



NICNAS Existing Chemicals Information Sheet

Diisononyl Phthalate (DINP)

April 2012

What is DINP?

Diisononyl phthalate (DINP – CAS No 68515-48-0 and 28553-12-0) is a member of the group of esters commonly known as phthalates, used as solvents and plasticisers worldwide.

DINP was one of the nine phthalates declared for Priority Existing Chemical (PEC) assessment under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) in March 2006. The declarations were for public health risk assessment of their use in toys, child care articles and cosmetics.

After public and industry comment, in 2008 NICNAS released a series of hazard assessments on 25 phthalates (nicnas.gov.au/Publications/CAR/Other/Phthalates.asp). NICNAS also released a *Phthalates Hazard Compendium* (nicnas.gov.au/Publications/CAR/Other/Phthalate%20Hazard%20Compendium.pdf) which summarised and compared the uses and hazards associated with 24 ortho-phthalates, including DINP.

DINP is imported into Australia as a raw material or as a mixture for local formulation and in ready-to-use products. In 2002, the total volume of DINP imported for industrial uses was between 1000 and 10 000 tonnes, but by 2004 that had dropped to around 600 tonnes annually. There are no reports of DINP being manufactured as a raw material in Australia.

DINP is NOT listed in the Safe Work Australia List of Designated Hazardous Substances contained in the *Hazardous Substances Information System* (HSIS, <http://hsis.ascc.gov.au>), the *Standard for Uniform Scheduling of Medicines and Poisons* (SUSMP, www.tga.gov.au/industry/scheduling-poisons-standard.htm), or the National Transport Commission's *Australian Dangerous Goods Code* www.ntc.gov.au/viewpage.aspx?documentid=01147

There are currently no restrictions on the manufacture, import or use of DINP in Australia.

How is DINP used?

DINP is used in a diverse range of industrial products such as electrical wire and cables, flexible PVC sheeting, coated fabrics, automotive parts, building and construction (waterproofing), vinyl flooring, footwear, sealings, lamination film and in PVC-containing school supplies (such as scented erasers and pencil case).

DINP can be blended into a paste (plastisol), for coating (tapaulins, synthetic leather and wall covering) and rotomoulding (toys, play and exercise balls, hoppers) applications. DINP is also used in non-polymer applications such as adhesives, paints, surfactants and printing inks for T-shirts. It can also be found in plasticine, in several categories of toys (plastic books, balls, dolls and cartoon characters) and in baby products (changing mats/cushions) which could be placed in the mouth. DINP has also been found in other articles that may come into contact with children (clothes, mittens, coverage of pacifiers, PVC-containing soap packaging and shower mats).

However, in Australia DINP is used mainly as a plasticiser (plastic softener) for polyvinyl chloride (PVC) products and in other polymers for adhesives, laminators, resins, surfactants and screen printing inks, with a small proportion used in children's toys. In imported PVC toys, DINP is present at a concentration range of between 0.005% and 35%.

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Information on the use of DINP provided by Australian industry does not indicate that it is used in cosmetic and personal care products and there was no available information to indicate that DINP is used in cosmetics overseas. In addition, there is no available information to support the possibility that high molecular weight phthalates such as DINP might be substituted for low- and mid-molecular weight phthalates commonly used in cosmetics.

Background to NICNAS assessment

The purpose and scope of the DINP assessment was to determine the health risks to adults and children from the use of DINP in consumer products such as toys and child care articles, particularly after repeated or prolonged exposure.

The decision to declare DINP for assessment was based on:

- ubiquitous use of phthalates including DINP as plasticisers in industrial and consumer products
- consumer products being potentially significant sources of repeated and long-term exposure of the public to DINP through migration and leaching from the products
- concerns regarding potential adverse health effects, particularly reproductive and developmental effects, from DINP exposure, and
- current restrictions (interim) overseas for the use of phthalates including DINP in certain consumer products.

As a precautionary measure, restrictions (either interim or permanent) have been implemented in EU, USA and Canada on the use of DINP in toys and child care articles that can be placed in the mouth by children. Currently, Australia, Asia and other non-EU countries have no restrictions on the use of DINP in toys and child care articles.

Public exposure and health risk

NICNAS used a margin of exposure (MOE) approach in its assessment of public health risks from DINP exposure. Because there is no evidence of DINP being used in cosmetics in Australia or overseas, the assessment covered only the use of toys and child care articles by children.

Use of toys and child care articles by children

For the toy and child care articles exposure scenario, two exposure routes for children to DINP were considered: dermal exposure during normal handling of toys and child care articles, and oral exposure during mouthing, sucking and chewing of these products.

NICNAS used overseas *in vivo* and *in vitro* studies to determine migration rates for DINP from chewing. These studies indicated that children's mouthing behaviour, and therefore the potential for oral exposure, is greatest between six and 12 months of age, and a reasonable worst-case exposure scenario considered a maximal mouthing time of three hours per day, with a typical exposure scenario based on an average daily mouthing time of 49 minutes per day.

DINP has low acute toxicity, low skin and eye irritation and skin sensitising potential, so the risk of adverse acute effects for children arising from handling toys is low. NICNAS estimated health risks for children for both systemic (liver and kidney) toxicity and reproductive/developmental effects – both of which are potentially associated with repeated handling and mouthing of toys containing DINP. Overall, the risk estimates indicate low concern for children at the current reported levels of DINP in toys and child care articles.

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The effects of cumulative exposures to phthalates can arise 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 of children to DINP in toys and child care articles with or without DEHP at maximum 1%, together with co-exposure to another phthalate, DEP in cosmetics at maximum 0.5% in body lotions, are considered low, because cumulative MOEs for the three critical health effects identified are all above 100. An MOE of greater than 100 in risk characterisation is usually regarded as an indication of low concern as it encompasses the conservative default uncertainty factors of 10 each for intraspecies and interspecies variability.

Risks from cumulative exposure to DINP and other phthalates will be considered on completion of other phthalate PEC assessments, and if required, further risk mitigation measures may be recommended.

Conclusion / recommendation

Current risk estimates do not indicate a health concern from exposure of children to DINP in toys and child care articles even at the highest (reasonable worst-case) exposure scenario considered.

The risks from cumulative exposure of children to DINP in toys and child care articles with or without DEHP (at maximum 1%) together with co-exposure to DEP (at maximum 0.5%) in body lotions were found to be acceptable, based on current public health risk management measures.

No additional recommendations to the existing controls in place for the public health risk management for the use of DINP in toys and child care articles are required based on the findings of this assessment.

Secondary notification

Under Section 64 of the Act, secondary notification of a chemical that has been assessed may be required if there is a change of any circumstances that may warrant a reassessment. This could include:

- additional information becoming available on the adverse health effects of DINP
- DINP being used in cosmetic products
- additional sources of public exposure to DINP other than toys and child care articles and cosmetics being identified, or
- additional information or events that change the assumptions for estimating the cumulative risk in this assessment.

The Director of NICNAS must be notified within 28 days of the introducer becoming aware of any of the above.

More information

→ Hazard assessments on 25 phthalates (www.nicnas.gov.au/Publications/CAR/Other/Phthalates.asp)

→ *Phthalates Hazard Compendium* – 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.