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PHTHALATES – USEFUL PLASTICISERS WITH UNDESIRED PROPERTIES

Outline

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Summary

- What are phthalates and what is their use?
  Phthalates are primarily used as plasticisers for soft PVC. The chemical industry in Western Europe produces around one million tons of phthalates annually. More than 90% go into the production of soft PVC.
- How do phthalates find their way into the environment?
  Phthalates do not form a strong chemical bond in soft PVC. They evaporate from products, and they can leach or disperse through abrasion of plastic particles.
- How do phthalates affect humans?
  People are exposed to constant contamination from phthalates as a result of the frequent use of soft PVC in consumer products such as flooring, wallpaper, or food packaging. We absorb plasticisers primarily through the air and food. Phthalates or their degradation products (metabolites) are found in the blood or urine of almost everybody.
- Which are the most important plasticisers?
  The five most frequently utilized phthalates are DIDP (di-isodecyl phthalate), DINP (di-isononyl phthalate), DEHP (di(2-ethyl hexyl) phthalate), DBP (dibutyl phthalate) and BBP (benzyl butyl phthalate).
- What risks have been identified by EU-risk assessment?
  The member states of the European Union (EU) have classified the phthalates DEHP, DBP and BBP as toxic to reproduction. The risk assessment reveals risks for human health or the environment only in very limited areas of application – for example in childcare articles and toys. The EU Commission has banned any use of phthalates in these areas. In recent years the chemical industry has replaced phthalates that are toxic to reproduction with DIDP and DINP, which are not classified as hazardous substances. Nevertheless, there is a ban in Europe on the use of DIDP––and as a precautionary measure also DINP––in childcare articles and toys that can be placed in the mouth by children.
- What does the Federal Environmental Agency (UBA) recommend?
  - Substances that are toxic to reproduction, as well as carcinogenic and mutagenic substances, should generally not be released into the environment.
  - DINP und DIDP are suspected of accumulating in organisms, as well as being persistent in soil and sediments. The high quantities of soft PVC that are in use, and the structural similarity to DEHP imply that we can expect a strong dispersal in the environment. As a precautionary measure, UBA recommends avoiding the releases of DIDP and DINP into the environment.
  - The release of phthalates from soft PVC cannot be prevented. Whenever it is technically feasible and reasonable, UBA recommends a gradual replacement of soft PVC with alternative plastics (such as polyethylene or polypropylene). In certain applications, such as flooring, consumers can resort to other materials, such as tiles, wood, or carpets.

1. Phthalates – "the plasticisers"

The addition of plasticiser lends elastic properties to the hard and brittle plastic polyvinylchloride (PVC), thus enabling its use as a soft plastic.

About 35% of the raw PVCs produced are processed into soft PVC (PVCplus 2005). The so-called phthalates are the most frequently used plasticisers. According to the industry association "European Council for Plasticisers and Intermediates" (ECPI) about one million tons of phthalates are produced in Western Europe annually. More than 90% are used as plasticiser in the production of soft PVC (ECPI 2006). On average, products made from soft PVC consist of 30 to 35% plasticiser (AGPU 2006).

Products made out of or with soft PVC can be found in almost every household: Flooring, imitation leather, wallpaper, shower curtains, childcare articles, children's toys, packaging, shoes, as well as sports and leisure products can contain phthalates. Many medical devices––for example blood bags and infusion tubes–– are also made from soft PVC. Outdoors we encounter soft PVC in cables, roof insulation strips, car undersealings, and truck tarpaulins.

According to figures supplied by the "Working Group PVC and the Environment" (AGPU), the largest final users of soft PVC are:

- Construction industry (Cable, hoses, flooring, foil, wallpaper)
- Electrical and cable industry (coatings of cables and lines)
- Automotive manufacture (undersealings, interior trims, seals)
- Sports and leisure articles

Plasticisers are used in PVC in Western Europe in the following areas (AGPU 2006):

Cables	25%
Foils, roof sheeting	22%
Flooring	14%
"Extruded" articles – for example hoses and other endlessly formed plastic profiles	11%
Coated fabrics	10%
Plastisols – i.e. paste-like applications, for example in automobile undersealings	9%
Other	9%

Phthalates are compounds of phthalic acid (benzene-1,2-dicarboxylic acid) with various alcohols (phthalic acid ester). The following phthalates are the most important, based on quantities produced and consumed:

- Di-isodecyl phthalate (DIDP)
- Di-isononyl phthalate (DINP)
- Di(2-ethyl hexyl) phthalate (DEHP)

- Dibutyl phthalate (DBP)
- Benzyl butyl phthalate (BBP)

For a long time DEHP was the most frequently used phthalate. Because of public concern over its toxicity to reproduction, manufacturers in recent years partially replaced DEHP with DINP and DIDP. Taken together DINP and DIDP are currently the most widely used plasticisers in Western Europe. With the total amount of plasticiser consumption remaining unchanged, their share rose from 35% in 1999 to 58% in 2004. In the same period DEHP consumption fell from 42 to 22% (AGPU 2006).

2. How do phthalates enter the environment?

Phthalates are not chemically bound in soft PVC. They can evaporate from products or dissolve upon contact with liquids or fats. That is how they are released into the environment during the use of the final product. The European Union estimates that about 95% of environmental release of DEHP takes place during product use; production, processing and waste disposal contribute only about 5%[a].

