

Questions and answers on phthalate plasticisers

FAQ of the BfR and the German Federal Environment Agency (*Umweltbundesamt*, UBA),
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Phthalates are chemical compounds which are used as plasticisers for synthetic materials. There are various phthalates with different harmful effects on health - for example, some have an effect on the hormonal system, others on the liver. There are varying limits for the different phthalates to protect consumers. The use of certain phthalates is forbidden in some products such as toys, baby items, cosmetics and food packaging.

The Federal Environment Agency (UBA) has been regularly monitoring the levels of phthalate exposure in people in Germany for the last number of years. For a long time, one of the phthalates most frequently used and frequently detected in urine was DEHP. The main source of exposure is food. Small children also ingest DEHP through house dust and many items that they place in their mouths.

In everyday life, ingestion of the plasticiser DEHP can be reduced through simple dietary and hygiene habits. It is proven that having a varied diet, preparing fresh meals, consuming fewer convenience foods and changing product brands often (the same products can contain different levels of DEHP depending on the manufacturer) reduces the intake of DEHP. To decrease exposure to chemicals from house dust, floors and carpets should be cleaned regularly. Parents can protect their children by ensuring that small children do not put anything in their mouths that was not manufactured and intended for that purpose.

What are phthalates and what are they used for?

Phthalates are compounds of phthalic acid (1,2-benzenedicarboxylic acid) with different alcohols (phthalic acid ester).

Phthalates are primarily used as plasticisers for synthetic materials. Their addition lends elastic properties to the plastic polyvinyl chloride (PVC), which is in itself hard and brittle, and allows it to be used as a soft plastic. The chemical industry produces approximately one million tonnes of phthalates every year in Western Europe. More than 90% of these go towards the production of soft PVC. They are used, for example, in cables, cling film, flooring, pipes, wallpaper, and sport and leisure equipment.

Which phthalates are frequently used in plastics?

- Diisodecyl phthalate (DIDP)
- Diisononyl phthalate (DINP)
- Di(2-ethylhexyl) phthalate (DEHP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)
- Benzyl butyl phthalate (BBP)
- Di(2-propylheptyl) phthalate (DPHP)

DEHP was the most frequently used phthalate for a long time. Because of its toxicity to reproductive health and the public discussion of this issue, DEHP has been replaced in industry to some extent in the past number of years by the phthalates DINP and DIDP, which pose fewer toxicological dangers. DINP and DIDP are currently the most frequently used plasticisers in Western Europe. While the total usage of plasticisers remained approximately the same, the proportion made up by these two plasticisers rose from 35% in 1999 to 67% in

2008. During the same time period, the proportion made up by DEHP fell from 42% to 17.5%, according to information from the Working Group PVC and Environment (*Aktionsgemeinschaft PVC und Umwelt*).

Do phthalates pose risks to health?

The various phthalates have different effects on organisms. Some members of this group of substances are referred to as endocrine disruptors, which can damage health by changing the hormonal system. For example, some phthalates can have a negative impact on male reproductive function. The member states of the European Union (EU) have classified the phthalates DEHP, DBP, DiBP and BBP as toxic to reproductive health, for example. In animal trials, Di(2-propylheptyl) phthalate (DPHP) has a harmful effect on the pituitary gland (hypophysis) and on the vital endocrine hormone, the thyroid. The pituitary gland controls important bodily functions and the hormonal system of the body. With respect to DINP and DIDP, the toxic effects on the liver are the main concern. There are different limit values for the various phthalates in order to protect the health of consumers. The use of certain phthalates is also forbidden in some products.

Up until now, the EU's assessments relate only to the individual substances. Possible interactions between multiple phthalates are not considered. Recently, however, the view that certain phthalates should be assessed as a group is taking hold, because their effects can accumulate.

Why are phthalates present in food and house dust?

