



Substance name: Dibutyl phthalate
EC number: 201-557-4
CAS number: 84-74-2

**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 Dibutyl phthalate (DBP) as well as Information on Potential Alternatives to its Use”; prepared by COWI, IOM and Entec under framework contract ECHA/2008/2 (specific contract ECHA/2008/02/SR1/ECA.224). A secondary source has been the European Union Risk Assessment report (EC, 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 very high volumes used and the wide dispersive uses of DBP in preparations and in articles, **it is proposed to prioritise DBP for inclusion in Annex XIV.**

2 Identity of the substance

Chemical name:	Dibutyl phthalate (DBP)
EC Number:	201-557-4
CAS Number:	84-74-2
IUPAC Name:	Dibutyl 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 Dibutyl phthalate (DBP) 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 less than 10,000 tonnes/year in 2007 (Lassen et al., 2009). The manufacture has decreased over the last 10 years from 26,000 tonnes/year in EU-15 in 1998.

A net export of approximately 2,000 tonnes/year is estimated (Lassen et al., 2009).

Thus, it is estimated that the net use in the EU is approximately 8,000 tonnes/year in 2007.

5 Characterisation of uses and releases

5.1 Manufacture and uses

In the EU, three sites manufacturing DBP in 2005 have been identified, but one of these sites has now ceased the manufacture leaving only two manufacturing sites in 2007 (Lassen et al., 2009).

DBP is a specialist plasticiser often used in combination with other high molecular weight phthalates because it in itself is too volatile for PVC applications. Instead it is used as a gelling aid in combination with other plasticizers for nitrocellulose, cellulose ether, and polyacrylate and polyacetate dispersions. Applications mentioned include floor coverings, gelling additives, adhesives, dispersions and nitrocellulose

(Lassen et al., 2009). It is worthwhile noticing that DBP when used as a plasticiser is not chemically bound in the matrix.

The manufactured DBP is further processed in different formulation and processing steps, through which a wide range of end products are produced including adhesives and paints (Lassen et al., 2009).

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

Table 1 Maximum DBP use for formulation and processing in 2007 and 1998 (Lassen et al., 2009)

Process	Tonnage (t/y), 2007	% of total, 2007	Tonnage (t/y), 1998 *1
Polymers formulation and processing	5,700	69	13,500
Formulation and processing of fiber glass	160	2	
Non-polymeric, processing:			
Processing of paint	160	2	1,250
Processing of adhesives	1,900	23	2,500
Processing of grouting agents	80	1	200
Processing of other non-polymeric	250	3	550
Total processing (rounded)	8,300	100	18,000

*1 Source: EC (2004).

n.d. = No data

The estimated content of DBP in articles and preparations marketed in the EU is provided in Table 2 (Lassen et al., 2009).

Table 2 "Best estimated scenario" for DBP 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	
Polymers (incl. fiber glass), interior use	2,930	n.d.	n.d.	2,930	36
Polymers (incl. fiber glass), exterior use	2,930	n.d.	n.d.	2,930	36
Non polymer applications:					
Paint	160	n.d.	n.d.	160	2
Adhesives	1,900	n.d.	n.d.	1,900	23
Grouting agents	80	n.d.	n.d.	80	1
Other non-polymeric	250	n.d.	n.d.	250	3
Total end-product use (round)	8,250	n.d.	n.d.	8,250	100

n.d. No data

5.2 Releases

No information is available on releases to the working environment. In the RAR (EC, 2004) it was concluded that a worst case for exposure via inhalation is estimated at 5 mg/m³ (aerosol) based on measurements, and for dermal exposure to be at 650 mg/day on a skin area of 1,300 cm² based on the EASE model.

The highest concentrations in the indoor environment are expected in rooms with DBP plasticised floorings, 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 EU Risk Assessment Report for DBP (EC, 2004). The main releases are to air and waste water. The use of end products gives rise to the largest releases to the environment. The releases from landfill may in fact be higher than indicated if total releases until the DBP is ultimately degraded are considered, but no data on the long term fate of DBP in landfills have been made available.

