**Substance name: Benzyl butyl phthalate**
**EC number: 201-622-7**
**CAS number: 85-68-7**

# PRIORITISATION AND ANNEX XIV BACKGROUND INFORMATION

**14 January 2009**

**Disclaimer**

The present document has been developed by ECHA mainly based on the technical report "Data on Manufacture, Import, Export, Uses and Releases of Benzyl butyl phthalate (BBP) as well as Information on Potential Alternatives to its Use"; prepared by COWI, IOM Consulting and Entec under framework contract ECHA/2008/2 (specific contract ECHA/2008/02/SR1/ECA.224). Secondary sources have been the European Union Risk Assessment report (EC, 2007) and the "Emission Scenario Document on Plastic Additives" (OECD 2004).

Note that the information on alternatives is not intended to be an exhaustive analysis, but is only included in order to support the transitional arrangements and in particular the proposed application dates for substances proposed to be included in Annex XIV.

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**PRIORITISATION AND ANNEX XIV BACKGROUND INFORMATION**

## 1 Prioritisation

Given the high volumes used and the wide dispersive uses of BBP in preparations and in articles, **it is proposed to prioritise BBP for inclusion in Annex XIV**.

## 2 Identity of the substance

| | |
|---|---|
| Chemical name: | Benzyl butyl phthalate (BBP) |
| EC Number: | 201-622-7 |
| CAS Number: | 85-68-7 |
| IUPAC Name: | Benzyl butyl phthalate |

## 3 Intrinsic properties

The substance has been identified as a Substance of Very High Concern according to Article 57(c) as it is classified as Toxic to Reproduction, Category 2 as reported in the support document on Benzyl butyl phthalate (BBP) and the agreement of the MSC adopted on 1 October 2008.

## 4 Volumes

The substance is manufactured in the EU in a volume of approximately 20,000 tonnes/year in 2007 (Lassen et al., 2009). The manufacture has decreased dramatically over the last 10 years from 45,000 tonnes/year in EU-15 in 1994-1997.

A net export of approximately 12,000 tonnes/year is estimated (Lassen).

Thus, the use in the EU is estimated to be approximately 8,000 tonnes/year.

## 5 Characterisation of uses and releases

### 5.1 Manufacture and uses

In the EU, two manufacturing sites have been identified.

More than 70% of the BBP is used as a plasticiser in polymer products, mainly PVC for flooring. Plasticisers have the function of improving the polymer material's flexibility and workability by adding surface properties to flooring materials that minimise maintenance and give it a prolonged life. BBP is one of a number of substances used as plasticiser in PVC and other polymer materials. BBP is, according to industry, an unusual plasticiser because of its chemical asymmetry which results in unique performance properties (Lassen et al., 2009). It is worthwhile noticing that BBP when used as a plasticiser is not chemically bound in the matrix.

An additional use of BBP is in preparations, where sealants, adhesives, coatings and inks are the main products (Lassen et al., 2009).

The total use of BBP for formulation and processing is shown in Table 1.

**Table 1 BBP use for processing in 2007 (Lassen et al., 2009)**

| Process | Tonnage (t/y), 2007 | % of total, 2007 | Number of sites of use (2004/2006) |
|---|---|---|---|
| **Formulation and processing (at same site):** | | | |
| Plastisol coating for flooring | 3,840 | 48 | 9 (in 2006) |
| Coating of leather and textiles | 800 | 10 | <10 |
| Calendering of films | 560 | 7 | n.d. (few) |
| **Processing from compound:** | | | |
| Processing of hard PVC | 640 | 8 | n.d. |
| **Non-polymeric** | | | |
| Processing of sealants | 1,520 | 19 | 6 (formulation sites) |
| Processing of coatings and inks | 160 | 2 | n.d. (few) |
| Processing of adhesives | 400 | 5 | n.d. |
| Processing of other non-polymeric | 80 | 1 | n.d. |
| Total processing (rounded) | 8,000 | 100 | |

*1 Source: EC (2007).
n.d. = No data

The estimated content of BBP in articles and preparations marketed in the EU is provided in Table 2.

**Table 2 Estimated BBP tonnage in end-products marketed in the EU27 based on EU manufacture data 2007 (Lassen et al., 2009)**

| End-product use area | Tonnage, t/y | | | | % of total use |
|---|---|---|---|---|---|
| | EU Manufacture | Import | Export | End-product use | |
| Flooring | 4,290 | n.d. | n.d. | 4,290 | 54 |
| Film | 110 | n.d. | n.d. | | 0 |
| Coated fabric, upholstery, shoe uppers, luggage,etc. | 800 | n.d. | n.d. | 800 | 10 |
| Hard PVC | 640 | n.d. | n.d. | 640 | 8 |
| Non polymer applications: | | | | | |
| Sealant | 1,520 | n.d. | n.d. | 1,520 | 19 |
| Paints and ink | 160 | n.d. | n.d. | 160 | 2 |
| Adhesives | 400 | n.d. | n.d. | 400 | 5 |
| Other non-polymeric | 80 | n.d. | n.d. | 80 | 1 |
| Total end-product use (round) | 8,000 | n.d. | n.d. | 7,890 | 100 |

n.d. No data

## 5.2 Releases

According to the Emission Scenario Document on Plastic Additives (OECD, 2004), the major releases of phthalates from polymer conversion processes occur initially as gaseous phthalate. No information is available on releases to the working environment (Lassen et al., 2009).