Phthalates belong to the so-called semi-volatile organic compounds (SVOC). In contrast to volatile organic compounds (VOC) that evaporate from products over a shorter time period – for example solvents in colours – phthalates evaporate slowly but steadily during use. Once released into the environment they tend to cling to particles. In residences they are found mostly in house dust. Particles of dust bind phthalates and carry them in the air over long distances. That is how phthalates reach areas that are at a great distance from places where products containing plasticiser are manufactured or used. Low concentrations of the plasticisers DEHP have even been measured in the snow and ice of the Antarctic (UBA 1999).

The release of phthalates through leaching or abrasion occurs predominantly through use outdoors, for instance from undersealings, roof foils or truck tarpaulins. Phthalates also find their way into waste water through the cleaning of PVC flooring or when washing textiles imprinted with PVC. In sewage treatment plants they are deposited primarily in waste sludge. If the sludge is used as fertiliser, phthalates are deposited to the soil. Sporadic traces can even be detected in groundwater.

Humans absorb phthalates through food, the air we breathe, or through the skin. Infants and small children are especially at risk if they take toys or childcare articles containing harmful phthalates into their mouth. These plasticisers can dissolve in saliva and become absorbed into the body. The EU Commission has already banned the use of phthalates in childcare articles and toys (see Chapters 4 and 5). Through use in medical devices such as blood bags and infusion tubes, phthalates can directly enter the blood stream. Food may become contaminated by phthalate inputs into the environment. Phthalates can also find their way into food through packaging.

[a] EU Risk Assessment Di(2-ethyl hexyl) phthalate (DEHP), Draft (2006). (unpubl.)

As part of its Environmental Survey, UBA has for years been studying the exposure of adults and children to environmental contaminants. A 2001 pilot study conducted as part of the Child Environment Survey ("Kinder-Umwelt-Survey", KUS) analyzed the degradation products (metabolites) of phthalates in the urine of children and determined that in some children, mostly boys, the acceptable daily intake of DEHP was exceeded (Wittassek et al. 2006, Heger et al. 2005, Becker et al.. 2004).

3. Principles of hazard assessment, and EU risk evaluation of chemicals

As industrial chemicals that have been in use in Europe prior to 1981, phthalates are classified in the EU Regulation on the evaluation and control of the risks of existing substances (EEC 793/93) as priority substances. These are substances manufactured in annual quantities exceeding 1000 tons, for which there is cause for concern with regard to a potentially harmful impact on human health or the environment. The EU Member States work together to evaluate the risks that these priority substances pose to humans and the environment.

The term "risk" must be differentiated from "hazard". The evaluation of potential hazard answers the question of whether or not a substance demonstrates properties harmful to humans or the environment. Dangerous substances are classified according to the Regulation of Hazardous Substances in Chemical Compounds established under EC Directive 67/548/EEC. The hazard describes a potential harm. In contrast, the risk takes into consideration the probability of a hazard. The principle of EU risk assessment rests on a comparison between the substance concentration to which humans or the environment are exposed and the concentration level that does not lead to harmful effects. A risk exists when the anticipated concentration exceeds the effect threshold. Hazardous substances may therefore not pose a risk at low exposure. Conversely, high exposure to a substance of low toxicity can lead to a risk.

A risk assessment is based on time specific data. Changes such as an increase in production or new applications of a relevant substance can lead to previously unknown risks. Any conclusions suggesting that "the European risk assessment did not reveal any risk, and therefore the substance is safe to use in any quantity and any application/product" are unacceptable.

Moreover, risk assessments are always based on a series of assumptions and a limited state of knowledge. Laboratory experiments can only partially elucidate the complex processes in ecosystems and human organisms. Studies on potential effects—e.g. long-term effects on organisms—are often lacking or insufficient, for instance in the case of effects on the endocrine system, i.e. disturbances of the hormone system.

The methodology of environmental risk assessment is primarily suited for appraising local and regional effects of substances and cannot sufficiently appraise their global impact. EU environmental assessment of existing substances in the marine environment includes an additional hazard-related assessment: Toxic substances that are persistent and accumulate in high concentrations in organisms (bioaccumulative) and that are also classified as toxic are designated as PBT-substances,

whereas substances that are classified as very persistent and have strong propensity to bioaccumulate are called vPvB substances. PBT and vPvB substances give rise to fundamental concern, as it can never be ruled out that their long-term presence in the environment and accumulation in organisms will result in harmful effects. The introduction of such substances into the environment must be reduced through appropriate measures.

The criteria for PBT and vPvB assessments, as well as the specific criteria for risk assessment are coordinated throughout the EU in the "Technical Guidance Document on Risk Assessment" (TGD). PBT assessment is formally based on defined threshold levels. Thus, according to TGD a substance is rated as bioaccumulative if its bioconcentration factor in aquatic organisms exceeds 2000. This means that the concentration of the substance in an organism, for example fish, is 2000 times higher than in the ambient water.

The OSPAR (Oslo-Paris) Commission for the Protection of the Marine Environment of the North-East Atlantic also employs the PBT concept to identify chemicals for which there is an urgent need for action to reduce emissions.

According to the recently enacted Regulation on the Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH), which reformed European Chemicals Law, substances identified as PBT and vPvB are now subject to authorisation.

