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# Environment, Health and Safety Committee Note on: Why do we worry about phthalates?

## WHAT ARE THEY?

Phthalates are a group of man-made organic chemicals known as esters produced by the simple chemical reaction of an alcohol with phthalic anhydride. Various alcohols are used, typically, having a carbon chain length in the range $C_8$ – $C_{10}$ although alcohols with chain lengths of $C_4$, $C_7$, $C_{11}$ and $C_{13}$ are also used for specialist applications. The most commonly used *phthalate esters* (PEs) are di-2-ethylhexyl phthalate (DEHP) sometimes also referred to as DOP (dioctyl phthalate), diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP). PEs are clear liquids, with little or no smell and are of low volatility. They do not readily dissolve in water and are not persistent in the environment.

## USES

The most important use of PEs - more than 90% of European production - is as plasticisers for polyvinyl chloride (PVC) which they turn into a material which is soft, flexible, resilient and easier to handle. PVC consumes the largest volume of plasticisers since its molecular structure - more than that of any other polymer - allows it to have its properties modified by the incorporation of plasticisers. PEs are not just additives (like colourants or stabilisers) but are important components which largely determine the mechanical performance of polymers.

Applications of flexible PVC include a wide range of products from medical devices, such as tubing and blood bags, to the manufacture of clothing and footwear, electrical cable insulation, packaging, stationery, toys and baby care items, wall and floor coverings, roofing and automotive parts. In Europe, DEHP is the only plasticiser permitted for use in blood bags by the European Pharmacopoeia.

Phthalates have also been used to help prevent nail varnish from chipping, make perfume last longer and make tool handles stronger and more resistant to breaking. Others help adhesives, sealants, paints and many other products to be more effective.

## HOW DO THEY WORK?

PVC is a polar polymer with strong attractive and repulsive charges. Plasticisers also have strong polar bonds as well as long non-polar hydrocarbon chains. So when a plasticiser is added to PVC before it is processed, it is held in the polymer matrix by attractive forces between its polar bonds and those in the polymer. At the same time the non-polar chains in the plasticiser interpose themselves between the polymer chains, attenuating the PVC/PVC attractive forces and resulting in a far less rigid material.

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**BENEFITS**

Phthalate esters have proved popular because simply by varying the level and type of phthalate used enables the range of properties to be achieved that are required by a very wide variety of PVC products. Their use results in benefits such as ease of processing, flexibility, durability and low cost in applications such as cable insulation and sheathing, floor coverings, wall coverings and synthetic leather.

**RISKS ASSOCIATED WITH MANUFACTURE, USE AND DISPOSAL**

Because PEs are so widely used they have been subjected to extensive testing to determine their impact on health and the environment. Some, including DBP, BBP and DEHP, have been found, at high dose levels, to cause reproductive effects in rodents and have therefore been classified under the Dangerous Substances Directive (67/548/EC) as Toxic to Reproduction Category 2. It is evident that not all phthalates have the same effects on rodents and so others, including DINP, DIDP and the higher molecular weight phthalates, have not been classified or labelled.

Because of this DBP, BBP and DEHP have been included in the first “candidate list” of substances that may be subject to Authorisation (Annex XIV) for specific uses under REACH. Once included in Annex XIV, a company wishing to market or use such a substance must submit an application to the European Chemicals Agency (ECHA) for an authorisation. Substances cannot be placed on the market or used unless the company is granted an authorisation. Annex XIV also places responsibilities on industry to provide information in response to requests from consumers, (usually in the form of a safety data sheets) on the safe use of these substances on their own or in preparations and in articles.

Risk assessments, conducted under the EU Existing Substances Regulation (793/93/EEC) have been published for the five major phthalates (BBP, DBP, DEHP, DIDP and DINP) currently in use. No risks have been identified for any of the applications in which DINP, DIDP and DBP are used. However, occupational exposure limits have been defined to control emissions of BBP, DBP, and DEHP from processing plants. In addition, for DEHP, it is proposed that consideration should be given to restricting its use in food contact materials and some medical applications. The risk reduction strategies also propose that, for precautionary reasons, the use of phthalates in toys and child care articles should be limited.