The estimated releases to the environment from all activities are summarised in Table 3. The emission factors applied in this study are largely derived from the EU Risk Assessment Report for BBP published in 2007 (EC, 2007). The main releases are to air and waste water. The use of end products gives rise to the largest releases to the environment with washing of flooring as the largest single source. For releases to the air, both processing and end product uses add significantly to the total with no pronounced major emission source (Lassen et al., 2009).

**Table 3 Releases of BBP from manufacturing, formulation, processing, end-products use and disposal in the EU in 2007 (Lassen et al., 2009)**

| Activity | Tonnage handled | Emission to (t/y): | | |
|---|---|---|---|---|
| | t/y | Air | Soil | Waste water |
| EU manufacture of BBP | 20,000 | 0.1 | n.d. | 220 |
| Transportation of substance from manufacturing | 20,000 | 0 | 0 | 1 |
| Formulation | 2,800 | 1 | 0.3 | 4 |
| Processing | 8,000 | 19 | 5.3 | 10 |
| End-product uses | 8,000 | 29 | 4.0 | 121 |
| Disposal | 7,740 | 0.02 | 0.2 | 1 |
| Total releases (round) | | 50 | 10 | 360 |

Note: Figures are rounded and higher than actual figures.

## 5.3 Geographical distribution

According to obtained information, BBP is manufactured at two sites in the EU (Lassen et al., 2009).

BBP is used for formulation and processing at relatively few sites in the EU, cf. Table 1 (EC 2007).

The major use of BBP is for production of flooring, but in addition it is also used in a large and diverse number of articles and preparations, which are probably used widespread in the EU.

## 5.4 Conclusions on wide dispersiveness

The formulation and processing of BBP into preparations and in particular into polymer (mainly PVC) products take place at relatively few sites in the EU. The

articles and preparations produced are used throughout the EU. As BBP is not chemically bound in either preparations or articles, the potential for release and subsequent exposure is high. Consequently, there is a wide dispersive use of BBP and preparations and articles containing BBP.

## 6 Complexity of the supply chain

The main use of BBP is as plasticiser in polymers, mainly PVC. The main end product is flooring, which is produced from pre-mixed PVC compounds in a relatively simple production process and the number of actors in the supply chain can be considered as rather limited. Other uses are for polymers used for coating of leather and textiles and for calendering of films. Finally, BBP is used as component in preparations (incl. adhesives, sealants, coatings and printing inks), for which the number of actors in the supply chain and its complexity appear to be much higher (Lassen et al., 2009). The final preparations are often formulated from other pre-formulations that may be prepared by other formulators. Thus, the formulators of the final preparations are often located at the end of a relatively long and possibly complex supply chain.

As conclusion, according to available information, different types of industries and activities involving a large number of actors may be affected by the possible authorisation requirement and may need to get involved directly or indirectly in the preparation of applications. Thus, the supply chain is characterised as being relatively complex.

## 7 Alternatives

The decrease in production volumes in recent years reflects the fact that BBP has been replaced for many applications by other substances.

BBP is used in a number of applications and in particular flooring. BBP is used by the flooring industry together with other plasticisers because it adds surface properties to flooring materials that minimise maintenance and give it a prolonged life. When considering alternatives, BBP may be either replaced with a substance with similar technical properties or the plasticised PVC flooring may be replaced by another plasticised PVC flooring that may have a slightly different functionality (Lassen et al., 2009).

Alternatively the flooring (and other products) can be replaced by PVC with other plasticiser systems where the BBP is not needed. It is considered that some of the alternatives introduced to DEHP may be considered useful alternatives to BBP as well and a number of alternatives to DEHP have been assessed. It has not been assessed in detail to what extent the use of the alternatives can provide exactly the same functionality as BBP, e.g. with regard to the need for maintenance of flooring, as the alternatives have mainly been assessed as alternatives to DEHP (Lassen et al., 2009).

***Technical and economic feasibility and availability of alternatives***

The technical feasibility of replacing BBP for different applications depends on a range of performance criteria, including inter alia material compatibility, temperature performance, volatility, migration and permanence of plasticiser, efficiency, tensile strength, and hardness. The use of alternative plasticisers may imply some changes in processing and material composition and may imply some research and development as well as changes in process technology (Lassen et al., 2009).

BBP adds, as mentioned above, according to industry surface properties to flooring materials that minimise maintenance and gives it a prolonged life compared to other phthalates. The same property is probably also relevant for the use of BBP for coating of textiles. Use of alternatives may imply that the material would need more maintenance (Lassen et al., 2009).

