German Federal Institute for Risk Assessment

FAQ

Updated FAQ from 28 March 2024

Questions and answers about phthalate plasticisers

Phthalates are chemical compounds that are mainly used as plasticisers in plastics such as PVC. However, the phthalates are not bound in the respective plastics and can be released from them. Because phthalates were produced and used in large quantities in the past, they can be detected almost everywhere in the environment and as impurities (by contamination) in many foods. Moreover, phthalates and their degradation products are regularly found when investigating urine samples.

Depending on their chemical structure, phthalates can have different harmful effects on health. For example, some affect the hormone system, others the function of the liver. However, these effects start to occur above certain concentrations. As consumers in Germany and Western Europe only ingest very small amounts of phthalates overall, health effects are not expected. In the past, however, in some cases increased concentrations of phthalates were reported in children.

People mainly ingest phthalates through food, while young children are in addition increasingly exposed through house dust and articles they put into their mouths.

Different limit values have been set for the various phthalates depending on the area of application in order to protect the health of consumers. In some products, such as toys or food packaging, the use of certain phthalates has been banned or severely restricted for years. Accordingly, both the production of these phthalates in Europe and the intake of phthalates by the population has declined in recent years.

What are phthalates and what are they used for?

Phthalates are a family of chemical compounds that were used on a large scale in the past, primarily as plasticisers for hard and brittle plastics. The addition of 30 to 40 % plasticiser to plastic, for example, gives the hard and brittle PVC (polyvinyl chloride) elastic properties and makes it flexible (soft PVC). Therefore, phthalates were or are used, e.g., in cables, films,

floor coverings, hoses, sports and leisure articles, medical products and lid seals for screw-top jars for foodstuffs. Phthalates are also used in clothing, adhesives, sealants, paints, rubber materials, packaging as well as as coatings, solvents or hydraulic fluids. However, the use of phthalates is now prohibited in many products or their use is strictly regulated.

Phthalates are not bound in plastics and other materials and products and may be released from them. Thereby they can end up in the environment and in food. Because phthalates were produced and used in large quantities in the past, they can nowadays be detected almost anywhere in the environment using highly sensitive measuring methods.

From a chemical point of view, the substance group "phthalates" refers to compounds of phthalic acid that are esterified with various alcohols (phthalic acid esters). In this document, the term "phthalate" is used vicariously and exclusively for *ortho-phthalates* and not for *iso*- or terephthalates. The latter have raised significantly fewer concerns regarding health effects because of their different chemical structure.

Which phthalates were or are frequently used in plastics?

Around 700 phthalates were reported to the EU Chemicals Agency ECHA when the REACH Regulation came into force in 2007, but only a few of these were produced, used or used in the past on a large scale. In 2021, 32 phthalates were produced in Europe or imported into Europe in quantities of more than one tonne per year.

The names of the various phthalates are often abbreviated. The following substances are among the most frequently mentioned:

- BBP: Benzyl butyl phthalate
- DAP: Diallyl phthalate
- DBP (also: DNBP, DnBuP): Dibutyl phthalate
- DEHP: Di(2-ethylhexyl)phthalate, Bis(2-ethylhexyl) phthalate
- DIBP (also DiBuP): Di-isobutyl phthalate
- DIDP: Di-isodecyl phthalate, bis(8-methylnonyl) phthalate
- DINP: Di-isononyl phthalate, bis(7-methyloctyl) phthalate
- DNOP: Di-n-octyl phthalate
- DPP (also DnPP): Di-n-pentyl phthalate
- DPHP: Di(2-propylheptyl) phthalate, Bis(2-propylheptyl) phthalate
- DCHP: Dicyclohexyl phthalate

DEHP, DBP, DIBP and BBP were the most commonly used phthalates for a long time. Because of their reprotoxic properties proven in animal experiments, their use has been restricted and industry has partially replaced them with other phthalates over the past 20 years. For example, DINP and DIDP, which have a slightly different chemical structure, have been used. They are considered to be less toxicologically harmful.

The use of phthalates is now more strictly regulated overall and their use is restricted or even banned in some cases. As a result, new plasticisers that do not belong to the phthalate group have been increasingly developed and used in recent years.

According to information from the European Plasticisers Association, the annual consumption of plasticisers in Europe was more than 1.3 million tonnes in 2020. Despite the

existing bans in Europe, DEHP alone accounts for 40 % of the total annual consumption of plasticisers worldwide because it is still used and produced on a large scale in China, India and other Asian countries, the Middle East, Africa and Latin America. Despite import restrictions, some products imported from these regions contain high concentrations of DEHP, as shown by the notifications in the EU rapid alert system for consumer products RAPEX (Safety Gate). If products that exceed the permissible levels are found by customs or state surveillance authorities, they are withdrawn from the market.