4. At a glance: classification and evaluation of individual phthalates

4.1 Di(2-ethyl hexyl) phthalate (DEHP)

Classification according to EU Directive 67/548:

Human health	toxic for reproduction Category 2 [b]: - may impair fertility - may cause harm to the unborn child
Environment	not classified

EU risk assessment (not yet concluded)

Human health	Risks identified when used in toys and childcare articles, as well as in medical devices. Ban in force for toys and childcare articles.

[b] Category 1: Substances known to impair fertility in humans or known to cause developmental toxicity in humans.
Category 2: Substances which should be regarded as if they impair fertility in humans or as if they cause developmental toxicity in humans. Classification based on clear results in appropriate animal studies.
Category 3: Substances which cause concern for human fertility or which cause concern for humans owing to possible developmental toxic effects. Classification based on results in appropriate animal studies, which provide sufficient evidence to cause a strong suspicion.

	Risks for workers exposed to DEHP.
Environment	Risks for aquatic and terrestrial ecosystems in the immediate vicinity of DEHP processing industries.

PBT and vPvB assessment

Not classified as a PBT substance according to TGD and OSPAR criteria; nevertheless, it is a borderline case. High bioaccumulation potential and persistence in sediments and soils; classified as "toxic" because of its toxicity to reproduction.

More information on DEHP in Appendix 1.

4.2 Benzyl butyl phthalate (BBP)

Classification according to EU Directive 67/548:

Human health	toxic for reproduction Category 2 [b]:
	- may cause harm to the unborn child toxic for reproduction Category 3 [b]:
	- possible risk of impaired fertility
Environment	dangerous for the environment - very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment

EU risk assessment (not yet concluded)

Human health	No risks identified in the course of risk assessment.
	Ban in force for toys and childcare articles.
Environment	Risks identified for surface waters and sediments, as well as for the soil compartment.
	More information is required for final assessment of risks to aquatic ecosystems.

PBT and vPvB assessment

Not classified as a PBT substance according to TGD and OSPAR criteria. Does not fulfill criteria for classification as "persistent" and "bioaccumulating"; classified as "toxic" because of its toxicity to reproduction.

More information on BBP in Appendix 2.

4.3 Dibutyl phthalate (DBP)

Classification according to EU Directive 67/548:

Human health	toxic for reproduction Category 2 [b]:
	- may cause harm to the unborn child toxic for reproduction Category 3 [b]:
	- possible risk of impaired fertility
Environment	dangerous for the environment - very toxic to aquatic organisms

EU risk assessment (2003)

Human health	Risks for workers exposed to DBP.
	No risks identified for consumers.
	Ban in force for toys and childcare articles.
Environment	Risks for plants via the atmospheric pathway in the immediate vicinity of DEHP processing industries.

PBT and vPvB assessment

Not classified as a PBT substance according to TGD and OSPAR criteria. Does not fulfill criteria for classification as "persistent" and "bioaccumulating"; classified as "toxic" because of its toxicity to reproduction.

More information on DBP in Appendix 3.

4.4 Di-“isononyl " phthalate (DINP) und di-“isodecyl " phthalate (DIDP)

Classification according to EU Directive 67/548:

Human health	not classified
Environment	not classified

EU risk assessment (2003)

Human health	Risks identified when DIDP is used in children's toys and child-care articles.
	Ban in force for precautionary reasons for DIDP and DINP in children's toys and childcare articles.
Environment	No risks identified for DIDP and DINP.

PBT and vPvB assessment

Not classified as a PBT substance according to TGD and OSPAR criteria. Substances nevertheless have a high bioaccumulation potential; persistence in sediment and soil cannot be discounted. Wide dispersal of DINP and DIDP in the environment is expected due to the structural similarity with DEHP and the great quantities in use in soft PVC.

More information on DINP und DIDP in Appendix 4.

5. Restrictions of commercialisation and use according to Chemicals Law

The phthalates DEHP, DBP and BBP are already subject to a European ban that prohibits their use in some applications, for instance in toys and childcare articles (see Appendix 5*)*, in preparations such as varnish and paint sold to private consumers (see Appendix 6), as well as in cosmetics (Appendix 7). Moreover, the use of the phthalates DINP, DIDP and DNOP (di-n-octyl phthalate) in toys and childcare articles that children can put in their mouth (more in Appendix 5) is forbidden.

6. The Federal Environmental Agency's policy on phthalates and soft PVC

The chemicals assessment procedure conducted jointly by the EU Member States is an important tool for evaluating the risks posed by individual substances on the basis of scientific studies. In the opinion of the Federal Environmental Agency, however, current evaluation procedures for substances of special concern do not satisfy the requirements of a sustainable and precautionary policy on chemicals. According to EU chemicals assessment, substances that are carcinogenic, mutagenic, or toxic for reproduction, as well as bioaccumulative and persistent substances pose a risk only if their concentration in the environment exceeds a threshold beyond which "probable negative effects are to be expected". For precautionary reasons, UBA advocates that substances of very high concern should not be released into the environment.

Already in 1999 the Federal Environmental Agency formulated the following goals in a publication entitled "Handlungsfelder und Kriterien für eine vorsorgende nachhaltige Stoffpolitik am Beispiel PVC" ("Action areas and criteria for a precautionary sustainable substance policy, using the example of PVC") (UBA 1999):

- The release into the environment of xenobiotics with carcinogenic or mutagenic effects, or toxicity to reproduction, is to be avoided completely.
- The irreversible release into the environment of persistent and/or highly bioaccumulating xenobiotics is to be completely avoided, irrespective of their toxicity.

