



**Substance name: Bis(2-ethylhexyl)phthalate**  
**EC number: 204-211-0**  
**CAS number: 117-81-7**

**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 Bis(2-ethylhexyl) phthalate (DEHP) 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, 2008) and web information from the European Council for Plasticisers and Intermediates (ECPI, 2008).

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

### **2 Identity of the substance**

Chemical name:	Bis(2-ethylhexyl) phthalate (DEHP)
EC Number:	204-211-0
CAS Number:	117-81-7
IUPAC Name:	Bis(2-ethylhexyl) 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 Bis(2-ethylhexyl) phthalate (DEHP) and the agreement of the MSC adopted on 1 October 2008.

### **4 Volume(s)**

The substance is manufactured in the EU in a volume of approximately 340,000 tonnes/year in 2007 (Lassen et al., 2009). The manufacture has decreased dramatically over the last 10 years from 595,000 tonnes/year in EU-15 in 1997. Note that no information on manufacture in 1997 is available for the 12 current Member States that were not members in 1997.

A net export of DEHP on its own at approximately 50,000 tonnes/year in 2007 is estimated (Lassen et al., 2009), which is a slight decrease since 2005. In addition, a net export of DEHP in preparations at approximately 10,000 tonnes/year in 2007 is estimated (Lassen et al., 2009).

Thus, the net use in the EU is estimated to approximately 280,000 tonnes/year in 2007.

### **5 Characterisation of uses and releases**

#### **5.1 Manufacture and uses**

In the EU, seven manufacturing sites have been identified. The manufactured DEHP is further processed in different formulation and processing steps, through which a wide range of articles and preparations are produced (Lassen et al., 2009).

DEHP is one of a number of substances widely used as plasticiser in PVC and other polymer materials used for producing a range of products including flooring, roofing, cables, profiles and medical products such as blood bags and dialysis equipment. The content of DEHP in flexible polymer materials varies, but is often around 30% (w/w). It is worthwhile noticing that DEHP when used as a plasticiser is not chemically bound in the matrix (Lassen et al., 2009).

In addition, DEHP is used in a large number of various preparations including adhesives, sealants, rubber, lacquers, paints, and printing inks (Lassen et al., 2009).

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

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

Process	Tonnage (t/y), 2007	% of total, 2007	Number of sites of use (1999)
<b>Formulation and processing (at same site):</b>			
Calendering of film/sheet and coated products	44,000	16	74
Calendering of flooring, roofing, wall covering	21,000	7	20
Extrusion of hose and profile	35,000	12	82
Extrusion of wire and cable	49,000	17	62
Spread coating of flooring	24,000	8	21
Spread coating of coated fabric, wall covering, coil coating, etc.	47,000	17	115
Car undercoating	4,000	1	n.d.
Slush/rotational moulding, dip coating	6,000	2	n.d.
<b>Processing from compound:</b>			
Extrusion of cables, medical, and misc. products	21,000	7	n.d.
Injection moulding of misc. products	22,000	8	n.d.
Plastisol processing from compounds	900	0	n.d.
<b>Non-polymeric, processing:</b>			
Adhesives/sealant	7,000	2	n.d.
Lacquers and paint	900	0	n.d.
Printing ink	1,000	0	n.d.
Production of ceramics	20	0	n.d.
Total processing (rounded)	283,000	97	

\*) EC (2008)

n.d. No data

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

**Table 2 Estimated DEHP tonnage in end products marketed in the EU based on EU manufacture, import, export data (Lassen et al., 2009)**

End-product use area	Tonnage, t/y				% of total use
	EU Manufacture	Import	Export	End-product use	
<b>Indoor uses:</b>					
Flooring	33,000	2,000	4,800	30,200	10.6
Wall covering	11,000	700	1,600	10,100	3.5
Film/sheet and coated products made by calendering	44,000	13,600	16,400	41,200	14.5
Wires and cables	52,000	6,200	5,600	52,600	18.5
Hoses and profiles	31,000	1,600	3,000	29,600	10.4
Coated fabric and other products from plastisol	31,000	2,200	1,400	31,800	11.2
Moulded products	3,000	2,700	700	5,000	1.8
Other polymer applications	12,300	10,900	3,100	20,100	7.1
Non polymer applications:					
Adhesives and sealant	4,000	n.d.	n.d.	4,000	1.4
Lacquers and paints	500	n.d.	n.d.	500	0.2
Printing ink	1,000	n.d.	n.d.	1,000	0.4
Other non-polymeric	20	n.d.	n.d.	20	0.0
<b>Outdoor uses:</b>					
Calendered roofing material	600	n.d.	n.d.	600	0.2
Coil coated roofing material	3,000	n.d.	n.d.	3,000	1.1
Wire and cables - air	2,400	n.d.	n.d.	2,400	0.8
Wire and cables - soil	9,700	n.d.	n.d.	9,700	3.4
Coated fabric	12,800	n.d.	n.d.	12,800	4.5
Car undercoating	4,000	n.d.	n.d.	4,000	1.4
Hoses and profiles	3,700	n.d.	n.d.	3,700	1.3
Shoe soles	19,400	n.d.	n.d.	19,400	6.8
Non polymer applications:					
Lacquers and paints	400	n.d.	n.d.	400	0.1
Adhesives and sealant	3,300	n.d.	n.d.	3,300	1.2
<b>Total end-product use (round)</b>	<b>282,000</b>	<b>40,000</b>	<b>37,000</b>	<b>285,000</b>	<b>100</b>

