DBP

Scientific Facts on

Phthalate

Di-butyl phthalate

Source document:
ECB (2003)

Summary & Details:
GreenFacts

Level 2 - Details on Phthalate

This Digest is a faithful summary of the leading scientific consensus report produced in 2003 by the European Chemicals Bureau (ECB):
"Summary Risk Assessment Report (RAR 003) on Dibutyl Phthalate (DBP), 2003"

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

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Introduction: What are phthalates?

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. 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.

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

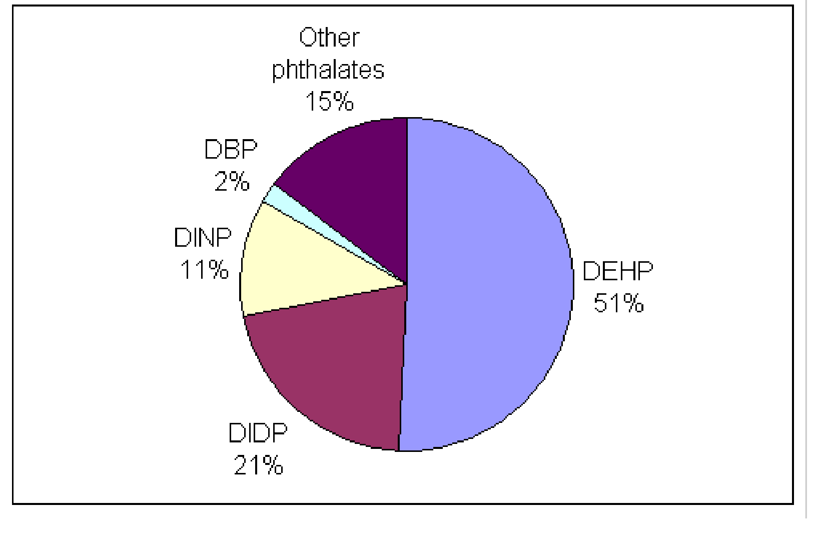
Table: Some examples of phthalates and their applications [see Annex 1, p. 9]

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.

By 2004, the final reports on DBP, DIDP and DINP had been published. The content of these reports was summarised by GreenFacts.

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.

Approximation of the relative importance of the consumption of four of the main phthalates in the European Union in the 1990s



These phthalates are used mainly as plasticisers in PVC products. The total amount of these phthalates produced for use in PVC in Western Europe was 877 000 tonnes in 1994, of which 191 000 tonnes was DIDP, 101 500 tonnes was DINP, and around 18 000 tonnes was DBP.

GreenFacts comment:
It should be noted that in 2008 the EU Risk Assessments on the most commonly used phthalate, DEHP (51% in the 1990s), and on BBP have been released.

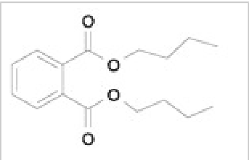
The Risk Assessment Reports (not yet summarised by GreenFacts) are available on the website of the European Chemicals Bureau:

- DEHP [see http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/dehpsum042.pdf]
- BBP [see http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/benzylbutylphthalatesum318.pdf]

1. What are the properties of dibutyl phthalate (DBP)?

DBP is an oily liquid that is soluble in fat and slightly 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 as "dangerous to the environment" (very toxic to aquatic organism). Moreover, it is considered as a possible cause of harm to the unborn child and as a possible risk factor of impaired fertility in humans.



The acronym DBP refers to dibutyl phthalate, which is also referred to as "1,2-benzenedicarboxylic acid, dibutyl ester (9CI)"

See overview table for DIDP, DINP and DBP [see Annex 2, p. 10]

2. How is DBP used?

There are currently 3 producers of DBP in the European Union. The estimated production in the European Union was around 26 000 tonnes in 1998, over two-thirds of which was used in the EU. Production has been steadily decreasing during the 1990's. Over 75% of DBP is used as a plasticizer in polymers such as PVC, 14% is used in adhesives, 7% in printing inks and 3% in other miscellaneous uses, including sealants and grouting agents used in construction as well as consumer products such as cosmetics.

3. Can DBP affect the environment?

DBP may be released into the environment, particularly water and air, during its production and subsequent life cycle stages, including disposal.

3.1 What happens to DBP released to the environment?

DBP does not readily break down in water. It does break down in the presence of air but breakdown is much slower in sediment, deep soil and groundwater.

In the atmosphere DBP is broken down by sunlight. Its half-life in the atmosphere is estimated at 1.8 days. Half-life is the time taken for half the amount initially present to disappear.

The results of a laboratory test indicate a high potential for bioaccumulation of DBP in animal tissues, strong binding to sewage sludge, soils and sediments and very low mobility in soil. Tests on certain freshwater organisms have shown high amounts of DBP metabolites (breakdown products) can be concentrated in the body (bioconcentration).

