.

You must indicate such data items, together with full reasons substantiating your claim for confidentiality (Subsection 75(1) of the Act).

In documents you submit to NICNAS, you must clearly identify items you wish to remain confidential.

NICNAS cannot grant applications for confidentiality of information falling within the scope of 'basic information' (Subsection 75(2) of the Act). The definition of 'basic information' is in the appendix containing definitions.

While some test data about the health and environment effects may be considered basic information, NICNAS will only publish a summary of this data. The full study reports will not be disclosed to the public.

You can apply for information to be dealt with confidentially in relation to these sections of the Act:

- an application for a Low volume chemical permit—Subsection 21ZB(1)
- written notice to the NICNAS Director of a change in circumstances or of new information, as required under the conditions of the Low volume chemical permit—Subsection 21ZB(2)

- an application for a Commercial evaluation permit—Section21P
- an application for a Controlled use permit—Section 220
- the notification of a New Chemical (including a Polymer of low concern)—Section 25
- the provision of further information to help with the assessment of a New Chemical-Section 29
- an application for early introduction of a non-hazardous chemical—Section 30A
- an application for extension of an original assessment certificate to cover other importers or manufacturers—Section 40D
- the notification of a New Chemical that has been notified and assessed under notification law in force in a state or territory—Section 42
- the notification of a New Chemical that has been notified and assessed under an approved foreign scheme (with Canada)—Section 45
- the provision of information for a prospective Priority Existing Chemical (PEC)—Section 50
- the provision of information for a PEC—Section 60
- the Secondary Notification of a chemical-Section 66
- information given to inspectors—Section 89.

You must apply to exempt information on the basis of confidentiality using the appropriate notification Form -1 or Exempt information Form-3 in conjunction with Form-1 as appropriate. You need to submit your completed forms with the required fee.

In all applications for exemption, the NICNAS Director weighs the public interest in publishing the information against the potential commercial harm to you, as applicant or notifier.

If the Director decides the application is justified, then the data items are classed as confidential and exempt from publication. You will receive notice of this in writing.

If the Director rejects the application you will be notified in writing of the decision. You can appeal to the Administrative Appeals Tribunal for a review.

Security information during assessment

Dossiers of information comprising the notification statement or permit application are only available to staff in government agencies conducting the assessment.

If assessments are to be handled under contract, confidentiality agreements would need to be signed.

Public access to information

The summary information of a chemical published in NICNAS's *Chemical Gazette* is available for public inspection and the public report is published on the NICNAS website.

Disclosure of confidential information in special circumstances

In special circumstances, the NICNAS Director may disclose certain items of confidential information about a chemical (Section 79 of the Act). This can be done:

- with your consent and—in the case of information given under an approved foreign scheme—the corresponding foreign government
- without your consent in an emergency, where the Director is satisfied that delay in disclosing could endanger occupational health and safety, public health or the environment.

In both these situations, the Director must be satisfied that the:

• disclosure is to assist in protecting occupational health and safety, public health or the environment

• public interest in disclosing the exempt (confidential) information outweighs your commercial interest.

In all cases of disclosure of exempt information, the Director must give you written notice and, if necessary, the relevant foreign government written notice (Section 80 of the Act).

2.13.2 INITIAL CONFIDENTIAL AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES LISTING

A few months before your assessment certificate expires, you, as certificate holder, will be contacted by NICNAS and informed that the assessed chemical is due to be listed on the AICS.

You can apply for the chemical listed in the confidential section of the AICS, or doing nothing, in which case the chemical will be listed in the public section of the AICS.

The process for this is outlined in the Volume 1 of the NICNAS Handbook, in the chapter on the Australian Inventory of Chemical Substance.

2.13.3 RE-LISTING A CHEMICAL ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES CONFIDENTIAL SECTION

According to the Act, the confidential status of a chemical is to be reviewed if it has been listed in the confidential section of the AICS for five years. A few months before the end of this five-year period, you will be given the option of applying to re-list the chemical in the confidential section. The process for doing so is identical to the process for the initial listing (see above).

2.14 APPENDIX N: AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES ONLINE SEARCHING ADVICE

This appendix provides guidance to help you search the Australian Inventory of Chemicals Substances (AICS).

It also provides information on when the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) must search for a chemical on the confidential section of the inventory on your behalf, in response to a request from you submitted on the appropriate form, available on the NICNAS website.

Sections of this appendix:

- Searching public section online
- Confidential AICS search

2.14.1 SEARCHING PUBLIC SECTION ONLINE

AICS online is a searchable list of chemicals on the public (non-confidential) section of the AICS. The AICS is used to distinguish new chemicals from 'existing' chemicals (more information is in the *NICNAS Handbook: A guide for importers and manufacturers of industrial chemicals in Australia*, Chapter 3).

If you do not find the chemical after searching the public section, you need to organise for NICNAS to search the confidential section on your behalf (see appendix on Confidentiality for more information).

Importers and manufacturers of chemicals should conduct an AICS search as the first step in complying with the law covering industrial chemicals.

If a chemical is listed on the AICS then, subject to certain obligations under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (Section 3.4), it does not need to undergo an assessment by NICNAS and can be introduced without prior notification by companies registered with NICNAS.

The tool for searching the AICS is available on the NICNAS website. The AICS is regularly updated.

Suggested strategy for searching

NICNAS strongly suggests you search AICS online using one of three chemical identifiers: Chemical Abstracts Service Registry Number (CAS RN); Chemical name; or Molecular formula.