## 5.2 Releases

No information is available on releases to the working environment. In the RAR (EC, 2008) it was concluded that a worst case for exposure via inhalation is estimated at 5 mg/m<sup>3</sup> (aerosol) based on measurements, and for dermal exposure to be at 650 mg/day on a skin area of 1,300 cm<sup>2</sup> based on the EASE model.

The highest concentrations in the indoor environment are expected in rooms with DEHP plasticised floorings and wall coverings, because of the large surfaces from where the substance can be released (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 RAR (EC, 2008). The main releases are to soil and waste water. The use of end products (articles) gives rise to the largest releases to the environment with washing of flooring, releases from underground cables and abrasive releases and pieces lost in the environment as the largest single sources. The releases from landfills may in fact be higher than indicated if total releases until the DEHP is ultimately degraded are considered, but no data on the long-term fate of DEHP in landfills have been made available (Lassen et al., 2009).

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

Activity	Tonnage handled t/y	Emission to (t/y):		
		Air	Soil	Waste water
EU manufacture of DEHP	341,000	1	4	220
Transportation of substance from manufacturing	345,479	0	0	29
Formulation	61,000	30	1	97
Processing	283,000	174	41	125
End-product uses, indoor	223,000	380	0	1,240
End-product uses, outdoor, non-abrasive leakages	33,000	30	3,980	500
End-product uses, outdoor, abrasive leakages	33,000	5	3,500	1,200
Disposal and recycling operations	275,133	9	48	10
Total releases (round)		600	7,600	3,400

\*1 The tonnage handled is the sum of EU manufacture and import

### 5.3 Geographical distribution

DEHP is manufactured at seven sites in seven different Member States (Lassen et al., 2009).

DEHP is used for formulation and processing at a large number of sites in the EU, and the number of sites is assumed to be 500 to 1,000.

DEHP is used in a very large number of diverse articles and preparations, which are used ubiquitously in the EU.

Thus, in conclusion, DEHP can be found in preparations and articles on the market throughout the EU.

## **5.4 Conclusions on wide dispersiveness of uses**

The formulation and processing of DEHP into preparations and in particular into polymer (mainly PVC) products take place at a large number of sites in the EU. The articles and preparations produced are used ubiquitously in the EU. As DEHP 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 preparations and articles containing DEHP.

## **6 Complexity of the supply chain**

The main use of DEHP is as plasticiser in polymers, mainly PVC. A large number of articles are produced from pre-mixed PVC compounds in a relatively simple production process (e.g., flooring, roofing, cables and profiles) (Lassen et al., 2009) and the supply chain could probably be characterised as consisting of only a few steps (i.e. mixing of DEHP into the PVC pre-mix and direct production of the end product from the pre-mix). However, the number of producers of end products is relatively high and these end products are installed by a high number of actors representing different types of construction industries, which adds to the coordination needed in case a future application for authorisation has to be prepared. Thus, the supply chain is characterised as relatively complex. Other uses in polymers may take place by downstream users further away from the manufacturers (e.g., use in coated fabrics) and the supply chain could probably also be characterised as complex.

A comparatively minor use of DEHP is as component in preparations (adhesives and sealants, lacquers and paints, printing inks) (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 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 complex.

## **7 Alternatives**

### **Alternative substances**

A number of potential alternatives to DEHP have been identified that may be applied for different application areas. Only a few of the alternatives have undergone a comprehensive environmental and health assessment combined with an assessment of the economic and technical feasibility of substitution. For some critical applications, non-phthalate alternatives are widely used, demonstrating the feasibility of substitution for at least these applications, but for many of the large volume applications like flooring or cable/wires, phthalates (mainly DINP) are still the plasticiser of choice (Lassen et al., 2009).