3.2 When is DBP released?

DBP can be released at different stages: production, distribution, processing, use, incineration and disposal. The expected releases during these stages have been taken into account in this assessment.

3.3 What levels of DBP are expected near the sources?

Predicted Environmental Concentrations (PECs) have been calculated for various environmental media located near sources of DBP.

At production, formulation and processing sites concentrations:

- in **surface water** range from 1 to 9 µg/l and up to 10 times higher in effluent from the sites.
- in **sediment** range from 0.1 to 1.2 mg/kg and levels in soil range up to 1.5 mg/kg.
- in **aquatic organisms** near to sources range from 2 to 8 µg/kg and in soil dwelling organisms range from below 0.1 up to 10 mg/kg.
- in **air** range from 0.02 to 2.4 µg/m^3, with highest levels around PVC processing plants.

3.4 What are the effects of DBP on the environment?

In tests on fish and aquatic invertebrates there were no adverse effects at concentration up to 100 µg/l. The Predicted No Effect Concentration of 10 µg/l for the aquatic compartment was obtained by dividing this figure by 10.

There are no test data on sediment dwelling organisms, but a $PNEC_{sediment}$ of 1.2 mg/kg wet weight could be estimated from the aquatic PNEC.

For microorganisms, a PNEC of 0.22 mg/l was obtained. This value is rather low since other tests show no effect of DBP on microorganisms at concentrations higher than the solubility of DBP. Further, DBP also seems to be readily biodegradable.

For the terrestrial compartment a Predicted No Effect Concentration of 2 mg/kg dry weight was derived using tests on maize.

Studies on the toxicity of DBP to plants showed a wide range of effects at airborne concentrations ranging from 1.2 µg/m^3 to 1 000 µg/m^3. It was therefore decided that further chronic exposure testing was needed to establish a more reliable Predicted No Effect Concentration for plants exposed via air. Tests with seven plant species led to a Predicted No Effect Concentration of 0.1 µg/m^3 for plants in air.

This may mean that eventually a label "toxic to flora" would be applied to DBP.

For top predators, based on the lowest observed adverse effect level of 52 mg/kg body weight in laboratory mammals, an oral Predicted No Effect Concentration of 104 mg/kg in food can be estimated.

3.5 What are the risks of DBP to the environment?

For the aquatic and terrestrial environments as well as in animals, the predicted environmental concentrations were all below the predicted no effect concentrations (PNEC). It is concluded that there is at present no need for further information and/or testing or for further risk reduction measures beyond those being applied already.

However, in the particular case of environmental releases of DBP when it used in construction work as a grouting agent, it is concluded that high levels may be reached in surface water. Therefore the environmental impact of these kinds of operations should be carefully assessed and monitored.

In the atmosphere, the Predicted Environmental Concentrations were all above the provisional Predicted No Effect Concentrations for plants. There was therefore a need for further testing for long-term effects in plants. This was done and the results published in an addendum to the Risk Assessment Report. As a result of these new tests it was concluded that there is a need for limiting the risks to plants, taking into account of risk reduction measures which are already being applied, at sites of PVC, adhesive or glass fibre production as well as for printing ink usage.

4. How can humans be exposed to DBP?

4.1 How can workers be exposed to DBP?

Workplace exposure to DBP may occur during the production of DBP, the production of products that contain DBP and the use of those products.

Exposure levels in DBP production by inhalation are estimated to be below 2 mg/m^3 with a reasonable worst case of 5 mg/m^3 averaged over a shift, with possible short-term exposure levels of up to 10 mg/m^3. The highest skin exposure during the production of DBP can occur when DBP is placed in drums and was estimated to be up to 420 mg/day. Estimated exposures during the processing of products containing up to 15% of DBP are the same as during the production of DBP.

In the end use of products, inhalation exposure to DBP is negligible for techniques that do not involve aerosols. For those that do involve aerosols, the reasonable worst-case exposure level is estimated to be 10 mg/m^3 averaged over a shift, with typical values of 2 mg/m^3 and short-term exposure levels of up to 20 mg/m^3. Skin exposure during prolonged spray application of products containing DBP is estimated to be up to 975 mg/day. Other activities with products containing DBP are expected to lead to lower skin exposure levels.

4.2 How can consumers be exposed to DBP?

In this asssessment, attention was focussed on products containing a relatively large concentration of DBP, such as cosmetics (especially nail polish and enamels), adhesives and regenerated cellulose film (cellophane) wrapped food. Attention was also given to the intentional and unintentional use of DBP in children's toys, in view of the general public concern on the use of phthalates in PVC toys.