Chemical Abstracts Service Registry Number

The most effective, easiest and quickest way to search the AICS is by the CAS Registry Number (CAS RN) often just called the CAS number—which is a unique number assigned by CAS to each specific chemical substances. CAS RNs can also be assigned to specific mixtures of chemicals. For example the mixture of fatty acids derived from coconut oil has the CAS RN 61788-47-4, and represents this unique mixture: lauric (C12) acid (45-53%); myristic (C14) acid (17-21%); palmitic (C16) acid (2-4%); oleic acid (5-10%); and a range of other individual fatty acid components each of which also has their own CAS RN.

Chemical name

The next most useful way to search the AICS is by the CAS preferred chemical name. However chemicals can also be known by many other names and these may not all be listed on the AICS. If you cannot find the chemical name you are searching for, then search under other names. Very few—if any—chemicals on the AICS are listed under their trade name, so searching this way is not recommended. You can check several Internet sites for information on other chemical names (see below).

• Molecular formula

The least useful way to search the AICS is by molecular formula. To increase your chances of searching this way, NICNAS recommends you search in combination with the chemical name search. Relatively few chemicals on the AICS are listed with their molecular formulas, and these are mostly relatively small molecules.

Internet sites

Several Internet sites can help you identify CAS numbers or chemical names. These are described below.

Chemical information databases

Here are some links that may be useful to find chemical information including CAS RNs. It should be noted that information on these links may not always be accurate.

• European Chemicals Agency

This 'Information on Chemicals' section is the 'gateway' to ECHA's public databases on chemical substances, which contain a plethora of information about chemicals in Europe.

United States Environment Protection Agency Aggregated Computational Toxicology Resource

ACTOR (Aggregated Computational Toxicology resource) is EPA's online warehouse of all publicly available chemical toxicity data and can be used to find all publicly available data about potential chemical risks to human health and the environment.

Cosing Database search page

This European Commission searchable database has information on cosmetic ingredients. It contains CAS RNs and International Nomenclature Cosmetic Ingredient (INCI) names and numbers.

• National Library of Medicine

This United States' site lists chemicals and available toxicity information. It is useful for listing chemicals that are not on major inventories.

• (M) SDS-Search

This (Material) Safety Data Sheet ((M)SDS) site provides safety data and CAS RNs.

• National Institute of Standards and Technology Chemistry (NIST) WebBook

This website of the U.S. Department of Commerce provides access to data compiled and distributed by NIST under the Standard Reference Data Program.

INTERNET SEARCH ENGINES

Any major Internet search engine can sometimes help you find information such as a chemical name or a CAS number, but you will need to verify the accuracy of results (as the sites are sometimes wrong).

You can narrow down search results using advanced search options ('contains phrase', 'exactly' etc.). An easier way is to add additional terms when you search. For instance if you are searching for a chemical name only and get more than 2000 hits, just add the term CAS number and re-search. The result will show you where both the chemical name and CAS number appear.

Search strategies for specific group of chemicals

More information on search strategies for polymers and cosmetics is in Appendix N1.8.

Where to find a CAS RN

CAS RNs are often included in a chemical's (M)SDS. You can obtain an (M)SDS by contacting the manufacturer or supplier. Sometimes you can find a CAS RN by simply entering a chemical name into an Internet search engine and/or by searching online catalogues of chemical suppliers. Other possible sources for CAS RNs are listed below.

CAS also offers a CAS RN search service (for a small fee) at: weblink to come. If you have detailed information on a chemical—such as a reliable chemical structure, names or occasionally even a trade name—then the CAS can find the CAS RN for you.

Information on assigning new CAS RNs is in the appendix on Chemical Abstracts Service.

CAS RN search

The CAS RN is a unique number assigned to a substance when it is entered into the CAS registry database. More information on CAS RNs is available here.

The format of the CAS number is three blocks of numbers separated by dashes (that is, XXX-XX-X). The first block can be between two and six digits; the second block has only two digits; and the last block is always a single digit. Discard any preceding zeros in the first block. For example, the CAS number for formaldehyde is 50-00-0, not 050-00-0. You need to enter the digits with the dashes (50-00-0) when searching the AICS.

If the CAS number you enter matches a CAS number listed on the AICS, the chemical details will be displayed on your screen. You can only search for one chemical using a CAS number. If the number entered is not precise and in the correct format (for example, too few or many numbers) you will receive an alert message. Note: the CAS number search field will not accept 'wild card' searches. As an example, to search for formaldehyde, enter the CAS number (50-00-0) into the search field and start your search by hitting 'Go'. Below are screenshots of before and after searching for '50-00-0'.

To print the results of your chemical search, click on Print this page displayed on the screen.

This will open the search result in a window suitable for printing (see example, below).

If there are no results for the CAS number then a negative search screen will appear stating 'No results found'.

Chemical name search

Chemicals are listed under their CAS-approved name, not their International Union for Pure and Applied Chemistry name.

Chemicals are more commonly known by names other than their CAS-approved name. Very few of these associated names or synonyms are included on the AICS. The few AICS entries containing synonyms are generally restricted to more commonly used chemicals.

In the formaldehyde example described in M1.5., six associated names are listed on the AICS. However, formaldehyde also has several more associated names, such as 'formol', that are not listed on the AICS. Therefore, if you search 'formol' you will not get a positive result, even though formaldehyde is listed.

The search engine for the chemical name search has been set up to search for name fragments. A fragment is defined as a word with a 'space' or 'bracket' or '-' or 'number' separating it from the next word.

Note: The chemical names are listed in different formats on the AICS (for example, extra space, bracket or sequence) and so you may get a negative result if you do not use the correct format. Below are three examples for simple chemicals that have different name formats:

- Methylethyl ketone is listed (for CAS RN 78-93-3) whereas ethylmethyl ketone and methyl ethyl ketone are not listed, though they represent the same chemical.
- Isopropyl benzeneis listed (for CAS RN 98-82-8) whereas searching on isopropyl benzene gives no result, though the chemical is the same.
- Sodium sulfate (CAS RN 7757-82-6) is more commonly known as sodium sulphate. Sulfate is the CAS approved name format.