These risk reduction proposals have been met via the following legislation:

- Directive 2007/19/EC amending Directive 2002/72/EC (Plastics materials intended to come into contact with food) states that in single use applications, such as cap seals and closures, only BBP, DINP and DIDP may be used and only in contact with non-fatty foods. In repeat use applications (tubes, conveyor belts, etc) BBP, DINP and DIDP can be used in contact with all food types whereas DBP and DEHP can only be used with non-fatty foods. In addition, specific migration limits for phthalates into the various food types must be met.

- Directive 2007/47/EC, amends three earlier directives concerning medical devices. It relates to devices intended to store or transport substances to or from the body. It states that such devices containing phthalates classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2 (in accordance with Directive 67/548/EEC) must be labelled that they contain such phthalates. Also the manufacturer must provide a specific justification for the use of these devices for the treatment of pregnant or nursing women and children.

- Directive 2005/84/EC states that DBP, BBP and DEHP may not be used in any toys and childcare articles and that DINP, DIDP and DNOP may be used only in those that cannot be placed in the mouth.

PEs have been shown not to accumulate in humans or animals. In the body, they are rapidly metabolised and the products excreted. Also they are readily biodegradable and have been shown not to persist in the environment. Phthalate esters have not been shown to cause cancer in humans; no PEs have been

classified as carcinogenic to humans by the International Agency for Research on Cancer (IARC) or under the European Dangerous Substances Directive and associated legislation.

The hazard classification and risk assessment of the PEs has been based on effects seen in rodents. At this time, there is insufficient scientific evidence to conclude that any PEs are endocrine disruptors in humans. Some PEs cause reproductive effects at high doses in rats and mice, by a process which involves the endocrine system. However, these effects have only been seen at exposure levels many times higher than those experienced by humans. One possibility is that DEHP can also cause toxicity to the male reproductive system in animals by a non-endocrine mechanism – by zinc depletion - in testicular sertoli cells.

Due to their classification as category 2 reproductive toxicants, DBP BBP and DEHP are not allowed, under the 7$^{th}$ amendment to the Cosmetics Directive, to be used in cosmetics. In fact they are not used deliberately in these applications and the Scientific Committee on Consumer Products is of the opinion that traces of up to 100 ppm total or per substance do not pose a risk to the health of the consumer (SCCP/1016/06 adopted March 2007)

The above information indicates that most phthalates, in the majority of applications, do not pose a significant risk to human health or the environment and the few risks which have been identified for certain PEs have been successfully managed via legislation.

**EXPOSURE ROUTES**

The amount of PEs found in finished products has little to do with potential exposure since that depends on whether the substances can migrate from the articles and that is determined by the way they were manufactured.

Contrary to public concerns, PEs cannot leach out of bottles containing drinking water or carbonated drinks as such bottles do not contain PEs. Most of these bottles are made of polyethylene terephthalate (PET) which, despite its similarity in name, is very different, chemically, from phthalate esters.

**CONTROL MEASURES**

People most likely to be exposed to PEs are those involved in the manufacture and processing of polymers. Possible exposure to PEs is controlled by the principles laid down in the Control of Substances Hazardous to Health (COSHH) Regulations in the UK. This entails, as a priority, control of emissions at source, by the application of engineering controls, ventilation, where necessary, and the wearing of personal protective equipment.

**ALTERNATIVES**

Different plasticisers are used to produce materials with different properties through variations in plasticiser structure that result from the particular acid and alcohol used in their formation. Adipate esters such as diethylhexyl adipate (DEHA) are also used as plasticisers. Other substances include polyesters, trimellitates, citrates, benzoates, phosphates and alkyl sulphonates. However, phthalate esters remain the most popular choice because of their best all-round performance.

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