The estimated total internal dose from each of these exposures was 0.027 mg/kg body weight/day from cellophane wrapped food and much lower from any other consumer exposures.

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

For the general public, the total daily intake through air, drinking water and food is estimated to be low including around local production and use sites. It ranges from 0.7 to just under 100 g/kg body weight/day depending on exposure circumstances.

DBP has been identified in human breast milk. The exposure via breast milk for infants is estimated to vary between 1.2 and 6 g/kg body weight/day.

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

If DBP is swallowed, about 90% is rapidly absorbed and excreted in the urine within 48 hours. Very little is eliminated via the faeces. About 60% of a dose of DBP applied to the skin of rats is absorbed into the blood and is excreted via urine within 7 days and about 12% via faeces. Human skin absorbs DBP more slowly than rat skin.

There is no information on absorption after the inhalation of DBP.

After absorption into the blood, DBP passes to the liver and from there can be excreted into the gut via bile, and absorbed into the blood again. In this way it "recirculates" in the body. But DBP does not accumulate in the tissues. The major part of DBP is broken down in the gut before absorption of some DBP and its breakdown products into the blood. DBP and its main breakdown product have been shown to cross the placenta and reach the embryo but it does not accumulate in the embryo.

A single dose, of DBP which is breathed in, swallowed, or absorbed through the skin has a low toxicity. DBP as appeared not to be irritating to the skin, eye or airways nor sensitising to skin. However, a 28-day study on rats showed that inhalation of DBP can cause local effects in the upper respiratory tract, but no sign of inflammation.

Repeated oral exposure to DBP mainly affects the blood, liver and kidney. No effects were seen at a dose of 152 mg/kg body weight/day. Some studies in rats show effects on the testis at 250 mg/kg body weight. Several laboratory tests show that DBP does not cause damage to the inherited genetic material in cells (chromosomes and DNA).

DBP has not been tested in mice or rats to see if it causes cancer, but, as has been observed with DEHP and DINP, it might be expected to cause liver tumours in rodents. However, the mechanism by which the phthalates affect the liver in rodents does not apply in humans. Thus, there does not seem to be concern about cancer in humans.

DBP is toxic to the embryo and fetus and causes malformations at high doses that are also toxic to the mother. There were no adverse effects on the embryo and fetus at 100 mg/kg body weight (NOAEL). There is also evidence from studies on rats that DBP affects aspects of development that are dependent on male hormones in male offspring at oral doses of 100 mg/kg body weight or more. There were no effects at 50 mg/kg body weight/day.

In a rat reproduction study, specifically designed to identify substances affecting hormones, slight toxicity to the embryo was seen at 52 mg/kg body weight. Thus, based on all available studies an overall lowest observed adverse effect level (LOAEL) of 52 mg/kg body weight can be established for oral exposure to DBP.

6. Does DBP pose risks to human health?

The human population may be exposed to DBP by swallowing it, by breathing it in, or through skin contact. Risks are assessed by comparing worst case exposures to the exposures at which no harmful effects were observed in animal studies. This gives the margins of safety (MOS).

6.1 Are workers at risk from exposure to DBP?

It is concluded that DBP is of no concern for workers with respect to acute effects, irritation, skin sensitization, carcinogenicity or reproductive toxicity. There is no information on possible respiratory sensitisation. It is concluded that there is at present no need for further information, testing or risk reduction measures beyond those being applied already.

For repeated exposure via skin, it is concluded that for one occupational exposure scenario, the use of products containing DBP in activities involving the use of aerosols, adverse health effects cannot be excluded, the lowest margin of safety being only 3.6. It is concluded that there is a need to limit the risks, taking into account any risk reduction measures that may already be in place. There are no concerns in relation to any other occupational scenarios.

For inhalation exposure, it is concluded there is no concern for health effects in any occupational scenario, except for local effects on the respiratory tract, where the margins of safety are less than 1. For these effects only, it is concluded that there is a need to limit the risks, taking into account any risk reduction measures that may already be in place.

The current occupational exposure limit value for DBP of 5 mg/m^3 is higher than the exposures causing local respiratory effects in animals. There is therefore a need to reconsider the current occupational exposure limit.

6.2 Are consumers at risk from exposure to DBP?

For **consumers**, the margins of safety are sufficiently high for both inhalation and ingestion, so there is no concern.

The margins of safety for inhalation exposure are high and it is concluded that there is no concern for humans indirectly exposed via the **environment** by inhalation, drinking water or food.

Comparing the maximum infant exposure via breast milk (6 µg/kg bw/day) with the overall oral lowest observed adverse effect level (LOAEL) of 52 mg/kg bw/day, a margin of safety of 8 667 can be calculated. This margin of safety is considered sufficiently high to conclude that there is no concern for breast-fed babies. It is concluded that there is at present no need for further information and/or testing or for further risk reduction measures beyond those being applied already.