If you do not have the CAS number or correct chemical name, ensure you have sufficient associated names so you can conduct a comprehensive AICS search. You can obtain associated chemical names or synonyms through Internet sources or other published documents.

Note: The AICS does not list trade names or International Nomenclature of Cosmetic Ingredients names.

You can enhance chemical names and molecular formula searches by using the wildcard '*'. This can be used in different search options.

Although the number of search results is not limited by the search engine used, i your search results in too many hits, you can refine the search. You can do so using the "Starts with", "Equals" and "Excludes" options.

There are several ways to search for a chemical name and these are described immediately below.

1. Contains

The search will be conducted on all words entered on the line. The sequence or preceding characters (including wildcards) are ignored. Wildcard option, '*', can be used at the end of words for search.

This is your best option if a chemical name is long and has many components (like those names for polymers). For example, if 'pentanoic acid' is entered on the search field, the search engine will break the name into two

fragments, 'pentanoic' and 'acid' and search for chemical names on the AICS that contain both fragments and each fragment. About 83 records are on the AICS with both of these fragments.

2. Starts with

This will search for any chemical name starting with the name entered. Here the wild card,'*', can be used at either side of the word for searches. This is the best option when using wildcards.

For example, if 'pentanoic' is searched, all chemicals where pentanoic as the first part of the name are displayed.

3. Equals

This search matches the combined fragments being searched (as opposed to the "contains" option where results containing all fragments and individual fragments are returned). In this option, spaces, brackets, commas and dashes are important and unless these are entered correctly the chemical will not be matched. Wildcards cannot be used with this option. It is useful when searching for individual chemical names (for example, benzene and water).

4. Excludes phrase

This option will exclude any word or phrase entered. Sequence is important in any phrase option. This will help you narrow search results.

For example, to narrow the search results for 'pentanoic acid' from 83 (using 'contains all words' option) to manageable numbers, the excludes phrase may be used. First identify the words or phrases in the list that you do not want in your results by scrolling down. Once these are identified, type the words on different search lines and use the option 'excludes phrase'.

You can use any combination of the operator phrases noted above to do your search.

Molecular formula search

Searching molecular formulae requires that the sequence in which the atomic symbols are entered must match the order used in the AICS entry, which is the order used by chemists—alphabetically for molecules, cations and then anions for salts.

Therefore, entering 'C6H6ON' will give no results while using 'C6H6NO' will produce two hits. We recommend you use this option cautiously, only to assist in narrowing chemical name searches.

The search options are:

1. Contains

This will search for atomic symbols entered on the line. As indicated earlier, the sequence of atoms is maintained during the search.

Use this option with caution as it may produce a negative result if the sequence on the AICS does not match the search phrase. A wildcard, '*', can be used in the search if the sequence of elements is not known. It is also possible to use more than one wildcard, for example, C*H12*NO.

2. Starts with

This will search for molecular formulae starting with the element entered. A wildcard, '*', is useful to get more hits and can be used at the start or end of the formula.

3. Equals

This search matches the exact molecular formula. This option is useful when you know the molecular formula. The wildcard is not useful in this search mode.

This option will exclude any atom/s entered.

Search strategies for specific group of chemicals

POLYMERS

Searching for polymers by name can be difficult as the names are long and chemical names are sometimes in different formats. Here are a few hints on how to search for polymers on the AICS.

Because of the complexity of polymer names, searching for polymers on the AICS—using the CAS RN—is the best option. However, if no CAS RN is available, it is best to break the chemical name into keyword fragments and search for a combination of these fragments to find the polymer. An example of a polymer chemical name search is below:

Example 1

Polymer to be searched: Phenol, 4,4'-(1-methylethylidene) bis-, polymer with (chloromethyl) oxirane, polymer with paraformaldehyde, 3-methylphenol, 2-methylphenol and 4-methylphenol.

This polymer name can be broken into these keyword fragments:

- Phenol
- Methylethylidene
- Chloromethyl
- Oxirane
- Paraformaldehyde
- Methylphenol.

Choose the search operator 'Contains' and input the fragments. Click 'Go' to search for the polymer and note the results corresponding to all words searched.

If there is more than one hit for the name combination, then all search results will be displayed. In this case only one chemical name was found on the AICS containing all terms.

Example 2

This example demonstrates a search sequence for a polymer where the supplied chemical name is different to the name listed on the AICS.

Polymer to be searched: Acrylic acid, polymer with acrylonitrile, butyl acrylate and styrene.

If the above polymer is searched for the keyword fragments 'acrylic acid', 'acrylonitrile', 'butyl acrylate' and 'styrene', the search will return as negative.

However, if synonyms for each keyword can be identified using the AICS or other sources, you can use them for the AICS search.

A synonym for acrylic acid on the AICS is: 2-propenoic acid.

Synonyms for butyl acrylate on the AICS are:

- 2-Propenoicacid, butyl ester
- Acrylic acid, butyl ester
- Butyl2-propenoate
- n-Butylacrylate.

Synonyms for acrylonitrile on the AICS are:

- 2-Propenenitrile
- Cyanoethylene.

Synonyms for styrene on the AICS are:

- Benzene,ethenyl-
- Ethenyl benzene
- Vinyl benzene.

A combination of these synonyms can be used for the search.

Several possible candidate polymers may be returned. You can identify the correct one manually from the list by clicking on the CAS number.

It is important to consider synonyms when conducting chemical name searches.