Phthalates are not chemically bound in soft PVC. They can evaporate from products or be transferred upon contact with food - especially fats and oils. These types of transfer take place when food is packaged in materials made from soft PVC. Phthalates can also get into food during processing, for example, when oil is conducted through PVC pipes containing phthalates. Phthalates find their way into house dust primarily by mechanical means, e.g. from flooring, and through deposits formed after release from wallpaper and the like.

Nowadays, phthalates can be detected everywhere in the environment. According to the EU, approximately 95% of the DEHP gets into the atmosphere during product usage and disposal, and only 5% during production and processing.

Does the intake of phthalates from food and other sources pose a risk to the health of consumers?

The BfR has estimated the intake of DEHP representatively for other phthalates. For this purpose, data on the consumption behaviour of children, teenagers and adults in Germany was considered, as well as the different intake routes via 37 food groups, toys, consumer products made from plastic (such as shoes, cosmetics and textiles), house dust, and the air inside cars.

The result: consumers ingest DEHP primarily orally - food is the main source of intake. As a rule, however, the intake quantities of DEHP from the various sources are so low that no risk to health exists. They are below the levels that can be taken in daily over a lifetime without health risks or any damaging effects on health.

Children, particularly small children, could have greater exposure to DEHP than teenagers and adults. They ingest plasticisers not only through food, but also to a greater extent through house dust and through many items that they put in their mouths. Studies within the scope of the UBA's Environmental Survey for Children showed that, in the period from 2003 to 2006, breakdown products of phthalates were detected in almost all urine samples. In

1.5% of children, the concentration was so high that negative effects on health could no longer be ruled out with adequate certainty. The exposure estimations of the BfR from 2012 confirmed these results. According to the results, in the worst case scenario, there could be a risk to health, particularly if foods permanently containing very high levels of DEHP are consumed.

- Press release: Plasticiser DEHP is ingested mainly through food
http://www.bfr.bund.de/en/press_information/2013/13/plasticiser_dehp_is_ingested_mainly_through_food-186815.html
- Phthalate levels in the German population: Exposure-relevant sources, intake pathways and toxicokinetics based on the example of DEHP and DINP
Volume I: Exposure through consumption of food and use of consumer products
http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/umwelt_und_gesundheit_01_2012_conrad_phthalatbelastung_bevoelkerung_band1.pdf
- Phthalate levels in the German population: Exposure-relevant sources, intake pathways and toxicokinetics based on the example of DEHP and DINP
Appendix to Volume I: Database on exposure through food and consumer products
http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/umwelt_und_gesundheit_02_2012_conrad_phthalatbelastung_bevoelkerung_anhband1_0.pdf
- Phthalate levels in the German population: Exposure-relevant sources, intake pathways and toxicokinetics based on the example of DEHP and DINP
Volume II: Supplementary measurements of DEHP, DINP and DiNCH in food and migration measurements in consumer products
http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/umwelt_und_gesundheit_03_2012_conrad_phthalatbelastung_bevoelkerung_band2_a.pdf
- Phthalate levels in the German population: Exposure-relevant sources, intake pathways and toxicokinetics based on the example of DEHP and DINP
Volume III: Human toxicokinetics study
http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/umwelt_und_gesundheit_04_2012_conrad_phthalatbelastung_bevoelkerung_band3_a.pdf

The exposure to DEHP is coupled with exposure to other phthalates which may have similar effects and could therefore increase the health risks.

Is the phthalate exposure among the German population regularly monitored?

The German Federal Environment Agency regularly conducts studies in which the degradation products of phthalates in urine samples of children and adults are measured. Degradation products of phthalates were detected in almost all tested urine samples in the Environmental Specimen Bank. These results are consistent with studies in other industrial countries.

One of the aims of the Environmental Specimen Bank is to check the effectiveness of measures taken and, if necessary, suggest other measures to improve the protection of the population and environment against harmful phthalates. Studies show that the levels of certain phthalates detected in young adults in Germany have decreased in the past twenty years. In contrast, the level of DINP, which is used as a substitute for DEHP, has increased fourfold. The measured values for DEHP, BBP and DBP reached their maximum in the mid-1990s. The concentration of DIBP did not change over the twenty-year measurement period.