The new European Chemicals Regulation REACH to some extent considers these precautionary principles. Substances with carcinogenic or mutagenic properties or

toxicity to reproduction (CMR substances) are henceforth subject to authorisation, as are substances classified according to future REACH criteria as persistent, bioaccumulative and toxic (PBT substances), and very persistent and very bioaccumulative (vPvB substances).

The phthalates DEHP, BBP and DBP are classified as toxic for reproduction. The results of EU risk evaluations in principle permit the use of these substances. They continue to be released into the environment, primarily through soft PVC products.

In the opinion of UBA, these substances, which are toxic for reproduction, should generally not be released into the environment.

For several years the chemical industry has been reducing the use of these phthalates by switching primarily to DINP and DIDP. However, these two phthalates have a high bioaccumulation potential, i.e. they can accumulate in the environment. In addition, their persistence in the soil and in sediments cannot be precluded. Their structural similarity to DEHP, and the great quantities used in soft PVC, will probably result in considerable dispersal in the environment. Moreover, the structural relation makes it likely that they may contribute jointly with other phthalates to harmful effects on the environment and in humans.

In accordance with the above-mentioned environmental objectives, UBA advocates avoiding the release of DINP and DIDP into the environment.

As the diffuse release of phthalates from soft PVC is basically unavoidable, the Federal Environmental Agency further advocates a gradual replacement of soft PVC with materials that give less cause of concern for the environment.

In accordance with the principle of precautionary environmental and health policy the Federal Environmental Agency recommends that consumers avoid products made from soft PVC as much as possible, in favour of those that are of less concern. Alternatives are described in Chapter 8.

7. Alternative plasticisers for PVC and other plastics

The market share in Western Europe of plasticisers without phthalates was approximately 7% in 2004 (AGPU 2006)[c]. Presumably these were mostly adipates (adipic acid esters), chiefly di(2-ethyl hexyl) adipate (DEHA) and di-isononyl adipate (DINA), as well as citrates (citric acid esters), primarily acetyl tributyl citrate (ATBC). Phosphates with flame retardant properties also serve as plasticisers. DEHA is used primarily in food packaging, the less volatile DINA mostly in flooring and wallpaper. ATBC is the principal substitute for phthalates in children's toys made from soft PVC. The plasticiser "DINCH", which is used mostly in children's toys and medical products is relatively new on the market.

These non-phthalate plasticisers have been variously tested with regard to their ecotoxicological and toxicological properties as well as their technical suitability (COWI 2001, TNO 2001, UBA 2003). Some of these plasticisers may well be more

[c] No further information given regarding the type of plasticiser.

environmentally friendly than phthalates. However, it is up to the manufacturers to demonstrate this before they proceed to mass production.

As these alternative plasticisers are not be firmly bonded in the plastic either, their widespread release into the environment is to be expected. UBA therefore advocates the use of plastics that have elastic properties even without any addition of plasticiser (see Chapter 8). For most soft PVC products there exist alternative materials without plasticisers or with only marginal concentrations of platicisers.

8. No need for plasticisers: products without soft PVC and phthalates

In principle there are alternatives to nearly all products that contain phthalates as plasticisers[d]. Which alternative materials are suitable depends on the area of application. Plastics such as polyethylene (PE) and polypropylene (PP) generally do not contain phthalates as plasticisers. Another advantage is that they do not require stabilisers containing heavy metals, and add less to the chlorine burden in waste materials. The use of completely different materials is frequently possible as well (see products listed below).

Regrettably, there is no obligation to label products in a way that would make it possible for consumers to identify which plastic has been used. Many manufacturers label their products voluntarily using the abbreviations and numbers in Appendix 4 of the German Packaging Regulation: polyethylene terephthalate (PET / 1), high density polyethylene (HDPE / 2), polyvinylchloride (PVC / 3), low density polyethylene (LDPE / 4), polypropylene (PP / 5), polystyrene (PS / 6). The largely identical abbreviations in DIN ISO 11469 apply to all other plastic products. The label is often placed in a triangle consisting of three bent arrows. If the plastics are not labelled, one can always inquire at the store or manufacturer.

8.1 Consumer products

In the search for alternatives to materials containing phthalates, products that may come into close contact with the consumers are of particular interest to human health, e.g. in medical products (bloodbags, etc.) and phthalate-containing pharmaceuticals, as well as products that come into direct contact with food, skin or indoor air.

Indoor products

People in Central Europe spend an average of 80 to 90% of their time indoors. Soft PVC is used extensively in indoor products, releasing substantial quantities of plasticiser. In the private realm at least, consumers can wield considerable influence on contamination in their residence, as they can choose low-emission alternative products. These exist for nearly all products:

Flooring: Tiles, wood, cork, rubber, linoleum or polyethylene do not contain phthalates or only very low concentrations of phthalates. But these products can contain and release components that may impact the environment or human health (Ehrnsperger, Misch 2005). That is why UBA recommends that consumers choose products designated with the "Blue Angel" environmental label.

[d] However, they may contain low concentrations of phthalates which are used as technical support agent for processing of the material. For example, PP and PE which are intended to come into contact with food may contain up to 0.05% DBP (Commission Regulation 2011/10/EU).