COSMETICS

Cosmetic chemicals are often known by their more common industry trade names for example, the INCI (International Nomenclature of Cosmetic Ingredients – see: http://ec.europa.eu/consumers/sectors/cosmetics/cosing/index_en.htm) name.

As most of these trade names are not on the AICS, searching with these terms will generally yield negative results. The strategies to find cosmetic ingredients are:

- Contact your supplier to get correct chemical details or ask them to check the chemicals and if possible to supply a CAS RN.
- Use Internet resources to find chemical information and use it to search the AICS. Note that information on these links may not be accurate.

Example:

Stearamide DEA

If you search with this term on the AICS, you will not get any results.

However you can find the CAS number on the Internet.

The CAS number for this chemical is 93-82-3 and using this information, you can search the AICS.

2.14.2 CONFIDENTIAL AICS SEARCH

If there is no match on the public AICS for the chemical name, CAS number or molecular formula, it may be that the chemical is listed in the confidential section of the AICS.

You cannot search this section yourself. Rather, you must organise for NICNAS to do so on your behalf by:

- completing the AICS-5 form
- providing evidence you have unsuccessfully searched the public AICS (for example, with a print-out of the search result)
- completing a Declaratory Statement that you have a bona fide intention to manufacture or import the chemical.

2.15 APPENDIX O: CHEMICAL ABSTRACTS SERVICE REGISTRY NUMBERS

This appendix describes Chemical Abstracts Service (CAS) numbers and their use by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), especially in relation to the Australian Inventory of Chemical Substances (AICS).

ABOUT THE CHEMICAL ABSTRACTS SERVICE

The CAS Registry File is an internationally recognised database of chemical substance information.

A CAS Registry Number[®] (CAS RN) is a unique and specific identifier of only one chemical substance and is independent of the numerous other methods that may be used to identify or describe a chemical.

CAS RNs and their associated CAS names are relied upon by regulatory agencies, industry, and scientific institutions world-wide as an accurate source of chemical information and a means of verifying chemical identity.

CHEMICAL ABSTRACTS SERVICE AND THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES

CAS nomenclature is the basis on which the AICS operates, with existing industrial chemicals being listed primarily by the CAS RN and CAS name. The CAS RN identification is therefore integral to distinguishing between new and existing industrial chemicals.

CHEMICAL IDENTITY INFORMATION FOR NEW CHEMICALS NOTIFICATIONS

You are required to provide this chemical identity information as part of your new chemical notifications:

- preferred index name—CAS name
- CAS RN (where assigned).

Alternatively, you can submit an International Union of Pure and Applied Chemistry name.

You need to submit a copy of the report from the CAS Inventory Expert Service if only a CAS name is available (that is, when a CAS RN has not been applied for).

Alternatively, supply a result from a CAS online search, or similarly, if a CAS RNis available.

Note: When assessing unknown or variable composition substances, NICNAS can ask for more information on the CAS name or CAS RN of immediate chemical precursors and reactants.

If you fail to comply with these requirements, your application may be deemed to be incomplete and NICNAS can return it under the NICNAS Screening Framework and Refund Policy (outlined in *Chemical Gazette*, February 2007).

Obtaining Chemical Abstracts Service names and numbers

The CAS Inventory Expert Serviceassigns CAS names and CAS RNs to new chemicals / chemical substances. Through this service, you can liaise directly with CAS experts to obtain CAS names and CAS RNs. This service includes the option of assigning a CAS name only, without a corresponding CAS RN.

More information on these services is available from CAS:

Phone: +1 614 447 3600 Facsimile: + 1 614 447 3713

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Website: <www.cas.org/> Email: help@cas.org/ Mailing address:

Chemical Abstracts Service CAS Registry Services PO Box 3012 Columbus, Ohio 43210 USA

2.16 APPENDIX P: NATURALLY-OCCURRING CHEMICALS

In the Act (see Legislation and Regulations), an industrial chemical which meets the definition of 'a naturallyoccurring chemical' is taken to be on the AICS, whether listed or not, and therefore does not require notification as a new chemical prior to manufacture or importation into Australia.

Similarly, an industrial chemical which meets the definition of 'a naturally-occurring chemical' is not within the definition of a 'relevant industrial chemical' in the Act (see Legislation and Regulations) and is therefore not considered when working out the value of introduced chemicals each year when applying for NICNAS registration.

Sections of this appendix:

- Definition of a naturally-occurring chemical
- Application of the definition
- Steam distillation
- Extraction of essential oils

2.16.1 DEFINITION OF A NATURALLY-OCCURRING CHEMICAL

A naturally-occurring chemical is defined in Section 5 of the Act as:

"(a) An unprocessed chemical occurring in a natural environment,

or

- (b) a chemical occurring in a natural environment, being a substance that is extracted by:
- (i) manual, mechanical, or gravitational means, or
- (ii) dissolution in water; or
- (iii) flotation; or
- (iv) a process of heating for the sole purpose of removing uncombined water

without a chemical change in the substance".

Guidance on these processes is included below.

It is noted that the definition of a naturally-occurring chemical is consistent with equivalent definitions in other notification and assessment schemes.

Unprocessed chemicals occurring in a natural environment

The first part of the definition of a naturally occurring chemical (part (a)) applies to chemicals which can be

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obtained from, for example, plants, micro-organisms or animals without any processing at all, for example blood and milk from animals. The definition also applies to certain inorganic matter such as minerals, ores, crude oil, coal and natural gas which can be, for example, obtained from the earth or sea without any processing.

Chemicals extracted without a chemical change

The second part of the definition of a naturally-occurring chemical (part (b)) applies to chemicals which occur in nature but which have been processed by certain means without any change in the chemical composition of the chemical. A description of these processes, with examples, is set out below.

