1 June 2009

Background document for dibutyl phthalate (DBP)

Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV

1. Identity of the substance

Chemical name:	dibutyl phthalate (DBP)
EC Number:	201-557-4
CAS Number:	84-74-2
IUPAC Name:	dibutyl phthalate

2. Background information

2.1. Intrinsic properties

DBP was identified as a Substance of Very High Concern (SVHC) pursuant to Article 57(c) as it is classified as Toxic to Reproduction, Category 2[1] and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

2.2. Imports, exports, manufacture and uses

2.2.1. Volume(s), imports/exports

The substance is manufactured in the European Union (EU) in a volume of less than 10,000 tonnes/year in 2007 (COWI, IOM & Entec, 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 (COWI, IOM & Entec, 2009).

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

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

[1] This document refers (here and in its other parts) to classification in accordance with Directive 67/548/EEC to keep the references in line with the entry in the published Candidate list. ECHA will update the Candidate list to follow the CLP Regulation ((EC) No 1272/2008) in future.

In the EU, three sites manufacturing DBP in 2005 were identified, but one of these sites has now ceased the manufacture leaving two manufacturing sites in 2007 (COWI, IOM & Entec, 2009).

The estimated releases from manufacturing of DBP in the EU in 2007 are as follows (COWI, IOM & Entec, 2009):

- Air: 0.1 t/y
- Soil: 0.0 t/y
- Waste water: 0.9 t/y

2.2.2.2. Uses and releases from uses

The manufactured DBP is either further processed - mainly as gelling aid and plasticiser - in various types of polymers (PVC and other polymers) or formulated as component in preparations (e.g. adhesives, grouting agents, paints).
DBP is a specialist plasticiser often used in combination with other high molecular weight phthalates. It is also 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 and dispersions (COWI, IOM & Entec, 2009). It is worthwhile noticing that DBP when used as a plasticiser is not chemically bound in the matrix.

This leads to a wide range of end products (COWI, IOM & Entec, 2009) in addition to interior and outdoor polymer applications such as e.g. advanced textile products, coating and primary packaging of medicinal products, military propelling charges, explosives, equipments for nuclear installations, catalysts for the production of polypropylene (RCOM, 2009).

DBP is also used as analytical standard for test and measurement instruments and as reagent in the manufacture of medicinal products and active pharmaceutical substances (RCOM, 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 (COWI, IOM & Entec, 2009)

Process	Tonnage (t/y), 2007	% of total, 2007	Tonnage (t/y), 1998 *
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

* 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 (COWI, IOM & Entec, 2009).

Table 2 "Best estimated scenario" for DBP tonnage in end-products marketed in the EU27 based on EU manufacture data 2007 (COWI, IOM & Entec, 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

The estimated releases to the environment from all activities are summarised in Table 3.

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 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) (COWI, IOM & Entec, 2009)

Activity	Tonnage handled	Emission to (t/y):		
	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

2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

As already mentioned in the sections above, according to available information DBP is currently manufactured at two sites in different Member States.
DBP is then further used for formulation and processing by major users at 50-100 sites in the EU; in addition, an unknown number of minor users exists (COWI, IOM & Entec, 2009). The different applications and relatively high amounts of DBP used may indicate that a large number of companies (assumed to be more than 1 000) are actually involved in the further processing and formulation of DBP down into the supply-chains throughout EU, through which a wide range of preparations and articles are finally produced. The supply-chains related to DBP contain in many cases several levels. Downstream users the preparations and users of articles containing DBP represent several different industry sectors (COWI, IOM & Entec, 2009).

In conclusion, according to the information available, the supply chains of DBP involve several levels and many different types of industries and activities with a large number of actors throughout EU.

2.3. Availability of information on alternatives

It appears that, following the classification of DBP as Toxic to reproduction (Cat. 2), DBP has already 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 2.2.1. Further, it appears for some applications the plasticised PVC has been replaced with other materials (COWI, IOM & Entec, 2009).

Although it has not been investigated whether suitable alternatives exist for all applications of DBP, there is not either explicit information on specific difficulties in substituting DBP in certain applications (COWI, IOM & Entec, 2009). However, from the information available, it appears that 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 (COWI, IOM & Entec, 2009).

Table 4 shows the possible applications of a non-exhaustive list of possible alternative substances (COWI, IOM & Entec, 2009).

Table 4 Applications specifically mentioned by suppliers of selected alternatives (COWI, IOM & Entec, 2009)

	DIBP[2, 3]	DINP[4]	DINCH[5]	GTA[6]	DGD[7]
Floor covering	x	x			x
Gelling additive	x				x
Non polymer applications:					
Adhesives	x		x	X	x
Dispersions	x		x	X	x
Nitrocellulose					x

It has to be noted that there seems to be a wide variability in the level of information available (and validity of data sources) on the hazard properties of these possible alternatives and, as such, drawing conclusions on whether overall risks to human health and the environment would be reduced if these substances were used to substitute DBP, is not straightforward (COWI, IOM & Entec, 2009).

According to the information available, 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. Therefore, if DBP can in principle be replaced by other phthalates and non-phthalate plasticisers, it may be at the expense of some of these properties. The technical feasibility of replacing DBP for different applications will then depend 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 also imply some changes in processing and material composition, and then a need for some research and development as well as changes in process technology (COWI, IOM & Entec, 2009). Thus, further investigations would be needed in order to assess the suitability of the possible alternative substances.