Flooring designated with the Blue Angel is free of toxic plasticisers and low in solvents and contaminants.

Wallpaper: Consumers also need not resort to wallpaper with PVC plasticised foam coatings (vinyl wallpaper). Instead they could use paper or simply paint the walls. Wallpaper and paint that are low in contaminants, and manufactured by resource-conserving processes are labelled with the "Blue Angel".

Furniture and household effects: Furniture made with imitation leather, shower curtains and table cloths could consist of soft PVC. To be on the safe side consumers should ask the distributor or manufacturer whether or not the products contain soft PVC.

Paint, varnish, sealants: The plasticisers DEHP, DBP and BBP, being toxic to reproduction in humans, are basically banned from use in paint, varnish and sealants sold to consumers (see Chapter 5). Wall paints designated with the Blue Angel do not contain plasticizers, and are low in solvents and formaldehyde. Varnish and sealants marked with the Blue Angel are completely free of phthalates, and the plasticisers that are used instead must be identified on the label. Overall, the total permissible content of plasticisers, solvents and preservatives in products labelled with the “Blue Angel” is reduced to a minimum.
Detailed information about the Blue Angel is available on the Internet at www.blauerengel.de, as is the leaflet "Ratgeber Blauer Engel — Gesund Wohnen" ("Blue Angel Guidebook—Healthy Living") (UBA and RAL 2005), which includes information on all relevant indoor product groups. Recent tests of plasticiser levels in products can be found on the website of the consumer foundation Stiftung Warentest at www.stiftung-warentest.de.

Food packaging nowadays rarely consists of soft PVC; it is primarily used in meat packaging, where soft PVC is especially useful because it allows the passage of oxygen. Phthalates are increasingly replaced with diethyl hexyl adipate (DEHA)[d], another controversial substance. The German Federal Institute for Risk Assessment (www.bfr.bund.de) recommends that coatings, foils and tubes containing phthalates should not come into contact with fatty foods (BfR 2006). Nevertheless, consumers hardly have a chance to verify this.

Medical products and pharmaceuticals: DEHP is contained in blood, infusion and dialysis bags, as well as in catheters made from soft PVC (BUND and HCWH 2004). Thus far phthalates are permitted as plasticisers in medical products; however, restrictions on use of DEHP in medical products in the EU are being discussed. The Federal Institute for Pharmaceuticals and Medical Products (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) in Bonn, which is responsible for monitoring these technical issues, recommends that DEHP should be replaced in medical products. The replacement of soft PVC is not yet feasible in all cases without compromising the quality of medical treatment, and therefore a decision regarding replacement must be made on a case by case evaluation of the various uses (BfArM 2006). In the field of medical products, hospitals should insist on the manufacture of replacement products. Furthermore, certain medicinal capsules contain the phthalate DBP (as well as the diethyl phthalate, DEP), which enables a controlled release of the active ingredients. Pharmacists can answer any questions regarding the presence of the plasticiser DBP in drug capsules by consulting the ABDA database. Usually it is also possible to find this information in the disclosure

[d] Due to its high lipid solubility, DEHA in packaging materials readily enters fatty foods (e.g. cheese), where it has often been detected.

note, in the section on "other ingredients". BfArM does not consider the ingestion of such pharmaceutical products as posing any acute hazard (www.bfarm.de).

Cosmetics contain phthalates such as dimethyl phthalate (DMP) or diethyl phthalate (DEP); however, they could be replaced with less critical alternatives. The package of cosmetics must contain information on the ingredients, although this is often written in English. The Federal Institute for Risk Evaluation (Bundesinstitut für Risikobewertung) in Berlin (www.bfr.bund.de) is responsible in Germany for the technical assessment of ingredients in cosmetics.

Indoor "fogging": a special case

The phenomenon known as indoor "fogging" has occurred since the mid-1990s: Within a few days or weeks black deposits begin to cover the surfaces of walls, ceilings or furnishings in residences (UBA 2005). The causes of these sooty deposits are as yet unclear. The black film appears primarily after renovation work or upon initial occupancy of a dwelling. It is believed that a basic cause are semi-volatile organic compounds (SVOC), which are increasingly contained in products used in construction and renovation as well as in home furnishings, in replacement of volatile organic compounds (VOC). SVOC––to which the phthalates belong–– escape from the products and form a slimy film directly on the product, or on walls or ceilings. This film binds suspended dust particles to create a sooty deposit[e]. There is usually no health risk, but for precautionary reasons it is recommended to determine the cause and remove the deposit as quickly as possible. The negative aesthetic implications and the expense associated with these deposits can be high in some cases. It is therefore advisable to rely on products that are low in contaminants.

Fogging effects also occur in new vehicles, as temperatures in the interior of a car can rise dramatically, especially on sunny days. Besides the appearance of deposits from SVOC, elevated concentrations of contaminants may occur in the air of the car's interior; this is perceived as the typical "new car smell".

8.2 Outdoor uses and quantitatively important product groups

The principal product groups with soft PVC are cables and foils as well as roof sheeting. Together they account for approximately half of the consumption of soft PVC. Especially problematic are diffuse emissions from outdoor uses of soft PVC in direct contact with the environment: e.g. the undersealing of cars, and truck tarpaulins. However, there are alternatives to soft PVC.