Extraction by manual, mechanical or gravitational means

The simplest method of separation is when a naturally-occurring chemical is removed from its matrix or another chemical by hand or machine without any change in the chemical composition. Processes which may be applicable include:

- Filtration, where the solid and liquid phases of a mixture are mechanically separated by passing the mixture through a porous medium
- Centrifugation, where the liquid phases or solid and liquid phases of a mixture are separated by mechanical/gravitational means
- Sedimentation, where the solid and liquid phases of a mixture are gravitationally separated by enabling the settling of solids in liquids
- Cold pressing, where the liquid of a liquid-solid mixture is separated by squeezing the matrix to obtain the liquid
- Sieving, where the solids in a mixture can be separated on the basis of particle size.

Extraction by dissolution in water

In this separation method (for water-soluble chemicals), the only solvent which can be used to extract the chemical from other components in a mixture is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the chemical from being naturally-occurring.

Examples of this process include the extraction of sugar from sugar beets using water, the leaching of soluble tea from tea leaves and the extraction of a water-soluble chemical from a mineral ore.

Extraction by flotation

Flotation is a physicochemical property-based separation process widely used in mineral processing to separate minerals from waste rock or solids. Flotation is based on the use of wettability differences of solid particles, where mineral ore is pulverised and mixed with water and certain special chemicals that cause preferential wetting of the solid particles. The unwetted particles are carried to the surface by air bubbles to obtain a mineral concentrate, for example lead, zinc and copper concentrates.

Extraction by a process of heating for the sole purpose of removing uncombined water

Heat can be used to purify or concentrate chemical compounds by removing uncombined water. For the purposes of meeting the NICNAS definition of a naturally-occurring chemical, the heat applied is not to serve any other purpose, for example the heat necessary for steam distillation. An example of this extraction process would be the drying of a wet clay or mineral, where moisture is not chemically-bound to the substrate.

2.16.2 APPLICATION OF THE DEFINITION

In determining whether a chemical meets the definition of a naturally-occurring chemical, a number of factors need to be considered, including:

- How was the substance obtained?
- Has the substance been obtained after some form of processing?
- If so, what type of processing?
- Was heat used in the processing?
- Was there any likelihood of chemical change during processing?

The physical processes that are included in the definition are restricted to those processes where no change in the composition of the chemical during extraction will occur.

If the chemical or mixture containing the chemical has been imported, for example in a product, documentation may be required from the supplier to assist in determining whether the substance meets the definition of a naturally-occurring chemical.

2.16.3 STEAM DISTILLATION

Distillation is the separation process based on the difference in composition between a liquid mixture and the vapour formed from it. The difference in composition is due to the different effective vapour pressures of the components in the liquid mixture. The vapour is then condensed to a liquid (the distillate). In steam distillation, steam is used to lower the distillation temperatures of high boiling organic compounds that are immiscible with water. In the process, steam is charged to the matrix to volatilise the hydrophobic liquid and carry it across to a chilled condenser for subsequent liquefaction and separation from water. Variations in temperature, pressure and distillation time are used to control the process.

Steam distillation is commonly used to extract chemicals from plant material, for example the extraction of essential oils from leaves, bark or other plant materials. In the steam distillation of essential oils, the hot steam helps to release the aromatic molecules from the plant material as the steam forces open the pockets in which the oils are kept in the plant material. The temperature and pressure of the steam need to be carefully controlled to prevent burning of the plant material or the essential oil. Also, the distillation must be allowed to continue for such time to sufficiently extract the oil's components from the plant as some components are released more quickly than others.

Under the current NICNAS definition of a naturally-occurring chemical, steam distillation is not regarded as an allowable process as it does not meet the extraction requirements of part (b) of the definition, in particular, the use of heat for a process other than the removal of combined water. In addition, there is uncertainty regarding the potential for chemical change during steam distillation. The scientific literature cites reports of chemical change during the thermal degradation of heat-sensitive compounds and the hydrolysis of other compounds.

2.16.4 EXTRACTION OF ESSENTIAL OILS

An essential oil is the volatile oil derived from some part of a plant, for example the leaf, stem, flower or peel, and usually carries the odour or flavour of the plant. Essential oils are usually lipophilic compounds and therefore usually not miscible with water. Some essential oils are nearly pure single compounds, for example oil of wintergreen, however, most are mixtures of many chemicals.

Essential oils are generally extracted by distillation, including steam distillation. Other processes include cold pressing, for example for citrus peel oils, solvent extraction, supercritical fluid extraction (with CO_2) and hydro distillation. In some cases, extracted essential oils are further processed to remove undesirable components, for example rectification of peppermint oil to remove dimethyl sulfide.

Therefore, for the purposes of new chemicals notification and NICNAS registration, introducers of essential oils need to determine whether their oil meets the NICNAS definition of a naturally-occurring chemical. Most importantly, the process used for extraction needs to be compared with the allowable processes in the definition of a naturally-occurring chemical, and any likelihood of change in chemical composition during the extractive process needs to be examined. The use of heat during extraction, for example by steam distillation, or chemical change during the extraction process will disqualify the oil from being regarded as a naturally-

occurring chemical. Numerous studies have indicated differences in chemical composition between the natural plant oil and the commercial oil. Also, the scientific literature contains numerous studies citing the variations in chemical composition between oils extracted by different means.

As a guide, non-invasive processes carried out at room temperature may fulfil the definition of a naturallyoccurring chemical, for example cold pressing, however, processes requiring the application of heat during extraction, unless to remove water, are subject to uncertainty regarding chemical change during the extraction process. Also, some oils may have water-soluble components which are hydrolysed in treatment with water or steam.

