GreenFacts
Facts on Health and the Environment

DEHP

Scientific Facts on

Diethylhexyl phthalate

Source document:
ECB (2008)

Summary & Details:
GreenFacts

Level 2 - Details on Diethylhexyl phthalate

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/

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- 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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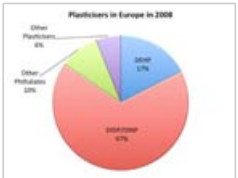
Introduction: What are phthalates?



[see Annex 1, p. 9]
Consumption of plasticisers in Europe in 2008

Phthalates are plasticisers that are added to other materials to make them softer and more flexible.

They are widely used in a range of polymers such as PVC that are found in a wide variety of consumer products including floor- and wall covering, furnishing, toys, car interior, clothing, hoses etc. Phthalates are also added to paints and lacquers, adhesives and sealants, printing inks etc.

Because phthalates are not chemically bound to the material they are added to, they can be released from the products that contain them, for instance into water and air. The emission of phthalates occurs during all the stages of the life cycle of a product from production, through use, to disposal.

A range of different phthalates exist, each having specific properties, applications, and potential health effects.

Five of the most widely used phthalates are di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP) and benzyl butyl phthalate (BBP). These phthalates have been assessed within an EU program on Risk Assessment for new and existing chemical substances.

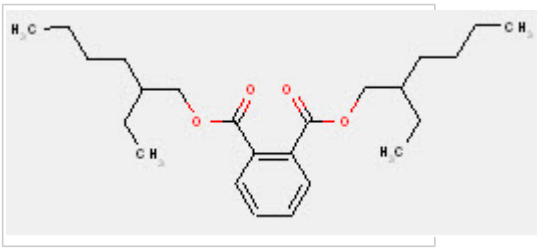
In Europe, between 1990 and 1995, the average annual consumption of plasticisers was 970 000 tonnes, of which 894 000 tonnes were phthalates. For comparison, the worldwide plasticiser consumption is estimated at 3.5 million tonnes.

The phthalates described in this digest are used mainly as plasticisers in PVC products.

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

DEHP is a colourless oily liquid that is soluble in fat and not very soluble in water. It is not very volatile so does not vaporise readily into the atmosphere.

Under the European Union classification system that applies to labelling of chemicals in commerce it is classified for human health as "toxic to reproduction" (may impair fertility, may cause harm to the unborn child).



The acronym DEHP refers to di(2-ethylhexyl) phthalate, which is also referred to as "bis(2-ethylhexyl) phthalate". It is an isomer (a specific chemical form) of "dioctyl phthalate".

2. How is DEHP used?

In 1994 an estimated one to four million tonnes of DEHP was produced globally Production volumes in the European Union have decreased, from 595 000 tonnes in 1997 to 221 000 tonnes in 2004. Over 95% of DEHP in the European Union is used as a plasticiser in polymers, mainly PVC. Flexible PVC containing DEHP has many uses including toys, flooring, cables, profiles, roofing, and in medical products such as blood bags and dialysis equipment.

DEHP is also used in polymers other than PVC, and in non-polymer products such as sealants, adhesives, paints, lacquers, printing inks and ceramics. It is estimated that around 800 plants in Europe use DEHP or preparations containing DEHP.

Editor's note: The plasticizer market has evolved significantly in the last few years since the publication of the source document. Non-phthalate have taken a growing part of the market. In 2011 they represented 22% of the European plasticizer market, and are projected to increase to 30% by 2020. Long-chain phthalates such as DIDP and DINP have been growingly replacing shorter-chain phthalates such DEHP on the European market, where DEHP accounted for 37% of the market in 2001, and was down to 13% by 2010. Source: European Council for Plasticisers and Intermediates (ECPI)

3. Can DEHP affect the environment?

3.1 When is DEHP released?

DEHP is released into the environment during production, transport, storage, use and disposal. DEHP is not tightly bound to the polymer used to make plastic or other products, and most of its release in the environment is from the use and final disposal of end-products.

3.2 What happens to DEHP released to the environment?

DEHP is released into air and waste water from sewage sludge and from solid waste. It enters the air as a vapour or as solid particles. DEHP breaks down quite rapidly in air. Its half-life in the atmosphere is estimated to be 1 day. It breaks down slowly in water, sediment and soil where there is less oxygen. DEHP is not broken down into simple chemicals – the main breakdown product is the monoester (mono-ethylhexyl phthalate or MEHP), that is known to have adverse effects on reproduction in mammals.

