

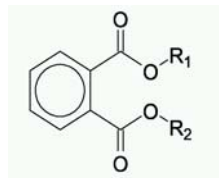
newsletter

Phthalates - PVC plasticisers

There is currently intensive discussion about the potential ecological and health risks of DEHP (diethylhexylphthalate), a widely used plasticiser. As of the end of 2004, DEHP and DBP (dibutylphthalate) will be banned in the EU in preparations such as cosmetics, paints and adhesives.

**Phthalates,
areas of use**

The class of substances known as phthalates (salts and esters of *o*-phthalic acid) comprises a group of chemical compounds produced on a scale of several million tonnes per year, placing them in the category of important industrial chemicals.



R₁ and R₂ are hydrocarbon residues
Examples:
DEHP : R₁ = R₂ = Di(2-ethylhexyl)
DMP : R₁ = R₂ = methyl

About 90% of phthalates are used in the production of plastics, especially as plasticisers for the manufacture of PVC. In addition, they are contained in grease-free lubricants, anti-foaming agents and solvents, and are used as the liquid carrier medium in pesticides, cosmetics, perfumes and insect repellents. The global consumption of plasticisers is estimated at 3-4 million tonnes per year, including about 1 million tonnes in Europe.

The main representatives of the phthalates and their applications

Phthalate	Applications	
DEHP, DNOP, DINP, DIDP	PVC (eg floor coverings, pipes and cables, fitted carpets, wall coverings, footwear soles, vinyl gloves, medical equipment products, vehicle components), dispersions, varnishes/paints, emulsifying agents, packaging (for food)	
DMP, DEP	Bodycare products, perfumes, deodorants, pharmaceutical products	DMP: dimethyl-phthalate DEP: diethylphthalate
BBzP	PVC (eg transformers, floor coverings, pipes and cables, fitted carpets, wall coverings), sealing/jointing compounds, packaging (for food), artificial leather, conveyor belts for food	BBzP: butylbenzyl-phthalate
DBP	PVC, cellulose plastics, dispersions, varnishes/paints (including nail varnishes), adhesives (especially polyvinyl acetate), anti-foaming agents and wetting agents in the textile industry, bodycare products, perfumes, deodorants, pharmaceutical products (time-release medicines), packaging (for food)	DBP: dibutylphthalate DEHP: di(2-ethylhexyl)-phthalate DNOP: di-n-octyl-phthalate DINP: di-iso-nonyl-phthalate DIDP: di-iso-decyl-phthalate

Physical properties

Phthalates are colourless liquids with low volatility and almost no odour; they are hardly soluble in water but are easily soluble in oil or grease. They are added to plastics in concentrations of up to 40-50% in order to make hard unprocessed plastics (particularly PVC plastics) flexible and soft. They do not form a chemical bond with the plastic, so it is relatively easy to release them from the plastic again; alternatively, they gradually migrate out of the plastic.

DEHP, toxicity, absorption

DEHP (CAS No [1 17-81-7]), also frequently called DOP (dioctylphthalate), has been the most commonly used plasticiser for several decades. This chemical accounted for approximately 30% of the plasticisers used for industrial purposes in 2004; it is regarded as the industrial standard, and is considered to be "well investigated" in terms of its health risk. The main metabolite of DEHP is MEHP (monoethylhexylphthalate). Decomposition differs between individual rodents, primates and humans; for example, there are differences in the quantity excreted with the urine. DEHP is not acutely toxic: its LD₅₀ value (rat, oral) is 30 g/kg of body weight. Accordingly, it is the chronic risk to health which is important as far as people are concerned.

The following effects are under discussion on the basis of investigations using experiments on animals:

- after repeated administration: toxic effects on the testicles, kidneys and liver
- carcinogenic effects: DEHP is carcinogenic in rats and mice (tumours in the liver and testicles; leukaemia)
- fertility: destruction of testicle tissue
- embryotoxicity and teratogenicity: DEHP influences the ability to reproduce (fertility) and it may lead to developmental disorders
- genotoxicity and mutagenicity: DEHP and its metabolites are regarded as non-genotoxic substances and as not harmful to the genotype

EU Risk Evaluation of DEHP (March 2004)

Critical effects	NOAEL (No Observed Adverse Effect Level)	MoS (Margin of Safety)
Kidneys	29 mg/kg/day	1700
Testicles	4.8 mg/kg/day	282
Fertility	20 mg/kg/day	1200
Development	4.8 mg/kg/day	282

It should be remembered that the effects which have been found are based on the results of animal experiments, and the majority of them cannot be transferred directly to humans. The consequences for humans of contamination with DEHP are still a matter of dispute and have not yet been definitively clarified; limit values are based on the safety principle in many cases. DEHP can be absorbed orally, through the skin, by inhalation and through the blood (via medical equipment products containing PVC, such as dialysis tubes). The main route of entry into the environment is via the air, eg due to escapes from refuse dumps or during waste incineration, from the production of DEHP or soft PVC, and due to escapes from the plastic while it is in use. Indirect exposure via the environment is estimated at approximately 17 µg/kg/day (Int. J. Hyg. Environ. Health 206, 1-7; 2003). 90% of DEHP decomposes in soil within about 30 days, depending on the quality and condition of the soil and its oxygen content.

Limit values

Limit values and statutory regulations regarding DEHP differ from country to country. In many European countries, for example, its use in children's toys

or food packaging is prohibited or regulated. As of the end of 2004, DEHP and DBP will also be banned from preparations for cosmetics, paints and adhesives within the EU. Since 1987, the USA has had a limit value for DEHP in materials for food storage: max. 3% (Code of Federal Regulation).

DEHP in medical equipment products

There has long been discussion about a potential health hazard due to the use of DEHP in medical equipment products, and about various measures to minimise the risk – especially given that EU Directive 67/548/EEC only calls for separate identification of **chemicals** containing DEHP, and not of plastic products. This Directive stipulates that chemical products with a DEHP component of more than 0.5% must carry dangerous substance identification codes R60 ("may impair fertility") and R61 ("may cause harm to the unborn child"). However, this regulation does not apply to medical equipment products, some of which contain up to 40% DEHP. It was for this reason that the members of Health Care Without Harm, the network that advocates an environmentally compatible health sector, stressed the need for a regulation in their study entitled "Preventing Harm from Phthalates, Avoiding PVC in Hospitals" dated 23 June 2004. The following recommendations were made:

- manufacturers should encourage further development of alternative lower-risk DEHP-free products, and they should step up their efforts to make progress in this area;
- manufacturers should provide users with comprehensive information about alternative products they could use, and the products should be identified accordingly;
- alternative products should be used in intensive neonatal therapy if they are available and if they are suitable for the therapeutic purpose in question.

The FDA had already arrived at similar results when it considered the risk in 2001.

The main risk groups where higher DEHP concentrations have been found include prematurely born, newly born and unborn babies, together with children up to the end of puberty. At the moment, it is still impossible to make a reliable forecast as to whether, and on what scale, increased exposure to DEHP actually leads to health impairments.

Information for the underwriter

Insurance losses due to phthalates, and especially to DEHP, are conceivable in the product liability and recall sectors in particular. Above all, this involves products that are used for risk groups, such as medical equipment products used for premature babies. Another point to be taken into account is that the bodily injury may only emerge at a later stage. This means that DEHP has long-tail exposure. Environmental liability insurers could also be affected. DEHP occurs ubiquitously, so long-term injuries for people are conceivable; however, no specific statements on this aspect can be made yet. For these reasons, developments in this area should be monitored so that the risk can be re-assessed if necessary.

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