2.17 APPENDIX Q: STOCKHOLM CONVENTION: (1) INTERNATIONAL PERSISTENT ORGANIC POLLUTANTS CRITERIA (2) NATIONAL ENVIRONMENTAL PERSISTENT BIOACCUMULATIVE AND TOXIC CRITERIA

This appendix provides information concerning the Stockholm Convention on Persistent Organic Pollutants (POPs) and its requirements.

The Stockholm Convention is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically and accumulate in the fatty tissue of humans and wildlife.

More information is in Volume 1 of the NICNAS Handbook, in the chapter on International obligations.

Information is also available on the International Engagement webpage.

PERSISTENT ORGANIC POLLUTANTS CRITERIA

As part of Australia's obligations under the Stockholm Convention, NICNAS assessors must consider these criteria when assessing new and existing industrial chemicals:

- For persistence
 - evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months
 - evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the convention.
- For bioaccumulation
 - $\circ~$ evidence that the bioconcentration or bioaccumulation factor in aquatic species for the chemical is >5000 or, in the absence of such data, that the log K_{ow} is >5
 - evidence that a chemical presents other reasons for concern, such as high bioaccumulation in other species, high toxicity or ecotoxicity
 - monitoring data in biota indicating that the bioaccumulation potential of the chemical is sufficient to justify its consideration within the scope of the convention.
- For long-range transport potential
 - measured levels of the chemical in locations distant from the sources of its release that are of potential concern
 - monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred by way of air, water or migratory species
 - environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, and the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical

migrating significantly through the air, its half-life in air should be greater than two days.

- For adverse effects
 - evidence of adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this convention
 - toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

PERSISTENT BIOACCUMULATIVE TOXIC CRITERIA FOR AUSTRALIA

The Stockholm Convention criteria for POPs covers *very* persistent and *very* bioaccumulative substances. However, a chemical deemed persistent or bioaccumulative may not carry values as high as those prescribed in the POP criteria (and hence warranting collective international action) but would still merit additional consideration in their assessment.

Chemicals deemed to be persistent, bioaccumulative and toxic (PBT) may not be adequately addressed by traditional risk assessment methodologies.

PBT chemicals are not eligible for certain new chemical notification categories. Therefore, to identify PBT chemicals, NICNAS considers Australia's environmental PBT criteria (set out in Table P1) when screening and assessing new industrial chemicals and assessing existing industrial chemicals.

More information on the criteria can be found in the Environmental Risk Assessment Guidance Manual for Industrial Chemicals located on the Environment Protection and Heritage Council's website at: </www.ephc.gov.au/taxonomy/term/75>.

- For persistence
 - evidence that the half-life of the chemical in water is greater than two months, or that its half life in soil is greater than six months, or that its half-life in sediment is greater than six months, or that its half-life in air is greater than 2 days
- For bioaccumulation
 - A bio-concentration factor (BCF) of >2000, or in its absence, a log K_{ow} greater than 4.2
- For toxicity (environmental)
 - for toxicity to the aquatic environment: the levels classified as Category Chronic 1^[1] under long term aquatic hazard of the proposed globally harmonised system (GHS) classifications
 - o if inadequate chronic toxicity data are available (and providing the substance is not readily biodegradable and/or the experimentally determined BCF is ≥500), the levels classified as Category Chronic 1 based on acute toxicity of the proposed GHS classifications
 - toxicity to other (terrestrial) organisms or evidence such as endocrine disruption effects should be considered on case-by-case—the former should be compared with the ecotoxicity categories the Department of the Environment has developed for agricultural and veterinary chemicals.

[1] OECD Series on Testing and Assessment No 27: Guidance Document On The Use Of The Harmonised System For The Classification Of Chemicals Which Are Hazardous For The Aquatic Environment – see: www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2001)8&doclanguage=en.

SUMMARY OF AUSTRALIAN ENVIRONMENTAL CRITERIA FOR PBT^[1] CHEMICALS

Persistence

For PBT purposes a chemical is considered persistent in a particular media if its half-life in it exceeds the following:

Media	Half-life
Water	2 months
Soil	6 months
Sediment	6 months
Air	2 days

Bioaccumulation

For PBT purposes a chemical is considered to be bioaccumulative if it has a BCF (bioconcentration factor) or BAF (bioaccumulation factor) of >2000, or in the absence of any BCF/BAF measurement, a log $K_{ow} \ge 4.2$.

Toxicity

For PBT purposes, in respect of aquatic toxicity, a chemical may be considered toxic under the following circumstances (corresponding to criteria for GHS chronic category 1).

	Chronic NOEC ^[2] or EC _x (Effect concentration) (for fish)	≤0.1 mg/L
	and/or	
Non-rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic NOEC or EC _x (for crustacean)	≤0.1 mg/L
	and/or	

	Chronic NOEC or EC _x (for algae or other aquatic plants)	≤0.1 mg/L	
Rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic NOEC or EC _x (for fish)	≤0.01 mg/L	
	and/or		
	Chronic NOEC or EC _x (for crustacean)	≤0.01 mg/L	
	and/or	and/or	
	Chronic NOEC or EC _x (for algae or other aquatic plants)	≤0.01 mg/L	
Substances for which adequate chronic toxicity data are not available (providing criteria for P and B are met)	96 h LC ₅₀ (for fish)	≤1 mg/L	
	and/or		
	48 h EC ₅₀ (for crustacea)	≤1 mg/L	
	and/or		
	72 or 96 h ErC ₅₀ (for algae or other aquatic plants)	≤1 mg/L	
	and the substance is not rapidly degradable and/or the experimentally determined BCF is 3 500 (or, if absent, the log $K_{\rm ow}$ 34).		
Toxicity to other (terrestrial) organisms	Should be considered case-by-case, compared with the 'highly toxic classifications' the Department of the Environment (formerly DSEWPaC) has developed for agriculture and veterinary chemicals.		