The results of laboratory tests indicate a high potential for bioaccumulation (increasing concentrations over time) of DEHP in organisms that live in water and it binds strongly to sediment, soil and sewage sludge. It does not bioaccumulate in plants.

3.3 What levels of DEHP are expected near the sources?

Predicted environmental concentrations (PECs) have been calculated for various environmental media located near sources of DEHP.

- At DEHP production sites, concentrations in surface water range from 1 to 220 µg/l and in sediment from 7.5 to 2045 mg/kg.
- Concentrations in surface water and sediment at non-polymer formulation and processing sites are predicted to be around half those at production sites.
- Concentrations in surface water and sediment at polymer processing sites are predicted to be lower, by around 10-fold or more, than the concentrations at production sites.
- Concentrations in surface water and sediment at sewage treatment plants and waste handling sites are lower still, up to 3.6 µg/l in surface water and up to 30 mg/kg in sediment.
- Predicted environmental concentrations in soil range up to 354 mg/kg at polymer processing sites, up to 103 mg/kg at non-polymer formulation and processing sites, and 3 mg/kg or less for sewage treatment plants and waste handling sites. No figures are given for soil at DEHP production sites.

3.4 What are the effects of DEHP on the environment?

Studies have shown that there are no adverse effects on organisms only exposed to DEHP via water, and at concentrations below the water solubility.

Concentrations of DEHP up to 160 mg/kg in food are without any effect on fish. However above this concentration, DEHP can have adverse effects on fish.

It does not have harmful effects on microorganisms in sewage sludge, up to at least 2000 mg/l.

No adverse effects have been observed in soil-dwelling organisms, up to at least 130 mg/kg soil.

The accumulation of the product in the food chain means that top predators might be more at risk. For those top predators, a concentration of 33 mg/kg of food is considered to be without adverse effects, based on tests showing damage to the testis in laboratory animals that were fed a diet with a higher concentrations than 33 mg/kg. For bird reproduction, the concentration without adverse effects is much higher at 1700 mg/kg of food.

3.5 What are the risks of DEHP to the environment?

There is no concern for aquatic organisms exposed via water, as there are no effects below the water solubility level of DEHP. Similarly there are no concerns for exposure via the atmosphere.

For organisms living in sediment or soil, the predicted concentrations that might be found in the environment are higher than concentrations predicted to have no effect (PNEC), there are also risks for food chains based on organisms living in sediment or soil. The scenarios illustrating possible risks to the food chain were emissions from polymer and non-polymer processing sites, giving predicted environmental concentrations that were higher than predicted no-effect concentrations for birds eating mussels and mammals eating earthworms.

It is concluded that while further information and/or testing would be needed to refine the risk assessment, risk management measures implemented and applied to other environmental media will eliminate the need for further information on organisms living in soil and sediment.

4. How can humans be exposed to DEHP?

Humans can be exposed to DEHP at the workplace, through industrial use of products containing DEHP, or as consumers (through indoor air, car interiors, toys, medical equipment, and the general environment).

4.1 How can workers be exposed to DEHP?

Inhalation and deposition on the skin represents the main path of exposure of DEHP at the workplace. Exposure to DEHP via inhalation ranges from 5 mg (production) to 10 mg (industrial uses) per cubic metre of air. Exposure of the skin ranges from 420 milligrams per kilogram body weight (mg/kg bw) per day for industrial uses of DEHP, through 650 mg/kg bw/day for production of DEHP, to 1300 mg/kg bw/day for industrial end-use of products containing DEHP.

Total internal exposure to DEHP in the workplace is estimated to be in the range of 1-2 mg/kg bw/day. This reflects the very poor absorption of DEHP through the skin.

4.2 How can consumers be exposed to DEHP?

Exposure of consumers can be via various sources such as toys, car interiors and medical equipment. Exposure is considered for two separate age-groups (children/adults), as the availability of DEHP to the tissues is expected to be higher in children than in adults. It has been estimated that exposure is highest for children, due to toys and child-care products that contain DEHP, and for patients undergoing medical treatment.