Some of the alternatives have been shown to cause reproductive toxicity and have not been evaluated further. Others seem not to have widespread use today. DINP is, however, included as it represents the main alternative to DEHP applied today (Lassen et al., 2009).

It has not been the aim to make a comprehensive data collection and assessment of all potential alternative substances and, for this reason, a limited number of substances have been selected, representing the most used alternatives and some alternative substances that, based on previous studies, seem to be promising from a health and environmental perspective. The rejection of some substances for the further assessment should not be interpreted to imply that these substances would not be suitable and acceptable alternatives to DEHP (Lassen et al., 2009).

The following substances were selected for the more detailed assessment (Lassen et al., 2009):

- Di-iso-nonyl phthalate (DINP) (CAS No 68515-48-0, 28553-12-0);
- Di(2-ethylhexyl) terephthalate (DEHT) (CAS No 6422-86-2);
- Butyryl trihexyl citrate (BTHC) (CAS No 82469-79-2);
- Di-isononyl-cyclohexan-1,2-dicarboxylate (DINCH) (CAS No 166412-78-8);
- Alkylsulphonic phenyl ester (ASE) (CAS No 91082-17-6).

Non-phthalate alternatives have mainly been applied for applications where there has been a concern as to human exposure to the substance: toys, medical products, packaging for food and water beds are examples. Applications for which the selected alternatives are specifically mentioned by suppliers of the alternatives are shown in Table 4, but the substances may probably be used for other applications as well (Lassen et al., 2009).

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

	DINP	DEHT	BTHC	DINCH	ASE
Flooring and wall covering	x	x			
Film/sheet and coated products	x	x		x	x
Medical products			x	x	
Wire and cable	x				
Coated fabric and footwear		x		x	x
Toys		x			x
Automotive	x				
<b>Non polymer applications:</b>					
Adhesives				x	x
Printing inks				x	x
Sealants (glass insulation, construction)	x				x

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).

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 on alternative substances***

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 human health or the environment would be introduced if these were to be substituted for DEHP is not straightforward for all substances (Lassen et al., 2009). Thus, no firm conclusions on the suitability of the alternative substances identified can be reached at this stage.

#### ***Alternative materials***

Besides the replacement of DEHP with other plasticisers, the soft PVC may be replaced with other materials. However, comparison of DEHP/PVC with alternative materials is complicated by the fact that the materials cannot be compared on the basis of the difference in health and environmental profiles only, but that for a comprehensive comparison it is necessary to include many other technical aspects and environmental parameters. For a full comparison of the materials it is thus necessary to compare the materials in a life cycle perspective taking also into account e.g. the life-span of the materials, the energy consumption by manufacturing and the maintenance of materials (Lassen et al., 2009).

#### ***Alternative materials for resilient flooring***

Three materials have been assessed as alternatives to DEHP/PVC, of which cork and linoleum appeared according to the authors to have equal or better environmental, health and safety, performance and cost profiles (cited in Lassen et al., 2009).

#### ***Alternative materials for wall coverings***

For wall coverings numerous alternative materials were assessed, including woven glass textiles, a wood fiber/polyester blend, cellulose polyester blends, a wood pulp/recycled paper blend, biofiber products, and polyolefin/synthetic textiles. According to the authors, each appeared to present a feasible alternative to DEHP/PVC for wall covering applications (cited in Lassen et al., 2009).

#### ***Conclusion on alternative materials***

The available studies demonstrate that for many applications of DEHP/PVC, alternative materials seem to be available. Many of the materials seem to have equal or better environmental, health and safety, performance and cost profiles, but clear conclusion are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments. The available studies demonstrate the complexity in the evaluation, and it is deemed that more unambiguous conclusions cannot be drawn based on the information currently available (Lassen et al., 2009).

## 8 Existing Community legislation relevant for possible exemptions

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

Entry 30: Substances (e.g. DEHP) 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: DEHP 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

ECPI (2008). European Council for Plasticisers and Intermediates (ECPI). Information on website at: <http://www.ecpi.org> and <http://www.dehp-facts.com/>

European Commission (2008). European Union Risk Assessment Report, Bis(2-ethylhexyl) phthalate (DEHP). European Commission, JRC, EUR 23384 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 Bis(2-ethylhexyl) phthalate (DEHP) as well as information on potential alternatives to its use. COWI, IOM & Entec report to ECHA.