As the use of many phthalates has been restricted by law in Europe, the use of DEHP has fallen sharply in Western Europe in particular. Significantly fewer degradation products of DEHP are now being detected in the environment as well as in urine samples taken from the population.

What health effects do phthalates have on the human organism?

So far, health effects of phthalates have mainly been observed in animal studies. According to these studies, phthalates have different effects on health depending on their molecular structure.

Some of the most frequently used phthalates worldwide are toxic to reproduction. In high concentrations, they are harmful with respect to reproduction and can also damage organisms that are still developing. Studies on rats and mice have shown that the reproductive capacity of male animals in particular can be reduced by the effects of certain phthalates (e.g. DEHP). The damage occurs while the reproductive organs are still developing in the unborn animal.

In addition, some phthalates can impair the hormone system and are therefore also known as endocrine disruptors. For example, it has been observed that these phthalates can disrupt the onset of puberty in animals. In animal studies, the thyroid and pituitary gland were damaged by DPHP. Both control important body functions. Animal studies have also investigated influences on the female hormone system, which still need to be clarified further.

In the case of the phthalates DINP and DIDP, harmful effects were particularly observed on the liver The livers of animals became enlarged and signs of cell damage were detected.

It may be assumed that the health effects observed in the animal studies can also occur in a similar form in humans. However, it is difficult to detect these directly. It requires complex epidemiological studies in which larger groups of people are observed over long periods of time. In some epidemiological studies associations have been reported between phthalate intake in the population and male fertility. Other studies, however, did not confirm these observations. Therefore, these epidemiological studies do not allow to draw any conclusions onthe causality between phthalate intake and the health effects investigated.

Is there a health risk to consumers from phthalate intake?

According to current knowledge, the present-day intake of phthalates does not pose a significant risk to the health of adult consumers. Animal studies have shown that various phthalates have harmful properties. However, these effects only occurred when the animals were exposed to comparatively high phthalate concentrations over a long period of time.

However, the quantities that consumers consume with their food are so low that, according to current knowledge, negative effects on health are not to be expected.

In 2019, the European Food Safety Authority EFSA, with the involvement of the BfR, reassessed the health effects of five phthalates that can be used in plastic food contact materials (DBP, BBP, DEHP, DINP, DIDP). Four of these phthalates (DBP, BBP, DEHP and DINP) were considered as a group in the assessment because they show comparable reprotoxic effects. For this phthalate group, a group-TDI has been set for the tolerable daily intake (TDI). The TDI describes the amount that can be ingested daily over a lifetime without causing adverse health effects. For all four phthalates together, the TDI is therefore 0.05 mg per kilogram of body weight - the equivalent of 3 milligrams per person per day, assuming a body weight of 60 kg. The group-TDI is calculated in the form of so-called DEHP equivalents, i.e. conversion factors are used for the individual substances depending on their potency compared to DEHP.

This new TDI was compared with the actual intake of the phthalates in question by the population. The intake was already significantly lower in 2019. Accordingly, EFSA came to the conclusion that the current intake of DBP, BBP, DEHP, DINP and DIDP via food is not expected to cause any impairment to health.

These results are consistent with data from the BfR MEAL study. During the investigations in 2019 and 2020, the concentrations of 28 phthalates in prepared foods were also determined. The concentrations measured were also very low.

In studies conducted as part of the European human biomonitoring project HBM4EU the total intake of phthalates was analysed - via food, inhaled air and skin. The quantities of phthalates ingested by humans every day were determined across Europe. For DEHP, DINP, BBP and DBP, the estimated daily intake was 0.1 to 1 µg/kg body weight. This is 500 to 50 times below the TDI of 50 µg/kg body weight.