Because DBP is not explosive, flammable or oxidizing, these properties are not considered to pose a hazard to workers. For those properties, there is at present no need for further information and/or testing or for further risk reduction measures beyond those being applied already.

7. Is further research needed?

Further testing to adequately characterise the toxicity of DBP in air to plants concluded that there is further need for risk reduction beyond those which are currently applied. Therefore, atmosphere releases of DBP by production sites should be reduced in order to protect plants.

For effects on the aquatic compartment (including sediment), soil and the food chain, there is at present no need for further information or testing or risk reduction measures beyond those which are being applied already.

For workers, due to concerns about the effects of repeated dermal exposure from "aerosol forming activities" and concerns for adverse local effects in the respiratory tract as a consequence of repeated inhalation exposure in all workplace exposure scenarios, there is a need for limiting the risks. It is possible that in some industrial premises adequate worker protection measures are already being applied.

For consumers, the end products containing DBP and the sources of exposure are unlikely to pose a risk for consumers (adults, infants and new-borns) following inhalation, skin contact and ingestion. The indirect exposure via the environment is unlikely to pose a risk to humans following the main route of exposure, the oral route.

Annex

Annex 1:

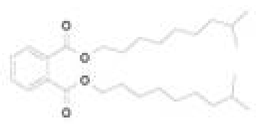
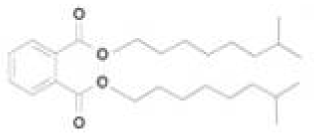
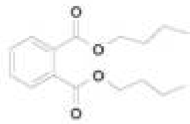
Some phthalates and their applications

Acronym	Full name	Examples of applications
BBP	Butyl-Benzyl-Phthalate	perfumes, hair sprays, adhesives and glues, automotive products, vinyl floor coverings
DBP*	Di-Butyl-Phthalate	[PVC], perfumes, deodorants, hair sprays, nail polish, printer inks, insecticides
Di(2-ethylhexyl) phthalate (DEHP)	Di-Ethyl-Hexyl-Phthalate	Perfumes, flexible PVC products (shower curtains, garden hoses, diapers, food containers, plastic film for food packaging, bloodbags, catheters, gloves, and other medical equipments such as tubes for fluids, etc.)
DIDP*	Di-Isodecyl-Phthalate	vinyl wall and floor coverings, gloves, wrapping food packaging
DINP*	Di-Isononyl Phthalate	Toys, vinyl floor coverings, gloves, wrapping food packaging, drinking straws, graden hoses
DEP	Di-Ethyl-Phthalate	Perfumes, deodorants, hair gels and mousses, shampoos, soaps, hair sprays, nail polish, body lotions
DCHP	Di-Cyclo-Hexyl-Phthalate	Laboratory research
DOP	Di-Octyl-Phthalate	Flexible plastic-based products
DMP	Di-Methyl-Phthalate	Deodorants

Source: Institut national de Santé Publique Québec

Annex 2:

Structure and uses of the three phthalates assessed by the ECB

	DIDP	DINP	DBP
Other names	di-isodecyl phthalate	di-isononyl phthalate	di-butyl phthalate
	1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10 rich	1,2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9 rich	1,2-benzenedicarboxylic acid, dibutyl ester (9CI)
Average formula	$C_{28} H_{46} O_4$	$C_{26} H_{42} O_4$	$C_{16} H_{22} O_4$
			
Description	Oily liquid, low water solubility, non-volatile		
Uses	95% : PVC *plasticiser* 5% : *polymer*-related uses other than PVC (e.g. rubbers), non-polymer applications including paints, *sealing compounds*, textile inks, lacquers, adhesives		75%: polymer plasticiser (PVC and others) 14%: adhesives, 7%: printing inks 3%: other uses, including cosmetics
EU Production	1994: 200 000 tonnes (EU-12)	1994: 107 000 tonnes (EU-12)	1998: 26 000 tonnes (EU-15)
Largest uses in quantity			
wires and cables	27 400 tonnes/year	14 510 tonnes/year	na
flooring	20 055 tonnes/year	10 658 tonnes/year	na
shoe soles	15 843 tonnes/year	8 313 tonnes/year	na
car undercoating	14 516 tonnes/year	7 714 tonnes/year	na

Source: GreenFacts based on ECB Summary Risk Assessment Reports on DIDP [see http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/didpsum041.pdf] (2003), DINP [see http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/dinpsum046.pdf] (2003), and DBP [see http://ecb.jrc.it/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/SUMMARY/dibutylphthalatesum003.pdf] (2003-2004)