

Are medical devices containing DEHP-plasticized PVC or other plasticizers safe for neonates and other groups possibly at risk?

→ WHAT IS DEHP AND WHY IS IT USED?

DEHP (di-(2-ethylhexyl) phthalate) is a phthalate, a chemical substance used to soften plastics like PVC (Polyvinyl Chloride). Phthalates are used in medical devices such as blood bags, tubing, catheters and disposable gloves to make materials more pliable and comfortable to use.

→ WHAT ARE THE CONCERNS ABOUT DEHP?

The problem is that DEHP, like other phthalates, leaches out of the device it is used in and dissolves into fluids, like blood or liquid nutrients, or comes in contact with the skin, like through wearing gloves. This raises concerns about possible health effects, but surprisingly, can also serve a useful purpose. When used in blood bags, for example, DEHP leaches into the blood being stored and acts as a stabiliser, helping to preserve the blood for a longer time.

But, although DEHP helps keep blood stable in storage, what happens when DEHP gets inside the body? Well, nearly everyone already has DEHP inside their bodies, mainly from exposure through diet (from food packaging), and indoor dust and air. This amount of exposure, however, is usually well below what has been set as the Tolerable Daily Intake.

Having multiple exposure sources makes it difficult to study DEHP exposure through medical devices in isolation - and all the more important to be vigilant about overall exposure levels.

→ WHAT DO STUDIES SHOW?

Many studies have explored what effect DEHP might have on the body's reproductive, hormonal and immunity systems as well as its potential to cause cancer or behavioural changes.

Study results have led to DEHP being classified as a 1B toxin to the reproduction system. The 1B rating means that results were mainly based on animal data. These studies also showed that immature young animals are more susceptible to testicular toxicity by DEHP than older mature animals. In addition DEHP seems to cause more severe reproductive toxicity than alternative plasticizers.

Rodents are more susceptible to male reproductive toxicity than non-human primates. In humans, in vitro testing on testis tissue from male foetuses had no effect whereas DEHP exposure suppressed testosterone production in testis tissues from adult men. As with any in vitro testing, where studies are done on isolated cells/tissues, scientists know that results might differ if the cells and membranes were inside the body. Indeed, human studies looking at various possible effects including testosterone production and semen quality were either inconclusive or inconsistent.

Again based on animal tests, DEHP was classified as possibly carcinogenic because DEHP can cause liver cancer in rodents, through a mechanism that is relevant for rodents but not for man. Although the results of animal studies cannot be extrapolated to human beings, the possibility of DEHP causing liver cancer in humans through other mechanisms cannot be ruled out.

DEHP also seems to have the potential to interact with the immune system under certain exposure conditions, for example when the exposure is through the blood stream, as when medical devices are used intravenously.

→ WHAT'S BEING DONE TO REDUCE EXPOSURE?

A Tolerable Daily Intake value of DEHP was established by the European Food Safety Authority at 48 µg per kg bodyweight per day, based on the No Observed Adverse Effect Level (NOAEL) for reproductive toxicity in rats. This TDI value was rounded up to 50 µg per kg

bodyweight per day. This means that the intake of that dose every day, over an entire lifetime, does not compromise human health.

The TDI is based on a lifelong continuous exposure, not on the short-term exposure involved in most medical treatments, and can be considered a protective reference value for exposure to medical devices. When DEHP exposure is far below the TDI, the risk can be considered negligible.

Adult haemodialysis patients have the highest exposure to DEHP because the TDI is exceeded during their long and intense treatments. Neonates and infants (especially those in Neonatal Intensive Care Units) also have high exposure due to multiple treatments they require, and they are at greatest risk because of their relative low body weight and developmental stage. Bear in mind, that many interventions that result in phthalate exposure also save lives, so they should not be avoided, although exposure to phthalates should be reduced as much as possible.

Alternative materials are being developed as potential replacements for DEHP, but more data are needed to better understand their leaching properties, and in some cases their potential toxicity, as well as their impact on the medical effectiveness of treatments.

This fact sheet is based on the Opinion of the independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): 'The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk (2015 update)' **June 2015**

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