



## NICNAS Existing Chemicals Information Sheet

### Phthalates

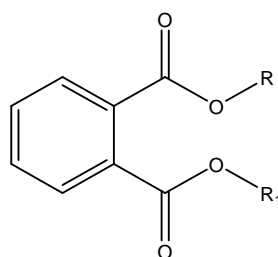
December 2009

#### What are phthalates?

Phthalates (pronounced "thal-ates") comprise a large family of chemicals characterised by a benzene ring structure linked to two side chains.

Generally, the term phthalate is used to identify the *ortho* chemical configuration, where side chains arise from adjacent carbon atoms of the benzene ring, such as depicted in Figure 1. Numerous phthalate chemicals exist and are distinguished on the basis of the chemical structure of the side chains.

Figure 1 – Typical structure of *ortho*-phthalates



#### What are phthalate chemicals used for?

Phthalate esters are the most common group of chemicals used as plasticisers (plastic softeners) worldwide, most frequently for polyvinyl chloride (PVC) plastics. Plastics containing phthalates are used in both industrial and consumer applications such as electrical cable insulation, flooring, carpet backing, automotive parts, footwear, children's toys and exercise balls.

Phthalates are also used as solvents in lubricants, paints, adhesives, inks, cosmetics and other household products.

#### What are the human health issues associated with phthalate chemicals?

Phthalates used as plasticisers are added to plastics to provide molecular "lubrication" which then imparts softness and malleability to the plastic. For this function, they must remain chemically unbound within the plastic. Unbound phthalates can migrate and leach from plastics, with the potential for human exposure from the use of phthalate-containing products.

# NICNAS Existing Chemicals Information Sheet

In addition to the potential for human exposure from the use of products, some phthalate chemicals are known to possess toxic effects in animals, for example, reproductive effects in the developing young. The question arises as to whether health effects seen during animal testing are likely to occur in humans from the use of phthalate-containing products.

## How is NICNAS assessing phthalate chemicals?

In Australia in 1999, the ubiquity of phthalates in plastic products and concern over health effects led to phthalates as a chemical group being nominated to the NICNAS Candidate List. Chemicals requiring assessment as Priority Existing Chemicals (PEC) are chosen from the Candidate List on a priority basis.

In response to sustained concerns over potential human health effects, NICNAS embarked on a two phase regulatory assessment strategy for phthalates. The first phase involved identification of those phthalates likely to be used or in actual use in Australia, followed by assessment of these phthalates for their comparative level of hazard (toxicity). The second phase consists of individual public health risk assessments for phthalates used in consumer applications with the potential for repeated or prolonged human exposures, especially of the young. Nine phthalates have been selected for public health risk assessments.

### Phase 1

#### Hazard assessments

As a result of international regulatory reviews, literature searches and a call for information from industry in 2004 and 2006, 24 *ortho*-phthalates and a terephthalate (dimethyl terephthalate) were identified as in current or potential industrial use in Australia. Consideration of both the actual and potential use of phthalates is important as there are many phthalate chemicals and some can be substituted for others in certain applications. Hazard assessments for these 25 phthalates have now been completed by NICNAS.

These individual hazard assessments, accompanied by a Phthalate Hazard Compendium in which the toxicities across 24 *ortho*-phthalates are summarised and compared, were released in 2008 and are available from the NICNAS website. For all 24 *ortho*-phthalates, the Compendium contains summarised information on use, physicochemical properties and toxicity. Data gaps are also highlighted.

The hazard assessments and Phthalate Hazard Compendium provide a unique, comparative information source that can assist industry in the identification of phthalates with lower toxicity profiles.

Available data indicate that phthalates which are absorbed orally, or via the skin and lungs, are rapidly metabolised and excreted through the urine and faeces. The toxicity of different phthalates varies significantly, being related principally to side chain length (see Figure 1). The toxic effects in experimental animals (rodents) are associated predominantly with the "transitional" phthalates possessing side chains with carbon backbones of C4-6. In addition, phthalates with side chains deviating from the common single bonded branched or linear carbon structures show toxicity profiles that often differ from other phthalates of similar molecular weight. This indicates that backbone length alone without regard for additional structural features in the side chains cannot be relied on solely as predictive of potential toxicity.

# NICNAS Existing Chemicals Information Sheet

## Phase 2

### Risk assessments

NICNAS is undertaking an analysis of the health risks from the use of nine phthalate chemicals in consumer applications associated with repeated or long-term exposure, especially of the young. These consumer applications are children's toys, childcare articles and cosmetics.

Nine *ortho*-phthalate chemicals – diethyl hexyl phthalate (DEHP), diisodecyl phthalate (DIDP), dimethyl phthalate (DMP), diisonyl phthalate (DINP), dibutyl phthalate (DBP), butylbenzyl phthalate (BBP), di-n-octyl phthalate (DnOP), diethyl phthalate (DEP), and bis(2-methoxyethyl) phthalate (DMEP) are currently undergoing public health risk assessments for these specific uses. These phthalates were declared as Priority Existing Chemicals (PECs) on 7 March 2006.

The first of these public health risk assessments (DEHP) has now been released to applicants for corrections, the first step prior to release for public comment. The draft report will be released for public comment at the end of January 2010 for a 28 day public comment period.

Several additional phthalate risk assessments (DINP, BBP, DBP) are scheduled for release during 2010.

### **Overseas activities on phthalate chemicals**

Overseas, regulatory restrictions have been enacted for individual phthalate chemicals for specific consumer applications.

In the European Union (EU), in 2005 DEHP, DBP and BBP were restricted for use in cosmetics, because of their classification as CMR (carcinogen, mutagen or reproductive toxicity) substances. In the EU, any chemical classified as a CMR chemical is restricted for use in cosmetics.

Also in the EU, in 2007 DEHP, DBP and BBP were permanently restricted to a content of 0.1% w/w or less in all children's toys and childcare articles. Three other phthalates, DINP, DIDP and DnOP were restricted similarly for use in toys and childcare articles that can be mouthed by children, regardless of the age group designation of the toys. The restrictions for DINP, DIDP and DnOP, which have lower toxicity than DEHP, DBP and BBP and are not classified as CMR substances are more precautionary in nature. The restrictions arise particularly from diverging interpretations of available toxicity information and questions over the extent of likely human exposures given the unpredictability of child behaviour and uncertainties over the extent of use of certain phthalates in the market.

In the US, restrictions on these 6 phthalates in toys and childcare articles were recently enacted (2009). However, the Consumer Products Safety Commission is also currently reassessing DINP, DIDP and DnOP to determine whether the restrictions for these phthalates in toys and childcare articles should continue to apply. These restrictions do not extend to use in cosmetics.

Canada is currently also considering similar restrictions to the EU on these 6 phthalates for use in toys and childcare articles. There are no current restrictions on use in cosmetics.