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Scientific Facts on Diethylhexyl phthalate

Source document: ECB (2008)

Summary & Details:

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Context - Diethylhexyl-phthalate (DEHP) is a substance that is mainly used as an additive in plastics to make them more flexible.

Its widespread use in everyday and medical products has raised some concerns about its safety.

Does DEHP pose a risk to health or the environment?

	Introduction: What are phthalates?	.2
1.	What are the properties of diethylhexyl	
	phthalate (DEHP)?	.2
2.	How is DEHP used?	.2
3.	Can DEHP affect the environment?	.2
4.	How can humans be exposed to DEHP?	.3
5.	What health effects can DEHP cause in	
	laboratory animals?	.3
6.	Does DEHP pose risks to human health?	.3
7.	Are further research and additional risk	
	reduction measures needed?	.4
8	Conclusions	4

This Digest is a faithful summary of the leading scientific consensus report produced in 2008 by the European Chemicals Bureau (ECB): "Bis-(2-Ethylhexyl) Phthalate, DEHP), Summary Risk Assessment Report"

The full Digest is available at: https://www.greenfacts.org/en/dehp-dietylhexyl-phthalate/

- 1 This PDF Document is the Level 1 of a GreenFacts Digest. GreenFacts Digests are published in several languages as questions and answers, in a copyrighted user-friendly Three-Level Structure of increasing detail:
 - Each question is answered in Level 1 with a short summary.
 - These answers are developed in more detail in Level 2.
 - Level 3 consists of the Source document, the internationally recognised scientific consensus report which is faithfully summarised in Level 2 and further in Level 1.

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0. Introduction: What are phthalates?

Phthalates are widely used as additives in a wide range of plastics and other materials that are found in many consumer products. They make plastics, such as PVC, soft and flexible. As they are not chemically bound to plastics, they can be released from consumer products. There is public concern about phthalates because of their widespread use and occurrence in the environment as well as their potential effects on human health.

There is a wide range of different phthalates, each having specific properties, uses, and health effects. In the European Union, five of the most widely used phthalates have been reviewed by the European Chemicals Bureau (DEHP, DBP, DINP, DIDP, and BBP).

1. What are the properties of diethylhexyl phthalate (DEHP)?

DEHP is a chemical form of dioctyl phthalate or DOP

DEHP has the same core structure as DBP, DIDP and DINP, but has longer, branched side chains attached, each having 8 carbon atoms.

DEHP is a colourless oily liquid. It is soluble in fat and not very soluble in water.

2. How is DEHP used?

In 1994, an estimated one to four million tonnes of DEHP were produced in the world. Since then, in the European Union the use of DEHP has decreased to around two thirds. Like DBP, DIDP and DINP, DEHP serves mainly as a plasticiser in polymers, such as PVC, that are used to manufacture a wide range of products including cables, profiles, flooring, roofing and equipment.

3. Can DEHP affect the environment?

- 3.1 DEHP can be released into the environment at all stages of its life cycle: in production, distribution, processing, use, incineration and disposal. Most of the DEHP released into the environment is due to the use and disposal of flexible PVC products. DEHP is not chemically bound to the polymer products that it is added to.
- 3.2 DEHP breaks down slowly in water, however it can remain for a long time in soil and sediment. It accumulates in organisms living in sediment and soil.
- 3.3 Concentrations of DEHP are particularly high in waste water, surface water, sediment, and soil close to industrial sites where DEHP is either produced or processed.
- 3.4 DEHP does not appear to have adverse effects on organisms in the environment. It is not toxic to microbes, plants or animals, except to fish if present at high concentrations in fish food.
- 3.5 The European Union Risk Assessment Report (the source of the present summary) concluded that because of the presence of DEHP in water, sediment and soil around industrial sites:
 - further information is needed on possible risks for organisms living in sediment and soil. Risk reduction measure taken because of effects on the food chain

- involving these organisms (see below) may, however, eliminate the need for further information.
- there may be adverse effects in food chains of organisms living in water or on land and there is a need for risk reduction measures.
- risk reduction measures already being implemented should be taken into account.