Within the population, children are more exposed to phthalates than adolescents and adults. Children absorb plasticisers not only through food, but also to a much greater extent than adults by putting articles in their mouths. These articles may themselves contain phthalates or be covered in dust contaminated with phthalates. Studies conducted in Germany as part of the German Environmental Health Study (GerES IV, formerly known as the Children's Environmental Survey, KUS) conducted by the Federal Environment Agency UBA between 2003 and 2006, degradation products of phthalates were found in almost all urine samples. In 1.5 % of the children, the concentrations were so high at that time that an impairment of health could no longer be ruled out with sufficient certainty. In the following study (GerES V) from 2014 to 2017, the concentration of DEHP in the urine of three to 13-year-old children was four times lower. In a few cases, the HBM guideline values (HBM-GV, see below) were exceeded. This was the case for DBP in 1.18 % of cases (12/2256 children) and for DEHP in 0.05 % of cases (1/2256 children). Despite the general decrease in exposure, the combined intake of the phthalates DBP, BBP, DEHP and DINP in GerES V estimated from the measured values was still higher than the tolerable daily intake of 0.05 mg per kilogram of body weight for the majority of three – ten-year-olds. More recent studies carried out between 2016 and 2022 in the Europe-wide HBM4EU project show that phthalate concentrations in children and adolescents have also decreased in Europe in recent decades.

What is human biomonitoring (HBM) and what is an HBM value?

With the human -Biomonitoring (HBM) involves analysing human samples for the presence of certain substances. Specifically, these are mainly urine samples, but also blood, saliva, breast milk, hair or tissue samples. In many cases, it is not the actual, potentially harmful original substances that are detected, but their degradation products (metabolites), which are formed by the body's own metabolism. The analysis allows conclusions to be drawn about the exposure of the individuals analysed across all uptake pathways. In Germany, for example, such samples are analysed in the environmental specimen bank and used for time trend analyses. HBM projects in Germany include the various phases of the German Environmental Study on the Health of Children and Adults (GerES), at European level, for example, the HBM4EU and the PARC project. The aim is to monitor the exposure of the population to exogenous substances or pollutants and to recommend mitigation measures if necessary.

In Germany, so-called HBM values are derived as a guideline for assessing the measured concentrations of individual substances. While statutory limit values usually refer to external concentrations, HBM values describe concentrations in the respective sample species under consideration - for example, concentrations in urine. In Germany, the Human Biomonitoring Commission (HBM Commission), which is based at the Federal Environment Agency UBA, is responsible for setting the relevant values. In this HBM Commission the BfR is present as an observer. It sets so-called HBM-I and HBM-II values.

The HBM I value represents the concentration of a substance, e.g. in urine or blood, below which, according to the current state of knowledge, impairment of health is not to be expected. The HBM-II value indicates the concentration above which an impairment of health appears in principle possible that is considered relevant for those affected.

However, exceeding the HBM II value does not mean that an impairment to health will necessarily occur. However, it does give reason to investigate the cause of the increase and, if possible, to minimise or eliminate it.

For an assessment of the concentrations present in human samples, so-called HBM Guidance Values (HBM-GVs) were also derived for some selected substances as part of the HBM4EU project, which are to be interpreted similarly to the HBM-I values.

HBM values are not established in law and do not have the same status as the limit values derived by EU panels and agreed in documented procedures, such as acceptable or tolerable daily intake levels of the European Food Safety Authority (EFSA) or reference DNELs (Derived No-Effect Levels) derived by the Committee for Risk Assessment (RAC) at the European Chemicals Agency (ECHA). HBM values serve as orientation values for the toxicological classification of HBM measurement results.

What is known about the recent findings of the substance mono-n-hexyl phthalate (MnHexP) in urine samples?

The State Agency for Nature, Environment and Consumer Protection of North Rhine-Westphalia (LANUV) has detected the substance mono-n-hexyl phthalate (MnHexP) in follow-up analyses of older urine samples (LANUV, 2024). The substance was also detected in urine samples from adults as part of the sixth part of the German Environmental Health

Study (GerES VI) currently being conducted by the Federal Environment Agency (UBA). MnHexP can form as a metabolite from various phthalates, for example DNHP, decylhexyl phthalate or certain other mixed-chain phthalates, or can be directly absorbed in the form of MnHexP.

Based on animal studies, the starting substances in question are considered reprotoxic. The presence of a metabolite in urine indicates exposure, but not whether there is an immediate health risk. However, because of the reprotoxic properties of both MnHexP and its possible precursors, the intake of these substances should be reduced as far as possible.

However, the concentrations of the substance mono-n-hexyl phthalate (MnHexP) detected in urine samples do not give cause for increased concern following an assessment by the Federal Institute for Risk Assessment (BfR). On 21 March 2024, the BfR derived a provisional tolerable daily intake (TDI) for the possible starting substance DnHexP. The TDI indicates the amount of a substance that can be consumed orally every day over a lifetime without presenting an appreciable health risk. The result shows that people are only exposed to a small extent of the provisional TDI. Adverse health effects are therefore very unlikely in these cases. The detected concentrations are within a range that has also been detected for other phthalates in the context of serial studies.