[1 Persistent, bioaccumulative and toxic chemicals

[2] No Observed Effect Concentration

2.18 APPENDIX R: SUMMARY OF APPLICATIONS UNDER THE ACT

This appendix is a summary in tabular form.

It summarises sections of the Act: *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth), which you can access at the Legislation and Regulations webpage.

It refers to the applications you may need to complete and submit to NICNAS, in order to obtain permits and certificates.

These are all described in the relevant sections of the Handbook:

- Notification categories for new chemicals
- Notification processes and procedures for new chemicals

SUMMARY OF APPLICATIONS UNDER THE ACT

Subject	Location in the Act	
Exempt Chemical for Site-Limited Research and Development	Paragraph 21(3)(b)	
Exempt Chemical for Volume-Limited Research and Development	Paragraph 21(6)(a)	
Exempt Small Amount Chemical (cosmetic and non-cosmetic)	Subsection 21(4)	
Exempt Chemical (other)	Paragraph 21(6)(b)(c)	
Secondary Notification	Section 65	
NICNAS registration	Section 80	
New Chemicals assessments		
Commercial Evaluation Chemical	Section 21B	
Low volume chemical	Section 21S	
Controlled use permit	Section 22	
Polymers of Low Concern	Section 24A	
Limited Notifications	Subsection 23	
Standard Notifications	Subsection 23	
Extension of Original assessment certificate	Section 40A	
Other types of application and assessment		

Provision of a Draft Assessment Report	Regulation 15(5)
Self Assessment	Section 23A
Section 30A Early Introduction Permit	Section 30A
Section 30 Permit	Section 30
Provision of an Approved Foreign Report	Section 44(5)
Variation of Schedule Requirements	Section 24
Exempt/confidential Information	Sections 21P, 21ZB, 25, 29, 30A, 40D, 42, 45, 60,66, 75 and 89
Variation of Assessment Report	Section 37
Variation of Full Assessment Report	Section 40
Variation of Draft Priority Existing Chemical Assessment Report	Section 60
Listing on Confidential Section of the Australian Inventory of Chemical Substances	Subsection 14(3)
Re-Listing on Confidential Section of the Australian Inventory of Chemical Substances	Section 19
Status of Holder of Confidence	Section 17
Priority Existing Chemical Assessment	Subsection 55(1) and 55(1A)

2.19 APPENDIX S: APPEALS

An applicant or notifier may appeal many decisions made by:

• the Minister for Health and Ageing, who is responsible for NICNAS, or

• the NICNAS Director.

This appendix lists decisions made by the Minister or Director under the *Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth)* (see Legislation and Regulations) that you can appeal to the Administrative Appeals Tribunal (AAT - see http://www.aat.gov.au).

TO MAKE AN APPEAL

To have a decision reviewed, you must make a written application to the AAT setting out the:

- decision to be reviewed
- reasons for requesting the review.

The table (below) details the range of decisions that can be made, and who (Director of NICNAS or Minister for Health and Ageing) is empowered to make the decision/s.

The AAT has offices in each state, but its principal registry offices are in Sydney and Brisbane.

Contact details for each principal registry office

SYDNEY Administrative Appeals Tribunal GPO Box 9955 Sydney NSW 2001

Email: Sydney.Registry@aat.gov.au Phone: 02 9391 2400

BRISBANE Administrative Appeals Tribunal GPO Box 9955 Brisbane QLD 4001

Email: Brisbane.Registry@aat.gov.au Phone: 07 3361 3000

The AAT also has a freecall telephone service: 1300 366 700

DECISIONS WITHIN THE ACT

Decision under Section	Made by	Subject: A decision
14(4)	Director	to include a chemical in the confidential section of the Australian Inventory of Chemical Substances five years after the issuing of an assessment certificate.
15AA(7)	Director	to include or not include a chemical in the Inventory [along with] specified particulars [under the power to include previously regulated chemicals in the Inventory]
17(4)	Director	on whether to treat an applicant as the holder of a confidence about a chemical.
18A(2), 19(9)	Director	to reject a person's reasons against the transference of a chemical from the confidential to the non-confidential section of the Australian Inventory of Chemical Substances.
20AA(6)	Director	to remove a chemical wrongly included in the Australian Inventory of Chemical Substances.
20E(3)	Director	that an application for listing an eligible chemical should be refused.
21H(1)	Director	to refuse the application for a Commercial Evaluation Permit on the grounds that the quantity requested is not reasonably needed.
21H(2)	Director	to refuse the application for a Commercial Evaluation Permit on the grounds that the period requested exceeds one year.