The BBP can, however, be replaced by other phthalates and non phthalate plasticisers although it may be at the expense of some of these properties. Alternatives to DEHP for applications where both DEHP and BBP are used would therefore be considered as possible alternatives to BBP as well with the reservation that not all properties may be matched (Lassen et al., 2009).

BBP has in recent years been extensively replaced by other plasticisers for a number of applications, and a range of alternatives are available from suppliers of plasticisers (Lassen et al., 2009).

A number of previous assessments of, in total, 18 potential alternative substances to phthalates have been reviewed and, on this basis, five alternatives were selected for further assessment. The main direct alternative to BBP in flooring, and other applications, has been dipropylene glycol dibenzoate (DGD) that has some of the same technical properties as BBP (Lassen et al., 2009).

An overview of possible alternatives for the main uses is provided in Table 4 (Lassen et al., 2009).

**Table 4 Applications specifically mentioned by suppliers of selected alternatives (Lassen et al., 2009)**

| | DGD | ASE | DINP | DEHT | DINCH |
|---|---|---|---|---|---|
| Flooring | x | | x | x | |
| Calendered film | | x | x | x | x |
| Spread coated fabric | x | x | | x | x |
| **Non polymer applications:** | | | | | |
| Adhesives | x | x | | | x |
| Paints/lacquers | | x | | | x |
| Sealants (glass insulation, construction) | x | x | x | | |

It has not been investigated in detail whether alternatives exist for all applications of BBP. However, no information is available indicating applications for which the substitution of BBP would be particularly difficult (Lassen et al., 2009).

***Hazard profiles of selected potential alternatives***
The following substances were selected for the more detailed assessment (Lassen et al., 2009):

- Dipropylene glycol dibenzoate (DGD) (CAS No 27138-31-4)
- Di-iso-nonyl phthalate (DINP) (CAS No 68515-48-0, 28553-12-0);
- Di(2-ethylhexyl) terephthalate (DEHT) (CAS No 6422-86-2);
- Di-isononyl-cyclohexan-1,2-dicarboxylate (DINCH) (CAS No 166412-78-8);
- Alkylsulphonic phenyl ester (ASE) (CAS No 91082-17-6).

In order to assess the toxicity of the selected alternatives, information on the intrinsic properties, including their human health hazard profile has been collected. On this basis tentative Derived No Effect Levels (DNELs) for critical endpoints have been established (cf. Lassen et al., 2009).

The level of information available on the hazard properties of these potential alternatives varies and is not comparable with that for BBP in all cases. This should be taken into account in making any comparisons of these substances with the hazards/risks of BBP (Lassen et al., 2009).

With regard to potential environmental hazards and risks of alternatives, a number of existing assessments and databases on hazardous effects have been reviewed. In some cases, PNEC values have been drawn from existing assessments. In others, information on the hazardous properties of the potential alternatives has been provided (Lassen et al., 2009).

***Conclusions***
It is evident from the data reviewed that there is a wide variability in the level of information available (and validity of data sources) amongst the potential alternatives and, as such, drawing definitive conclusions on whether any additional risks for the environment would be introduced if these were to be substituted for BBP is not straightforward for all substances (Lassen et al., 2009). Thus, no firm conclusion on the suitability of the alternative substances identified can be reached at this stage.

**Other materials**
Besides the replacement of BBP with other plasticisers, the soft PVC itself may be replaced with other materials. A range of alternative materials to PVC have been investigated in detail in previous studies. The available studies demonstrate that, for many applications of DEHP/PVC, alternative materials exist at similar prices, but no comparisons to BBP containing PVC have been available. These other studies suggest that many of the materials seem to have equal or better environmental, health and safety, performance and cost profiles than DEHP/PVC, but clear conclusions are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments (Lassen et al., 2009).

## 8 Existing Community legislation relevant for possible exemptions

It is noted that BBP is restricted in accordance with Directive 76/769/EEC as follows:

Entry 30: Substances (e.g. BBP) which appear in Annex I to Directive 67/548/EEC classified as toxic to reproduction category 1 or 2, shall not be placed on the market for supply to the general public as a substance on its own or in preparations when the individual concentration is equal to or greater than 0.5%. This does not apply to medicinal or veterinary products, cosmetic products, motor fuels, mineral oil products intended for use as fuel, fuels sold in closed systems, and artists' paints.

Entry 51: BBP shall not be placed on the market or used on its own or as a constituent of a preparation at concentrations higher than 0.1% by mass of the plasticised material, in toys and childcare articles.

Thus, for these restricted uses, no authorisation can be granted.

## 9 Other information

Not available.

## 10 References

European Commission (2007). European Union Risk Assessment Report, Benzyl butyl phthalate (BBP). European Commission, JRC, EUR 22773 EN.

Lassen, C., J. Maag, L.B. Hubschmann, E. Hansen, A. Searl, E. Doust & C. Corden (2009). Data on manufacture, import, export, uses and releases of Benzyl butyl phthalate (BBP) as well as information on potential alternatives to its use. COWI, IOM & Entec report to ECHA.

OECD (2004). Emission Scenario Document on Plastic Additives. Organisation for Economic Co-operation and Development, Paris.