Diethylhexyl phthalate (DEHP)

This fact sheet is a summary of the Priority Existing Chemical (PEC) report at the time it was assessed and published. More information on the chemical can be found in the Inventory Multi-tiered Assessment and Prioritisation (IMAP) human health report.

CAS No: 117-81-7

Diethylhexyl phthalate – known as DEHP – was declared for public health risk assessment as a Priority Existing Chemical in March 2006 by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the *Industrial Chemicals (Notification and Assessment) Act 1989*.

The decision to assess DEHP was based on:

- the ubiquitous use of DEHP and other phthalates (phthalates, or phthalate esters, are specific compounds of phthalic acid used mainly as plasticisers (plastic softeners) in industrial and consumer products
- the potential for adverse health effects – particularly reproductive effects – from exposure to DEHP leaching from products, especially for sensitive sub-populations such as children, and
- concern in Australia and current restrictions overseas for the use of DEHP in certain consumer products.

The purpose and scope of the assessment was to determine the risks to adults and children from DEHP in consumer applications with particular potential for repeated or prolonged exposure. The consumer uses of DEHP for which public health risk assessments were conducted were cosmetics and children's toys and childcare articles.

Uses

DEHP is mainly used worldwide as a plasticiser (plastic softener) for a range of polyvinyl chloride (PVC) industrial and consumer products.

Reflecting worldwide use patterns, in Australia DEHP is used in industrial and consumer applications, mainly as a plasticiser for PVC products, but also in other polymers for coatings, adhesives and resins. DEHP is also imported as a component of cosmetics - mainly perfumery products - with typical concentrations of approximately 0.05%. It is also reported to be used in toys, but detailed information on content is lacking.

Health effects

DEHP is rapidly and almost completely absorbed via the oral and inhalation routes. In contrast, dermal (skin) absorption is low and is unlikely to exceed 5%.

DEHP has low acute toxicity via all routes and low skin and eye irritation potential. There is no evidence of skin sensitisation for DEHP in animals or humans.

In rodents, repeated exposure to DEHP is associated consistently with adverse effects on the liver, kidneys and the reproductive system, mainly in males. Mononuclear cell leukaemia (MCL) and Leydig cell (testosterone secreting cells found adjacent to the seminiferous tubules in the testicle) tumours were also observed inconsistently in studies with rats.

Based on an understanding of the mechanisms of toxicity, the liver effects and MCL observed in rodents following DEHP exposure are regarded as species specific and not relevant to humans. For the kidney effects and Leydig cell tumours seen in rodents, relevance to humans cannot be excluded. However, data are insufficient to determine an association between DEHP

exposure and Leydig cell tumours.

Full details of the toxicological studies with DEHP are provided in NICNAS's DEHP Priority Existing Chemical Report, available from the NICNAs website.

Human studies of the potential effects of DEHP on fertility and development are limited. Overall, currently they do not identify consistent associations between DEHP exposure and reproductive parameters either in adults or children.

The reproductive effects of DEHP seen in rodents are considered relevant to humans based on consistent occurrence of these effects across rodent species and the underlying common modes of action (changes in steroidogenesis (production of steroids) and expression of genes critical for reproductive system development) between rodents and humans.

Overall, animal studies support a NOAEL (no observed adverse effect level) for fertility and developmental effects of DEHP (the most sensitive toxicological effect observed) in the dose range of 1–10 milligrams per kg bodyweight per day.

Public exposure and health risk

Use of toys and childcare articles by children

The main route of exposure of children to DEHP from toys and childcare articles is through oral exposure during intentional or inadvertent mouthing, sucking and chewing of these articles. Exposure through the skin during handling of these articles is minimal.

Given the low acute toxicity, low skin and eye irritation and the absence of skin sensitising potential for DEHP, the risk of adverse acute effects for children from handling toys and childcare articles was assessed as low. However, risk estimates for reproductive effects from mouthing, sucking and chewing of these articles indicated a concern, especially for those children whose mouthing, sucking and chewing behaviour may be more excessive than typical.

Use of cosmetic products by the general population

The main route of exposure to DEHP from use of cosmetics is through dermal contact. Inhalation exposure is also possible from products applied as aerosols. Current information does not indicate use of phthalates in products most prone to accidental oral ingestion such as toothpastes, mouthwashes, lipsticks and lip-glosses.

Given the low acute toxicity of DEHP, the risk of acute adverse effects for consumers exposed to DEHP through cosmetics was assessed as low. However, risk estimates for reproductive effects from use of multiple products containing DEHP indicated a concern for the general population, especially for individuals most at risk of reproductive developmental effects in their progeny i.e. pregnant and breastfeeding women.

Recommendations

The report contains two recommendations:

1. Regulation of DEHP in toys and childcare articles: the Australian Competition and Consumer Commission (ACCC) consider appropriate regulatory measures to limit exposure to DEHP resulting from the use of DEHP in toys and childcare articles where significant mouth contact may occur.
2. Poisons scheduling for public health: scheduling the cosmetic use of DEHP in Appendix C of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) to limit the potential exposure of the public to DEHP from use in cosmetics.Appendix C lists chemicals prohibited for sale, supply and use for specified applications.