Cables: In cable sheathing soft PVC can be replaced with plastics made of PE (polyethylene) or EVA (ethyl-vinyl acetate copolymers). Alternatives exist for all voltages (UBA 1999); they are technically suited, but somewhat more expensive than PVC cables. The material used in the sheathing can be recognized from the acronyms in the cables' labels, which have been harmonised at the European or standardised at the national levels, but these acronyms are not easy to understand by laypeople.

[e] Termed "adhesive effect" when the film forms directly on the product, and "fogging effect" when transport through the air is required.

Foils/Roof sheets: In most cases, soft PVC foils can be replaced with foils made from polyolefines (such as polyethylene or polypropylene) or other plastics, e.g. polyamide/ polyethylene compound sheets (PA/PE). Since foils can serve a variety of purposes with very different technical requirements, it is not possible to offer detailed recommendations. For roof sheets there are also alternatives made from thermoplastic polyolefines and EPDM (ethylen-propylen-terpolymer rubber), among other materials (MFJWS-SH 1999).

Undersealings: Underbody paint protects vehicles from corrosion and damage. There are alternatives to PVC, for instance materials made from polyurethane (PUR) (UBA 1999). PP/PE/Rubber compounds including recycling materials are also suitable.

Truck tarpaulins: Truck tarpaulins usually consist of polyester fibres coated with soft PVC. No plastic alternatives have succeeded in finding a market, due to the very high requirements for weather-proofing and mechanical firmness of truck tarpaulins. Targeted industrial research and development should be able to accomplish the desired material properties in potential alternative materials such as polyethylene, polypropylene or polyurethane.

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Appendix 1

Di(2-ethyl hexyl) phthalate (DEHP)

Until a few years ago DEHP was the most widely produced and used plasticiser in Western Europe. From 1979 to 1998 the consumption in Europe remained relatively constant at 400 000 to 500 000 tons per year (EU RA DEHP 2006). In 1999 almost 460 000 tons of DEHP were used, comprising almost 42% of the total consumption of plasticisers in Western Europe. In 2004 this percentage dropped to 22%, while the overall use of plasticisers remained approximately constant (AGPU 2006). About 97% of DEHP is used as plasticiser for PVC. On average the weight proportion of DEHP in plasticised PVC products is 30%. Other applications include paints and varnish, as well as other polymers (e.g. polystyrene, cellulose ester, rubber) (EU RA DEHP 2006). Because of the multitude of applications, especially in plasticised PVC, large quantities of DEHP have entered the environment. Its distribution in the environment is ubiquitous, and it can also be found in humans.

Classification according to EU Directive 67/548

Human health: Toxic for reproduction Category 2:

- may impair fertility
- may cause harm to the unborn child

Category 2 classification as toxic for reproduction is based on animal tests. (Substances known to impair fertility in humans are classified as Category 1.) Studies have shown that DEHP affects fertility, reproduction and development of the offspring in rodents. This suggests that DEHP may impair fertility in humans or have harmful effects on the development of the foetus in pregnant women. According to the present standard of knowledge, these are direct cytotoxic effects with "no effect levels", i.e. concentration thresholds below which there is no effect.

Environment: Not classified.

Results of EU risk assessment according to the Existing Substances Directive

The assessment is not yet completed. A draft was completed in March 2006. Rapporteur is Sweden.

Human health:

Various hazards to human health exist because of harmful effects on kidneys, testicles, fertility and development. With regard to children it must be taken into consideration that they are especially sensitive to human reproductive toxins, as their organism is still in development.

Risks have been identified in connection with the use in toys and childcare articles as well as medical devices. Moreover, risks arise for children who consume foods cultivated in the vicinity of DEHP processing industries, paper recycling plants, and waste treatment facilities.[f]
Employees of DEHP production and processing plants are at risk through inhalation (breathing) and dermal (skin) exposure.

Because of its human reproductive toxicity the use of DEHP in childcare articles and toys has been banned (see Chapter 5).

[f] A risk exists only in theoretical models, and not in the case of those facilities for which definite emission data are available.

Additional risk reduction strategies are under discussion mostly with regard to use in products in medical devices and food packaging.

Additional restrictions of commercialisation and use exist with regard to preparations and cosmetics (see Chapter 5).

Environment:

Risks for aquatic and terrestrial ecosystems have been identified in the vicinity of DEHP processing sites. Birds and mammals are exposed to additional risks through the food chain.[f]

PBT Assessment

DEHP is not a PBT substance according to the criteria established by TGD and OSPAR, although it does represent a borderline case: Because laboratory tests have demonstrated that it is readily biodegradable, DEHP is not classified as persistent. However, in aquatic ecosystems DEHP partially resists biodegradation through adsorption to particles and deposition in the sediment. Under anaerobic conditions DEHP seems not to be biodegradable. Moreover, the process of biological degradation is strongly dependent on temperature.

DEHP has a high potential for bioaccumulation. An 840-fold accumulation compared to the surrounding waters has been found in fish, and a 2500-fold accumulation in mussels. Because of some uncertainty in the tests with mussels DEHP has not been classified as bioaccumulative according to TGD criteria.

The criterion "toxic" is fulfilled by its classification as "toxic for reproduction, Category 2".

Although DEHP is not classified as a PBT substance, there is cause for concern due to its above mentioned properties, ubiquitous presence in the environment and capacity for long-term contamination of organisms.