The source for the elevated MnHexP levels in the urine samples of adults and children has not yet been clarified. Possible sources are being intensively investigated by various parties.

Di-n-hexyl phthalate as a possible starting substance was analysed in 226 foodstuffs as part of the BfR MEAL study. All analytical results were below the respective limit of detection.

Sunscreens containing a certain UV filter are also being discussed as a source for the occurrence of MnHexP. DnHexP itself is banned as an ingredient/component in cosmetic products, but it could be introduced into such products as an impurity of starting materials. According to the BfR's preliminary assessment, however, it is unlikely that the use of such contaminated products would cause any impairment to health.

Most of the starting substances in question are subject to strict restrictions on use throughout Europe, as they have been classified as substances of very high concern under the EU's REACH chemicals-regulation, among other things. In addition, further regulatory activities are planned by the ECHA.

At its meeting on 22 March 2024, the Human Biomonitoring Commission (HBM Commission) at the Federal Environment Agency (UBA) derived an assessment value (HBM-I value) for MnHexP in urine. The HBM-I value corresponds to the concentration of a substance in a body medium below which, according to the current status of the Commission's assessment, no adverse health effects are to be expected. Of the 750 samples analysed so far, all concentrations are below the new assessment value.

Why are food and household dust contaminated with phthalates?

Phthalates can be present in plastics and films, for example in soft PVC. The phthalates are not chemically bound to the soft PVC. They can, for example, migrate into food when they come into contact with it. This happens in particular when fatty or oily foods are packaged in or stored in materials made of soft PVC containing phthalates. Phthalates can also contaminate food during processing, e.g. when oil or other fatty foods such as milk are

passed through PVC tubing containing phthalates. Phthalates enter household dust primarily through mechanical exposure, e.g. through abrasion from floor coverings or release from other articles in the household that contain phthalates. Phthalates also enter and can be detected in the environment through the use of phthalate-containing products outdoors or through waste.

Can phthalates from plastic packaging such as stretch film migrate into food?

In principle, phthalates from plastics such as packaging or hoses can migrate into food and then be ingested. For this reason, strict rules apply to the use of phthalates in food contact materials. For example, the use of DBP, BBP, DEHP, DINP and DIDP is not allowed in disposable packaging and not for the packaging of fatty foods. If the use of these phthalates is necessary for technical reasons for the manufacture of a plastic, the permitted concentration has to be 0.05 - 0.1 %. At this concentration, the phthalates cannot develop their effect as plasticisers. Phthalate concentrations of 30 - 40 % are required for the plastic to become soft.

For materials that come into contact with food, the legal limit value for the phthalates DBP, DIBP, BBP and DEHP was redefined in 2023. A transfer of not more than 0.6 mg of these substances per kg of food from the plastic into the respective food are legal - calculated in DEHP equivalents. These quantities are so low that no impairment to health is to be expected even with daily intake.

Otherwise, not all soft plastics contain plasticisers. Polyethylene cling film, for example, is particularly flexible because of the plastic used and the manufacturing method and therefore does not need to contain plasticisers.

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

In principle, all staple foods such as fats, bread, fruit, vegetables and milk or dairy produce can contain traces of plasticisers as an impurity. There is no way for consumers to recognise whether a particular food contains phthalates and how high the concentration is. This can only be determined by means of a laboratory test. However, various tests have shown that foods only contain very small amounts of phthalates, if any at all.

To reduce the intake of phthalates via house dust in young children, floors and carpets should be cleaned regularly. It is also important to ensure that young children only put articles in their mouths that are made and intended for this purpose. Although DEHP and other phthalates are now banned in toys, these plasticisers are occasionally detected in imported products. This is substantiated by reports from the European rapid alert system RAPEX (Safety Gate).

How do I find out whether certain products contain phthalates that are harmful to health?

This is comparatively easy with the free smartphone app "Scan4Chem" from the Federal Environment Agency UBA. The app can be used to search for products by name or via the barcode printed on the packaging of many products. "Scan4Chem" accesses the product database of the European AskREACH project, in which over 35,000 products are currently listed. If a product is not listed, an enquiry can be sent to the manufacturer via the app. In

addition, the EU REACH chemicals regulation gives consumers the right to obtain information from manufacturers, importers or retailers as to whether a product contains substances of very high concern (SVHC) such as phthalates, which are harmful to reproduction. A response must be provided within 45 days. This applies regardless of whether the product is purchased. Alternatively, the "Web Scan4Chem" website can also be used to look up products in the AskREACH database or create sample templates for enquiries to the respective manufacturer.