In **children** the highest exposure estimates are due to:

- toys and child-care articles, 0.2 mg/kg/day
- long-term blood transfusion in children, 0.075 mg/kg/day
- blood transfusions in neonates, 1.7 mg/kg/day.

In **adults** the highest exposure estimate is due to:

- long-term haemodialysis, 3.1 mg/kg/day.

In adults the highest exposure estimate is due to:

4.3 To what extent can the general public be exposed to DEHP through the environment?

Indirect exposure of humans via multiple pathways in the environment is lower than consumer exposure.

For the general environment, exposure is estimated to be 0.017 mg/kg/day. For those living near industrial sites producing or using DEHP, exposures are estimated to be 0.002-0.067 mg/kg/day for adults and 0.020-0.312 mg/kg/day for children.

Exposure of infants fed on breast milk is estimated to be 0.006 mg/kg/day and that of infants fed on formula 0.013 mg/kg/day.

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

Tests in laboratory animals have shown that if DEHP is swallowed or inhaled, it is rapidly absorbed and metabolised via several pathways. It does not accumulate in the body. The main metabolites are the monoester, MEHP, and an alcohol, ethylhexanol. The metabolites are excreted via the urine. DEHP can be present in breast milk.

A single dose of DEHP which is swallowed or breathed in has low acute toxicity. It is also assumed to have low acute toxicity via the skin. DEHP is slightly irritating to the animal skin and eye but it is not a skin sensitiser.

Repeated oral exposure to DEHP mainly affects the testis (see also below) and the kidney. The highest doses that didn't cause adverse effect on these organs have been established. No effects were seen on the testis at a dose of 4.8 milligrams/kg bw/day in a rat study, which extended over 3 generations. In a long-term study in rats no effects were seen in the kidney at doses in the range 29-36 milligrams/kg bw/day.

Laboratory tests suggest that DEHP does not cause damage to the inherited genetic materials in cells (chromosomes and DNA).

Adverse effects are also seen in the liver of rats and mice, including liver cancer, but studies have indicated that the mechanism by which phthalates cause liver damage is not relevant for humans. Thus there does not seem to be concern for liver cancer in humans. DEHP also causes tumours in the testis and white blood cells (leukaemia) in rodents but the relevance of these effects for humans is not known.

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6. Does DEHP pose risks to human health?

The human population may be exposed to DEHP by swallowing it, for example in food, by breathing it in, and, to a much lesser extent, by skin contact. Risks are assessed by dividing worst-case exposures to the exposures at which no harmful effects were observed in animal studies. This gives the margin of safety (MOS).

6.1 Are workers at risk from exposure to DEHP?

The exposure of people working in industries where DEHP is produced or used has been estimated, and the highest exposures have been estimated for those working in industries using end-products containing DEHP. It is assumed that such working conditions involve relatively high temperatures, generation of aerosols and considerable skin contact.

It is concluded that DEHP is of no concern for workers with respect to acute toxicity, irritation, skin sensitisation, cancer or effects on the inherited genetic material of cells.

However, for those workers who repeatedly inhale, or have skin contact, DEHP might have toxic effects on the testis, fertility and kidney. There is also concern for toxic effects on the

embryo and fetus that could occur from shorter term exposures, if exposure occurs during pregnancy.

6.2 Are consumers at risk from exposure to DEHP?

For adult consumers the exposure scenarios considered important include indoor air, car interiors, and the use of PVC gloves. The margins of safety for these and other pathways of exposure are sufficiently high in order to give no concern for toxic effects.

For children the exposure scenarios considered important include indoor air, car interiors, child-care articles and toys, taking into account the transfer of DEHP into the saliva as a result of mouthing and sucking. It is concluded that there is concern for effects on the testis, fertility, and kidney if there is repeated exposure via the aforementioned products.

The exposure to DEHP via the use of medical equipment represents a health risk for both adults and children. This risk depends on the medical treatment, with the highest risk being associated with long-term haemodialysis for adults, or long-term blood transfusion and blood oxygenation outside of the body for children and newborns. The testis, fertility and kidney as well as the embryo and fetus could be affected.

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

6.3 Are people at risk from environmental exposure to DEHP?

Environmental scenarios take account the exposure to DEHP via consumption of contaminated food, which includes breast milk and infant formula.