DEHP is classified as bioaccumulative according to OSPAR criteria, which have lower threshold levels for bioaccumulation (OSPAR 2006). The OSPAR Commission estimates that DEHP poses a risk for the marine environment because of its toxicity to reproduction, potential endocrine effects, which have not been conclusively evaluated, and its potential for bioaccumulation (OSPAR 2006).

DEHP is a "priority substance" according to the EU Water Framework Directive and the Convention for the Protection of the Marine Environment, OSPAR, with the goal of gradually reducing its discharge and emissions.

Appendix 2

Benzyl butyl phthalate (BBP)

According to industry figures, consumption in Europe was almost 19 500 tons in 2004. The primary use, with a share of almost 60%, was as plasticiser in the PVC industry, mostly in flooring (41% of the total). It is also used in other polymers, e.g. in seals based on polysulfide, polyurethane and acrylic compounds, as well as glue, paint, and varnish (EU RA BBP 2005).

Classification according to EU Directive 67/548

Human health: Toxic for reproduction Category 2:
- may cause harm to the unborn child
Toxic for reproduction Category 3:

- possible risk of impaired fertility

Category 2 classification as toxic for reproduction is based on animal tests. (Substances known to impair fertility in humans are classified as Category 1).

Category 3 means that the substance gives rise to concern because of possible impairment of human fertility. This assumption is based on animal tests indicating an impairment of fertility.

Environment: Dangerous for the environment
- very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

Results of EU risk assessment according to the Existing Substances Directive

The assessment is not yet completed. A draft was completed in December 2005. Rapporteur is Norway.

Environment:

Additional information is required for a final assessment of the risk for aquatic ecosystems. Possible effects on reproductive and endocrine processes cannot be ruled out. Manufacturers are called upon to investigate these potential effects through long-term tests with fish.

According to the draft assessment, risks to surface waters and sediments, as well as to the soil compartment have been identified due to environmental inputs resulting from certain BBP manufacturing processes (e.g. for flooring).

Human health:

According to the standard of knowledge in the risk assessment there are no risks to human health. At the time of data collection for the risk assessment there were no BBP applications in childcare articles and toys, and therefore this was not considered in risk assessment.

BBP already belongs to the phthalates banned in toys and childcare articles (see Chapter 5) because due to its toxicity to reproduction its use in these products would constitute a health hazard to children.

Further restrictions on commercialisation and use apply with regard to preparations and cosmetic products (see Chapter 5).

PBT assessment

BBP is not classified as a PBT substance according to TGD and OSPAR criteria (EU RA BBP 2005; SCHER 2006; OSPAR 2006). BBP does not fulfill criteria for classification as "persistent" and "bioaccumulative"; classified as "toxic" because of its toxicity for reproduction.

BBP is classified as a "priority substance" under the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR). The OSPAR Commission views BBP as a substance with potential endocrine effects (OSPAR 2006).

Appendix 3

Dibutyl phthalate (DBP)

Almost 26 000 tons of DBP were produced in Europe in 1998, of which almost 8 000 tons were exported (EU RA DBP 2003). Exact data regarding production and consumption are not available. According to figures supplied by AGPU, approximately 65% of DBP is used in polymer processing, of which more than 90% is used in PVC. Approximately 30% of DBP goes into the manufacture of paint, emulsions, varnish and glue (AGPU 2006).

Classification according to EU Directive 67/548

Human health:	Toxic for reproduction Category 2:
	- may cause harm to the unborn child Toxic for reproduction Category 3:
	- possible risk of impaired fertility
Environment:	Dangerous for the environment - very toxic to aquatic organisms

Results of EU risk assessment according to the Existing Substances Directive

Risk assessment completed in 2003. Rapporteur is The Netherlands.

Environment:

Risks for plants through the atmospheric pathway have been identified in the vicinity of DEHP processing sites.

Human health:

Employees who handle DBP are at risk through inhalation (breathing) and dermal (skin) exposure. No further risks to human health are expected, according to the standard of knowledge of the risk assessment.

In the framework of the discussion of the hazard to children posed by phthalates in toys and baby products, EU Regulation 2005/84 bans DBP in these product groups because of their toxicity for reproduction (see Chapter 5).

Further restrictions on commercialisation and use apply with regard to preparations and cosmetic products (see Chapter 5).

PBT Assessment

DBP is not classified as a PBT substance according to TGD and OSPAR criteria (EU RA BBP 2005; SCHER 2006; OSPAR 2006). DBP does not fulfill criteria for classification as "persistent" and "bioaccumulative"; classified as "toxic" because of its toxicity for reproduction.

DBP is classified as a "priority substance" under the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR). The OSPAR Commission views DBP as a substance with potential endocrine effects (OSPAR 2006).

Appendix 4

Di-isononyl " phthalate (DINP) and di-isodecyl " phthalate (DIDP)

DINP and DIDP are mixes of isomers. DINP is a mixture of esters of o-phthalic acid with C8-C10 alkyl alcohols (rich in C9). There are two distinct DINP mixtures on the market, distinguished by their different manufacturing processes and isomeric distribution. DIDP is a mixture of esters of o-phthalic acid with C9-C11 alkyl alcohols (rich in C10). The exact composition of the mixes of isomers for DINP and DIDP is unknown. Two isomers are mentioned in the EU risk assessments as main ingredients. Presumably DINP and DIDP also have isomers in common.