21L	Director	to use specified conditions in a Commercial Evaluation Permit.
21U(3)	Director	to refuse an application for a Low Volume Chemical Permit.
21W(3)	Director	to grant a Low Volume Chemical Permit subject to specified conditions.
21W(4)	Director	to impose further conditions on a Low Volume Chemical Permit or to revoke or vary conditions already imposed.
21W(6)	Director	to cancel a Low Volume Chemical Permit.
24(1)	Director	to waive the requirements of the notification statement in the case of a chemical listed on a recognised international inventory of chemicals.
24(3)	Director	allowing the variation of information normally required by the Schedule in the notification statement.
24(4)	Director	to waive the requirements of the notification statement where particular matters specified in the Schedule are irrelevant, or unnecessary, for the assessment of the chemical.
27(1)	Director	to request further information about a matter relating to a requirement in the Schedule.
27(2)	Director	to request further information which is additional to the requirement in the Schedule, and

		which is necessary to complete an assessment.
27(4)	Director	that a notifier has complied with a notice to give additional information for the assessment of the chemical.
28(2)	Director	to suspend consideration an assessment until the notifier supplies further information required for the evaluation of the chemical.
30(1)	Minister	to grant to a notifier a permit to introduce a chemical before the assessment certificate is given.
30(3)	Minister	that information be published relating to a chemical which is subject to a permit.
30(5)	Minister	on conditions specified in a permit allowing a chemical to be introduced before an assessment certificate is given.
30A(3)	Director	not to grant an Early Introduction Permit.
30C(1)	Director	to revoke an Early Introduction Permit.
31(3)	Minister	to grant an additional 90 days in which to complete a thorough assessment and report.
37(2)(b)	Director	to grant an additional 90 days in which to complete a thorough assessment and report.
40(6)	Director	on varying a full public report as requested.

40F(3)(b)	Director	to refuse to vary an assessment report as requested.
44(1)(d)	Director	on whether the assessment under an approved foreign scheme is relevant to Australia.
44(2)(b)	Director	to adopt a report, other information and documents given under an approved foreign scheme.
44(5)	Minister	to grant an additional 90 days to complete an assessment report based on information provided under an approved foreign scheme.
51(1)	Minister	to declare a Priority Existing Chemical (PEC).
52	Director	that a chemical was wrongly included in Australian Inventory of Chemical Substances (AICS).
57(6)	Minister	to extend the period of six months to 12 months to complete a thorough assessment report for a PEC.
58(3)	Director	concerning information to be given for the assessment of a PEC.
60E(5)	Director	to refuse to vary a draft assessment report.
61(2)	Minister	to prohibit a particular activity involving a declared PEC.
65(2)	Director	to require a Secondary Notification.

67(1)	Minister	to suspend an assessment certificate or introduction permit, or to prohibit continuing introduction of a chemical, upon failure to comply with a Secondary Notification requirement.
68(6)	Minister	to grant an additional period of up to 90 days to complete a thorough assessment and report for a chemical subject to Secondary Notification.
69(1)	Director	to require persons who are not required to give a Secondary Notification of a chemical to supply information to assist in the thorough assessment of that chemical.
73(6)	Director	to revoke an assessment certificate because NICNAS has not been informed of a change in the holder of the certificate.
75(1)	Director	to allow specific items of information to be exempt from publication.
79(a)	Director	to disclose confidential information in the public interest.
80G(2)	Director	to refuse an application for registration.
80K(5)	Director	to refuse an application for renewal of registration.
80QA(1)	Director	on assessment of a registration charge.
80QC(3)	Director	in response to a reconsideration or review of an

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2.20 APPENDIX T: WEBLINKS USED IN THIS HANDBOOK

This appendix contains links to many of the sources of information used throughout the Handbook.

The links are to websites from which helpful information related to the notification of industrial chemicals can be sourced.

Sections of this appendix:

- NICNAS weblinks
- Websites of other Australian Government regulators, Departments and agencies
- International bodies

Note: This appendix is still under construction.

2.20.1 NICNAS

Note: This appendix is still under construction.

Weblinks for all addresses to be added when new NICNAS website is in operation.

NICNAS: www.nicnas.gov.au

NICNAS New Chemicals and other forms:

NICNAS forms:

NICNAS New Chemicals notifications fees and charges:

NICNAS registration fees and charges:

AICS:

Cosmetics Guidelines:

2.20.2 OTHER AUSTRALIAN GOVERNMENT REGULATORS, DEPARTMENTS AND AGENCIES

Note: This appendix is still under construction.

Links to all relevant Australian Regulatory agencies are provided in the Chemicals in Australia – Who's Who guide on the NICNAS website at: weblink to be advised

Administrative Appeals Tribunal (AAT): http://www.aat.gov.au).

Safe Work Australia documents: www.safeworkaustralia.gov.au/swa/AboutUs/Publications/NationalStandards/ IndexofNationalStandardsCodesofPracticeandrelatedGuidanceNotes.htm Standard for the Uniform Scheduling of Medicines and Poisons enforces the Poisons Standard: </www.tga.gov.au/ndpsc/susdp.htm>

National Association of Testing Authorities-testing standards - see: www.nata.asn.au/

2.20.3 RELEVANT INTERNATIONAL BODIES

Note: This appendix is still under construction.

Stockholm Convention

Chemical Abstracts Service (CAS)

OECD

Good Laboratory Practice (OECD)

International Organization for Standardization (ISO)

International Union for Pure and Applied Chemistry

European Union (EU) Existing chemical inventory

This inventory—the European Inventory of Existing Chemical Substances (EINECS)—can be searched by using the chemical name or EINECS numbers. This site is useful for identifying the CAS number when an EINECS number is available.

United States Environment Protection Agency (USEPA) Aggregated Computational Toxicology Resource

This site provides a range of data including CAS RNs and toxicological information.

Cosing Database search page

This European Commission searchable database has information on cosmetic ingredients. Contains CAS RNs, and International Nomenclature Cosmetic Ingredient names and numbers.

National Library of Medicine

This United States site lists chemicals and available toxicity information. It is useful for listing chemicals that are not on major inventories.

Material Safety Data Sheet (M)SDS-Search

This (Material) Safety Data Sheet ((M)SDS) site provides safety data and CAS RNs.

National Institute of Standards and Technology Chemistry WebBook

United States Environmental Protection Agency's EPI Suite (United States Environmental Protection Agency 2008, Estimation Programs Interface Suite[™] for Microsoft® Windows, v3.20)