For **children and adults** not living in the vicinity of industrial sites producing or processing DEHP there are no concerns about exposures to DEHP via air or soil.

For **adults** living near industrial sites producing or using DEHP there are no concerns.

For **children** living near such industrial sites, there is concern for effects on the testis, fertility, and kidney in case of repeated exposure via food grown locally. Similarly, the testes of children living near sewage treatment plants or paper recycling plants, might be affected if locally grown food is consumed.

There are no concerns for **newborns or infants** exposed via infant formula or breast milk.

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

Environment

There is still a need for further information and/or testing, especially for aquatic and terrestrial ecosystems, however, it is stated that current risk reduction measures are sufficient, if applied properly. For animals feeding on the aquatic or terrestrial food chains

there are concerns and there is a need for risk reduction measures, taking into account any that are already in place.

Further information or testing to refine the risk assessment for aquatic organisms living in sediment or terrestrial organisms living in soil may remove some of the concern but such data may be unnecessary if appropriate risk reduction measures are taken for these food chains.

Workers

For workers, repeatedly exposed to DEHP by inhalation or skin contact, there is concern that the testis, fertility, and kidney may be affected. Similarly, there might be adverse effects on the embryo or foetus during pregnancy even with shorter exposure times. For workers, there is a need for risk reduction measures due to concerns about effects on the testes, fertility and kidneys from repeated exposure via inhalation or the skin, and effects on the embryo and fetus when exposure occurs during pregnancy.

It is possible that in some industrial premises the worker protection measures that are already in place are adequate.

Consumers

For consumers, there is a need for risk reduction measures due to concerns about effects on the testis, fertility, and kidney for children exposed orally via toys, child-care articles and other multiple routes of exposure. Risk reduction measures which are already being applied shall be taken into account.

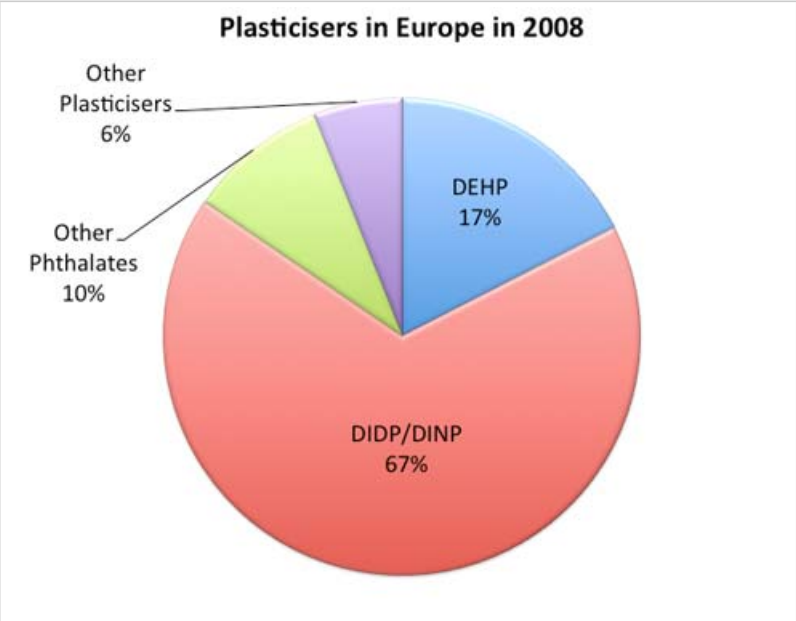
Similarly, risk reduction measures are needed due to concerns about effects on the testis and fertility for children undergoing long-term blood transfusion or neonates undergoing transfusion who are exposed to DEHP via medical equipment. . There are also concerns for adults undergoing long-term haemodialysis for effects on the testis, fertility, kidney, and on the embryo and fetus during pregnancy. Risk reduction measures which are already being applied shall be taken into account.

People exposed via the environment

There is a need for risk reduction measures due to concerns for effects on the testis, fertility, and kidney in children exposed via food grown near sites that use DEHP or that process products that contain DEHP, and due to concerns about effects on the testis in children exposed via food grown near sewage treatment plants or paper recycling plants. Risk reduction measures which are already being applied shall be taken into account.

Annex

Annex 1:
Consumption of plasticisers in Europe in 2008



Source: GreenFacts, based on data provided by the European Council for Plasticisers and Intermediates.