Table 3 "Best estimate scenario" of releases of DBP from manufacturing, formulation, processing, end-products use and disposal in the EU in 2007 (figures are rounded and higher than actual figures) (Lassen et al., 2009)

Activity	Tonnage handled t/y	Emission to (t/y):		
		Air	Soil	Waste water
EU manufacture of DBP	10,000	0.1	0.0	0.9
Transportation of substance from manufacturing	12,200	0.0	0.0	6.1
Formulation	2,380	5.2	0.2	6.2
Processing	8,300	6.7	10.3	9.0
End-product uses	8,250	141.0	115.0	281.0
Disposal	7,710	0.9	0.2	13.8
Total releases (round)		154	126	317

5.3 Geographical distribution

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

DBP is used for formulation and processing by major users at 50-100 sites in the EU. In addition, an unknown number of minor users exist (Lassen et al., 2009).

DBP is used in a diverse number of end products, which presumably are used widespread in the EU.

5.4 Conclusions on wide dispersiveness

The formulation and processing of DBP into preparations and into polymer products by major users take place at 50-100 sites in the EU. The end products are widely used in the EU. As DBP 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 DBP.

6 Complexity of the supply chain

DBP is either further processed, mainly as gelling aid in combination with other plasticisers in various types of polymers (PVC and non-PVC polymers), or formulated into preparations (e.g. adhesives, grouting agents and paints). These different applications may indicate a large number of companies (assumed to be more than 1 000) involved in the further processing and formulation of DBP in the supply chains, through which a wide range of preparations and articles are finally produced. Downstream users and users of the preparations and articles containing DBP represent several different industry sectors (Lassen et al., 2009).

In conclusion, according to available information, many different types of industries and activities involving a large number of actors may be affected by an authorisation requirement.

7 Alternatives

Following the classification of DBP as Reprotoxic (Cat. 2), DBP has been replaced by alternative substances for many applications, which is reflected in the steep decline in the total consumption of the substance as described in the section 3. Further, for some applications the plasticised PVC has been replaced with other materials (Lassen et al., 2009).

Relatively little is known about which alternatives have actually been used as alternatives to DBP as most studies on alternatives have focused on alternatives to DEHP with a production volume of more than 20 times the volume of DBP (Lassen et al., 2009).

Technical and economic feasibility and availability of alternatives

According to industry, DBP adds surface properties to flooring materials that minimise maintenance and give it a prolonged life compared to use of other phthalates. The same property is probably also relevant for the use of DBP for coating of textiles. Use of alternatives may imply that the material needs more maintenance (Lassen et al., 2009).

The DBP 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 DBP are used, would therefore be considered as possible alternatives to DBP as well with the reservation that not all properties may be matched. For this reason, studies of alternatives to DEHP and to phthalates in more

general (including DBP) have been reviewed for the identification of potential alternatives to DBP (Lassen et al., 2009).

The technical feasibility of replacing DBP 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).

DBP 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. The possible applications of these alternatives are presented in Table 4 below (Lassen et al., 2009).

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

	DIBP	DINP	DINCH	GTA *1	DGD
Floor covering	x	x			x
Gelling additive	x				x
Non polymer applications:					
Adhesives	x		x	X	x
Dispersions	x		x	X	x
Nitrocellulose					x

*1 Not specifically indicated on website but indicated by Lanxess for this study as alternative to DBP in adhesives and dispersions.

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

Hazard profiles of selected potential alternatives

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

- Di-iso-butyl phthalate (DIBP) (CAS No 84-69-5);
- Di-iso-nonyl phthalate (DINP) (CAS No 28553-12-0);
- Di-isononyl-cyclohexan-1,2-dicarboxylate (DINCH) (CAS No 166412-78-8);
- Glyceryl triacetate (GTA) (CAS No 102-76-1);
- Dipropylene glycol dibenzoate (DGD) (CAS No 27138-31-4).

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 and for some potential alternatives, PNEC values or other information on the hazardous properties have been identified (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 DBP 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.

8 Existing Community legislation relevant for possible exemptions

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

Entry 30: Substances (e.g. DBP) 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: DBP 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 (2004). European Union Risk Assessment Report, Dibutyl phthalate (DBP). European Commission, JRC, EUR 19840 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 Dibutyl phthalate (DBP) as well as information on potential alternatives to its use. COWI, IOM & Entec report to ECHA.