However, it is important to note that the listing of a hazardous substance in the app does not necessarily mean that the substance is absorbed after uptake by humans and has an adverse effect on health. Many substances found in products are either not released and absorbed or are only absorbed in such small quantities that they are not expected to cause any impairment to health.

Is the fact that humans can absorb different phthalates at the same time taken into account when setting limit values?

The various phthalates can differ in their effects. For this reason, originally the effects of individual phthalates were usually considered in health risk assessments. In more recent assessments, however, phthalates with comparable effects are now summarised as groups and assessed together. One example of this is the ban on DEHP, DBP, BBP and DIBP in various products, which has been in force since July 2020. It was based on a restriction procedure under the EU REACH chemicals regulation, in which these four phthalates were considered together.

The grouping of phthalates into substance groups has now become established in various assessment bodies: in its most recent assessment of phthalates, the EFSA also considered and evaluated several representatives of this group together, which are authorised for use in food contact materials. The European Chemicals Agency ECHA also recommends that several phthalates should be grouped together - and not just individual substances - when further regulating phthalates and setting limit values for their use.

In which products is the use of phthalates prohibited?

The use of the reprotoxic phthalates DEHP, DBP and BBP in baby products and toys was banned back in 2005, even before the EU REACH chemicals regulation came into force. Since July 2020, their use and the use of DIBP has also been severely restricted in numerous other products. Many products may no longer be placed on the market if one of the materials used in the product consists of more than 0.1% of these phthalates by weight. It does not matter whether only a single phthalate is contained or a combination of several of these phthalates. In toys and baby products that can be put into the mouth by children, other phthalates that are often used in other areas as alternatives to those already mentioned - for example DINP, DIDP and DNOP - are also prohibited. In addition, there is a general ban on the use of reprotoxic substances in mixtures for sale to the general public, for example in paints, sealants and household chemicals, which also includes the use of the phthalates mentioned.

In the area of food safety, the EU has largely restricted the use of phthalates. For example, limit values and restrictions apply to food contact materials regarding the quantity used and

the maximum permissible transfer into the respective food. In addition, they may not be used in articles for single use or come into contact with fatty foods or infant and young child food.

In the cosmetics sector, critical phthalates such as DEHP, BBP and DBP are banned under the EU Cosmetics Regulation.

What substitutes are available for phthalates?

Various alternatives have been developed to replace the use of phthalates, which are hazardous to health. On the one hand, certain less toxic phthalates, such as DIDP, are used as plasticisers. On the other hand, plasticisers that are not based on the ortho-phthalate *structure,* such as epoxidised soybean oils, adipates, citrates, adipic acid polyesters or cyclohexanoates, trimellitates, 1,2-cyclohexanedicarboxylic acid dinonyl esters (DINCH) and sebacates, are now also being developed and used.

For some of the alternatives, the available data suggests that they are less problematic than the reprotoxic phthalates used to date. The health effects of these alternative plasticisers have so far been less well studied than the phthalates that were used most frequently in the past. However, because of their potential use as phthalate substitutes, their health effects are now being increasingly investigated and their use is also regulated by law in some cases.

How do the authorities responsible for consumer health protection work together on the issue of phthalates?

In Germany, the regional authorities of the German federal states ("Laender") are responsible for checking compliance with the bans and legal limit values in products. These are usually part of the environmental or consumer protection ministries of the federal states.

The central task of the BfR is the scientific risk assessment of food and feed as well as substances and products as a basis for consumer health protection. The institute has no monitoring function, but it does investigate indications of risk. For example, the BfR has made proposals at various levels for the further regulation of phthalates, including in the EU Chemicals Regulation REACH and the CLP Regulation, and presented these in national and international committees.

As part of the BfR MEAL study, the concentrations of 28 phthalates in foods typically prepared by consumers were analysed. Initial evaluations of the study data indicate only low phthalate concentrations in foods.

The Federal Environment Agency UBA regularly measures the degradation products of phthalates in urine samples from children and adults. The evaluation of these data and retrospective analyses of archived urine samples from the Federal Environmental Specimen Bank have demonstrated that the exposure of young adults in Germany to some phthalates has decreased over the past twenty years. In addition, the Federal Environment Agency also analyses the occurrence of phthalates in environmental samples, for example in water bodies and rivers.

If abnormal levels of phthalates or their degradation products are found in tests, the various public institutions exchange their findings.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States ('Laender') on questions of food, chemicals and product safety. The BfR conducts independent research on topics that are closely linked to its assessment tasks.

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