You can find more information on the phthalate measurements of the Federal Environmental Specimen Bank under http://www.umweltprobenbank.de/de/documents/selected_results/16425.

In which products is the use of phthalates forbidden?

Due to their harmful properties, specific phthalates are forbidden in certain consumer products.

The phthalates DEHP, DBP and BBP, which are toxic to reproductive health, have been banned in baby items and toys in the EU since 2005. Other phthalates which are cause for concern and are often used as alternatives to those mentioned above, such as DINP, DIDP and DNOP (Di-n-octyl phthalate), are not permitted in toys and baby items which children could place in their mouths.

In accordance with the EU chemicals regulation REACH, phthalates which have been classified as toxic to reproductive health can also not be used in mixtures, e.g. paint, glue or fragrances, which are sold to the general public.

The use of phthalates in plastic packaging for food is subject to specific limit values for their transfer to food on the one hand and certain restrictions, such as bans on use and bans on contact with food containing fats and food for babies and small children, on the other.

In accordance with the EU cosmetics regulation, certain phthalates, including DEHP, BBP and DBP, may not be contained in cosmetic products.

Can food be contaminated with phthalates through plastic food packaging, such as cling film?

In the past, phthalates were also used in food packaging, such as jars with twist-off lids or plastic films. They were transferred from this packaging into food. In 2005, the BfR recommended that DEHP no longer be used in materials for food packaging. Since 2007, far-reaching restrictions have applied to certain phthalates which are harmful to reproductive health - such as DEHP - with respect to their use as plasticisers in food packaging. Instead, other plasticisers or phthalates with less harmful properties are used in the production of food packaging.

What kind of alternative substances are there?

There are many phthalates which are less of a cause for concern toxicologically speaking, such as DINP and DIDP, which can be used as alternatives to phthalates which are harmful to reproductive health. As compared to the phthalate DEHP, these alternative substances have a considerably higher TDI (tolerable daily intake), i.e. the amount that can be ingested daily for a lifetime without posing a risk to health. This also applies to many plasticisers from other substance classes, for example, epoxidised soybean oils, adipates, citrates, adipic polyester and cyclohexanoate.

Health assessments, e.g. of their use in plastics for contact with food, were carried out for all the substances listed. Limits for safe levels of transfer to food were derived from these assessments.

Who monitors the bans on the use of phthalates which are harmful to reproductive health or have other worrying effects?

In Germany, the monitoring authorities of the federal states are responsible for monitoring the bans. These authorities are usually part of the environmental or consumer protection ministries of the federal states.

How can I find out whether consumer products contain phthalates which are harmful to reproductive health?

Consumers have the possibility to ask manufacturers, importers or traders of consumer products whether these products contain phthalates harmful to reproductive health. The UBA has made a corresponding query form available on the website <http://www.reach-info.de/auskunftsrecht.htm>. The consumer only needs to enter the barcode on the product. A response must be given within 45 days. The EU chemicals regulation makes this right to information possible. This right applies regardless of whether the product is purchased or not.

How can consumers protect themselves from a high intake of DEHP?

All basic foods such as fats, bread, milk or dairy products, fruit, vegetables and so on can contain plasticisers. It is not possible for consumers to know whether a food contains these substances or not. This can only be determined by a laboratory test. As a rule, foods do not contain levels which are harmful to health.

The BfR recommends that consumers who wish to further reduce their intake of the plasticiser DEHP have a varied diet, prepare fresh meals, consume fewer convenience foods, and change product brands often, as the same products can contain different levels of DEHP depending on the manufacturer.

To reduce the ingestion of chemicals through household dust, floors and carpets should be cleaned regularly. It is also important to ensure that small children only place things in their mouths which were manufactured and intended for that purpose. Although DEHP is forbidden in toys, it is occasionally found in such products. This can be seen in reports from the European rapid alert system RAPEX. Older toys which were brought to market before the ban came into effect could also constitute a possible source of intake.