4. How can humans be exposed to DEHP?

Exposure of humans may occur because DEHP is present in the general environment, in the workplace and in consumer products

- 4.1 The highest exposures can occur in workplaces where DEHP or products that contain it are produced or processed. Workers are exposed through the air they breathe and through skin contact.
- 4.2 Exposure of the general public can be from various sources, such as indoor air, car interiors, PVC gloves, toys, medical equipment, and the general environment, including via breast milk and infant formula, and via food grown near production sites using DEHP. The highest exposures are through medical procedures, namely blood transfusions in newborns, and long-term haemodialysis in adults.
- 4.3 For those undergoing medical procedures for which medical equipment containing DEHP is used, exposure can be as high as, or slightly higher than that of workers producing DEHP or DEHP-containing products. Children exposed to toys and child-care articles can also have significant exposure levels.

Exposure from other sources is low.

Editor's note: DEHP has been banned in 2007 in the EU for usage in toys and childcare products.

5. What health effects can DEHP cause in laboratory animals?

DEHP is well absorbed by the body when swallowed or breathed in, but is poorly absorbed through the skin.

In laboratory animals DEHP mainly affects the testis and kidney Adverse effects on the embryo and fetus, particularly on the developing testis and on male sexual development, are considered to be of relevance to humans. In rodents, DEHP causes tumours in the testis and leukaemia but the relevance of these effect for humans is not known.

6. Does DEHP pose risks to human health?

Human exposures are compared with the highest exposures tested in laboratory animals and found to have no effect, in order to determine the margin of safety.

- 6.1 Workers are considered to be at risk from exposure to DEHP via inhalation and skin contact during production, processing or use of products containing DEHP, potentially affecting the testis, fertility, kidney, the embryo and fetus.
- 6.2 For other **adults** the only exposure that poses a potential risk is via treatment with medical equipment containing DEHP especially when it comes into direct contact with the blood. As for **workers**, the potential risks are for the testis, fertility, kidney, embryo and fetus. For **children**, there is similar concern from exposure to medical equipment as there is for adults and also concern due to exposure via toys and child-care articles.

Editor's note: DEHP has been banned in 2007 in the EU for usage in toys and childcare products.

6.3 There is concern that children living near sites of DEHP industrial production, processing or waste handling could experience negative health effects, including on the testis, fertility and kidney due to exposure via food. There is no concern for the rest of the general public exposed to DEHP via the environment, including breast-fed or formula fed infants.

7. Are further research and additional risk reduction measures needed?

The European Union Risk Assessment report concluded that, although certain risk reduction measures may already be in place, there is still a need for further information and research on/for limiting the risks on the environment, workers, children exposed via toys, child-care articles and medical treatment (transfusion and long-term haemodialysis) and for those living next to industrial sites.

- for the environment, there is a need for further information and/or testing and for limiting the risks, depending on the risk reduction measures already in place,
- for workers, there is a need to limit the risks, taking into account any risk reduction measures already in place,
- for children exposed via toys and child-care articles, there is a need to limit the
 risks, taking into account any risk reduction measures already in place, (Editor's
 note: DEHP has been banned in 2007 in the EU for use in toys and childcare
 products).
- for neonates and children undergoing transfusions and for adults undergoing long-term haemodialysis, there is a need to limit the risks, taking into account any risk reduction measures already in place, and
- for children exposed repeatedly via food grown locally near sites producing certain products containing DEHP, or exposed via food grown locally near sites recycling paper or municipal sewage treatment sites, there is a need to limit the risks, taking into account any risk reduction measures already in place,

8. Conclusions

Phthalates have played an important role in the creation of plastics and other materials that have many versatile uses in industry, in medicine and in consumer products.

In view of more recent research, raising concerns about possible environmental and health effects, the risks of exposure to phthalates are being kept under close review by national and international bodies.

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The reviews on DIDP, DINP, DBP and DEHP conclude that:

 more research may be necessary on the environmental effects of DIDP, DINP and DEHP;

- Children may be at risk through exposure from DIDP and DEHP in toys and child-care articles;
- Babies, children and adults undergoing certain medical procedures in which they are exposed to DEHP via medical equipment may be at a risk;
- in some workplaces, the exposure of workers to DBP and DEHP should be reduced;
- release of DBP in to the air from some workplaces should be reduced.