NICNAS Existing Chemicals Information Sheet

Draft Diethyl Phthalate (DEP) September 2011

What is Diethyl Phthalate and how is it used?

Diethyl phthalate (DEP) – CAS No 84-66-2 – is a member of the group of phthalic acid esters known as phthalates. DEP belongs to the Low Molecular Weight (LMW) group of with a molecular weight of < 250 Dalton and comparatively low viscosity and high volatility.

DEP is used, primarily as:

- a solvent and/or vehicle for fragrance in perfumes, cosmetics, personal care products, and nail polishes
- an alcohol denaturant[1] in toiletries, detergents and insecticides, and
- a plasticiser in plastic tools, automotive parts, toothbrushes, food packaging, medical tubing, soft plastic toys and child care articles.

DEP can also be used for non-polymer uses including as a dye application agent, adhesive and sealant.

In Australia DEP is used mainly in epoxy resins, cosmetics, personal care products and perfumes, with a small proportion in children's toys and as an alcohol denaturant.

Background to the NICNAS assessment

The decision to assess DEP was based on:

- ubiquitous use of phthalates, including DEP, as solvents and plasticisers in industrial and consumer products
- consumer products being potentially significant sources of repeated and long-term exposure of the public to DEP through their use in cosmetic and personal care products and toys
- concerns regarding potential adverse health effects, particularly reproductive and developmental effects, from DEP exposure, and
- current overseas activities including reassessment and review of the use of phthalates including DEP in certain consumer products.

NICNAS's assessment aimed to determine the health risks to adults and children from the use of DEP in consumer products such as cosmetics, toys and child care articles, particularly after repeated or prolonged exposure.

Health effects

Data from animal studies indicate that DEP is rapidly and almost completely absorbed following oral or inhalation exposure, with 100% bioavailability by these routes. Bioavailability via dermal (skin) absorption is not likely to

[1] A substance that changes the nature of another substance

exceed 10% in humans. Tissue distribution of DEP is widespread including foetal tissues but there is no evidence of accumulation. DEP is also rapidly metabolised to monoethyl phthalate (MEP) and excreted, predominantly via the urine.

In rodents, DEP has low acute toxicity via all routes, low eye and skin irritation / sensitising potential. In patients with dermatitis and other skin diseases, there are case reports of sensitisation to perfumes and plastic articles.

Available data do not support a genotoxic or carcinogenic potential for DEP, and DEP does not appear to be a potent testicular toxin in animal studies. However, DEP alters certain fertility-related parameters and induces developmental effects in newborn rodent pups. While human studies are limited, the adverse effects on fertility parameters and development are considered relevant to humans, where the exposure level of DEP is high and within a critical window of development.

Public exposure and health risk

Public health risks from DEP exposure were assessed by using a margin of exposure (MOE) approach for two exposure scenarios:

Use of toys and child care articles by children

The main route of exposure of children to DEP 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 eye and skin irritation and sensitising potential for DEP, the risk of adverse acute effects for children arising from handling toys is negligible. The risk of DEP-induced systemic toxicity and reproductive/ developmental effects, both of which are potentially associated with repeated handling and mouthing of toys containing DEP by children is considered negligible.

Use of cosmetic products by the general population

The main route of exposure to DEP from use of cosmetics in the general population is through dermal contact. Inhalation exposure is also possible from products applied as aerosols. Current information does not indicate use of DEP in products most prone to accidental oral ingestion such as toothpastes, mouthwashes, lipsticks and lip-glosses. In the absence of Australian specific data, exposure scenarios of daily use of combined cosmetic products were derived based on European use patterns of cosmetics.

Given the low acute toxicity, low irritation and sensitising potential for DEP, the risk of adverse acute effects for consumers exposed to DEP through cosmetics is very low.

Health risks for the general population were estimated for both systemic toxicity and reproductive / developmental effects, both of which are potentially associated with the repeated use of cosmetic products containing DEP, especially of leave-on products.

Overall, the risk estimates for general systemic toxicity indicate low concern for both children and the general population from use of cosmetic products containing DEP at the current reported levels. However, the risk of reproductive effects in adults through combined use of body lotion with DEP content above 0.5% and other cosmetics containing DEP is of concern. The risk of reproductive effects in children is also of concern, particularly in newborns, through use of body lotion alone when the DEP content is above 0.5%.

Effects from cumulative exposures can arise through use of cosmetics containing multiple phthalates acting on the same biological targets, from the effects of other components in a mixed phthalate used in toys and child care articles, and from combined exposure scenarios or multiple sources. Risks from cumulative exposure to DEP and DEHP for the two exposure scenarios considered (cosmetics and toys and child care articles) is not likely to be higher than that for DEP alone as risk management measures have been implemented for use of DEHP in cosmetics and toys.

Recommendation

It is recommended that the Delegate for Chemicals Scheduling consider listing DEP in body lotion preparations at greater than 0.5% in Appendix C of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) to limit the potential exposure of the public, particularly young children to high concentrations of DEP from use in these cosmetics.

More information

➔ In 2008, NICNAS released hazard assessments on 25 phthalates (www.nicnas.gov.au/Publications/CAR/Other/Phthalates.asp) and also released a phthalates compendium providing summary and comparative information on the use and hazards associated with 24 *ortho*-phthalates (www.nicnas.gov.au/Publications/CAR/Other/Phthalate%20Hazard%20Compendium.pdf).

➔ National Industrial Chemicals Notification and Assessment Scheme – NICNAS – contact NICNAS staff for assistance on Free Call 1800 638 528.

➔ Legislation mentioned in this information sheet can be found on the Australasian Legal Information Institute web site at www.austlii.edu.au.