By now DINP and DIDP are the most widely used phthalates in Europe. In 2004 their joint share of plasticiser consumption in Europe stood at 58% (AGPU 2006). This corresponds to nearly 580 000 tons. Overall, 95% of DINP is used for PVC applications; the remainder is used in rubber, paint and pigments, glue, varnish and sealants. DIDP is mostly used in PVC, mainly in manufacturing of cables and foils (AGPU 2006).

Classification According to EU Directive 67/548 for DINP and DIDP

Human health: Not classified

Environment: Not classified

Results of EU risk assessment according to the Wastes Directive

Risk assessments for DIDP and DINP were concluded in 2003. Rapporteur is France for both substances.

Environment: No risks were identified for either DIDP or DINP.

Human health: Health effects of DINP and DIDP mostly concern the liver.

No risks to human health have been identified for DINP. For DIDP risk reduction measures are required in its use in toys and childcare articles because of its toxicity to the liver. Further risks to human health have not been determined.

The use of DIDP and DINP is now banned for toys and childcare articles that can be taken into the mouth by children (see Chapter 6). This ban is justified in the regulations, because––due to missing or contradictory scientific information––a potential hazard from use in toys and childcare articles cannot be ruled out for children.

PBT assessment

Although DIDP and DINP have been found to be "readily biodegradable" in laboratory tests there are indications that these substances are nonetheless persistent in the environment.

The EU Commission's advisory Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) assumes that the strong tendency of DINP and DIDP to adsorb to particles and in body fat may drastically reduce its bioavailability and its biological degradation both in the environment and in organisms (CSTEE 2001a/2001b). The EU risk assessments assume a very long half-life (i.e. very slow degradation) in sediments and soil.

The chemical-physical properties of DINP and DIDP indicate a high potential for bioaccumulation. Tests on mussels revealed a 4000-fold accumulation of DIDP. As there are no reliable bioaccumulation data for DINP, the findings regarding DIDP were adopted in risk assessment of DINP (EU RA DINP 2003, EU RA DIDP 2003).

According to the information available for the EU risk assessment, it is not expected that DINP and DIDP will have harmful effects on aquatic organisms via the aqueous phase. They are not CMR-substances (carcinogenic or mutagenic or toxic for reproduction). Relevant effects on the endocrine system are unknown. The criterion as "toxic" is not met.

DINP and DIDP are not regarded as PBT-substances.

The high bioaccumulation potential and the expected persistence in sediments and in soil in conjunction with their high consumption levels, however, raise a concern that DINP and DIDP will become ubiquitous in the environment. The structural similarity to DEHP, which has been examined in much greater detail, leads to an expectation that a similar quantity will be released into the environment and may contribute to harmful effects in conjunction with other phthalates.

There are few environmental monitoring data available for the EU risk assessment. The comparison of DIDP and DINP concentrations to DEHP concentrations in identical studies shows that DINP and DIDP was measured in somewhat smaller concentrations, but nevertheless on the same order of magnitude as DEHP (EU RA DINP 2003, EU RA DIDP 2003). These studies date back to 1997, when DIDP and DINP were manufactured and processed in substantially smaller quantities. There are no up-to-date environmental monitoring data for evaluation of the present distribution in the environment.

The contamination of the general population with DINP was revealed by a 2005 biomonitoring study showing that 97% of people––not exposed on the job to DINP––had DINP metabolites in their urine (Koch 2005).

An unpublished biomonitoring study by the Institute for Labour, Social and Environmental Medicine in Erlangen and the Federal Environmental Agency examined 700 urine samples from the Human Samples Database collected from 1988 to 2003 and discovered a small but significant rise in the daily intake of DINP over this time period.

Appendix 5

Ban on the use of phthalates in toys and childcare articles:

Directive 2005/84/EC of 14 Dec. 2005 in amendment of RL 76/769/EEC, enacted in national German law in the Regulation on Consumer Goods (Bedarfsgegenständeverordnung), §3 in conjunction with Appendix 1 No. 8.

Conclusion:

• Toys and childcare articles containing DEHP, DBP or BBP in concentrations >0.1 mass % of the plasticising material are banned from commercialisation.

• Toys and childcare articles that can be taken into the mouth by children and that contain DINP, DIDP or DNOP (di-n-octyl phthalate) in concentrations >0.1 mass % of the plasticising material are banned from commercialisation.

Appendix 6

Ban of the sale to consumers of substances and preparations containing components that are toxic for reproduction:

Various amendments to Council Directive 76/769/EEC, enacted in national German law in the Regulation on Prohibition of Chemicals (Chemikalienverbotsverordnung), §1(1) in conjunction with Appendix 1 Section 20.

Conclusion:

• The phthalates DEHP, DBP und BBP, which are classified as toxic for reproduction, may categorically not be sold to private consumers as substances or preparations.

Preparations according to Chemicals Law are mixtures or solutions of 2 or more substances, e.g. paint and varnish.

This ban does not apply to articles. Articles are objects that are given a specific form, surface or configuration in manufacturing, which determine their function to a greater extent than their composition.

Appendix 7

Ban of phthalates in cosmetic products:

Various amendments to Council Directive 76/768/EEC, enacted in German law in the Cosmetics Regulation (Kosmetikverordnung), §1 in conjunction with Appendix 1.

Conclusion:

Among others, the phthalates DEHP, DBP und BBP are not permitted in the production and treatment of cosmetic products.