To conclude, there appears to be some information on alternative substances to DBP and alternative materials to polymers containing DBP for several uses. Furthermore the available information indicates substitution of DBP is already ongoing for certain uses. There also appears to be information available on potential alternatives and experiences in their use as substitutes to similar substances. However, there are only few documented references on availability of information on alternatives for some special applications.

[2] Di-iso-butyl phthalate (DIBP) (CAS No 84-69-5)
[3] DIBP is now classified as Toxic to Reproduction, Category 2 according to Commission Directive 2009/2/EC amending Council Directive 67/548/EEC (31st ATP) (RCOM, 2009)
[4] Di-iso-nonyl phthalate (DINP) (CAS No 28553-12-0)
[5] Di-isononyl-cyclohexan-1,2-dicarboxylate (DINCH) (CAS No 166412-78-8)
[6] Glyceryl triacetate (GTA) (CAS No 102-76-1)
[7] Dipropylene glycol dibenzoate (DGD) (CAS No 27138-31-4)

On the other hand, some of the available information on alternatives suggests that a more complicated situation to conclude whether or not the transfer to alternatives is feasible may appear. This is the case, for instance, where the identified potential alternative may have an impact on the specific properties that DBP provides to certain end products (e.g. affecting their maintenance).

2.4. Existing specific Community legislation relevant for possible exemption

It is noted that DBP is restricted in accordance with entries 31 and 51 of Annex I to Directive 76/769/EEC and entries 30 and 51 of Annex XVII[8] of REACH Regulation.

First, pursuant to entry 31 of Directive 76/769/EEC (and 30 of Annex I of Annex XVII of REACH Regulation) 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 equal to or greater than either the relevant concentration specified in Annex I to Directive 67/548/EEC, or the relevant concentration specified in Directive 1999/45/EC (i.e., is equal to or greater than 0.5%). Thus, placing on the market for supply to the general public of DBP in concentrations lower than 0.5% is permitted.

Article 56(6)(b) of REACH provides that the authorisation requirement does not apply to the use of substances in preparations below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC. Accordingly, the concentration limits specified for DBP in Directive 76/769/EEC (and in Annex XVII of REACH) are in fact the same as the concentration limits referred to in Article 56(6)(b). Therefore, the use of DBP below the concentration limits set out in Directive 76/769/EEC (and Annex XVII of REACH) does not need to be subject to an exemption from authorisation.

Furthermore, pursuant to entry 31 of Directive 76/769/EEC (and 30 of Annex XVII of REACH) the concentration limits described above do 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.

Pursuant to Articles 2(5)(a), 56(4) (c) and (d) and 56(5)(a) the provisions on authorisation under REACH do not in any event apply to medicinal or veterinary products, cosmetic products[9], motor fuels, mineral oil products intended for use as fuel and fuels sold in closed systems. Use of DBP in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

However, the use of DBP in artists' paints covered by Directive 1999/45/EC is not automatically exempted from authorisation under the REACH Regulation. In light of

[8] Annex XVII shall apply from 1 June 2009, until that Directive 76/769/EEC applies.

[9] In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health.

the fact that such use was already permitted under Annex XVII of REACH Regulation which is legislation imposing minimum requirements relating to the protection of human health, an exemption from the authorisation pursuant to Article 58(2) of the REACH Regulation for the use of artists' paints could be considered.

Second, pursuant to entry 51 of Directive 76/769/EEC (and entry 51 of Annex XVII of REACH) DBP shall not be placed on the market or used as a substance on its own or in a preparation, at concentrations greater than 0.1% by mass of the plasticised material, in toys and childcare articles.

The concentration limits set out in this entry are lower than the concentration limits set out in Article 56(6)(b). Use of DBP in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

It should be noted that it is not possible to grant an authorisation that would constitute a relaxation of a restriction set out in Annex XVII (Art 60(6) of REACH). Therefore, it is not possible to authorise, and by that not meaningful to apply for an authorisation for, the use of DBP in plasticised materials intended for the use in toys and childcare articles or the placing on the market of preparation for the supply for generic public.

2.5. Any other relevant information (e.g. for priority setting)

No data available.

3. Conclusions and justification

3.1. Prioritisation

DBP is manufactured in the EU in a volume of less than 10,000 t/y (in 2007). A net export is estimated to approximately 2,000 tonnes. Thus, a net use in the EU is estimated to be approximately 8,000 tonnes/year.

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.

Given the high volumes used and the wide dispersive uses of DBP in preparations and in articles, ECHA recommends to include DBP in Annex XIV.

3.2. Recommendation for Annex XIV entry

3.2.1. Transitional arrangements

Based on the information available, it is anticipated that the preparation of applications for authorisation will require a considerable collaborative effort by various actors, involved both within the same or different supply chains.

The information available also suggests that even though substitution has already started for several applications of DBP, the preparation of the analysis of alternatives may require some additional time for other uses, and in particular for the assessment of the risks of alternative substances or the changes in the process and/or the material composition which the use of the alternative may require (technical/economic feasibility).

Furthermore, some of the uses and potentially affected user groups are the same as for DEHP, which further supports setting the same application date for these substances.

Hence, in light of the available information, ECHA recommends a longer period for preparing applications than the minimum and the following transitional arrangements:

- *Latest application date*:
  30 months after the entry into force of the Decision to include the substance in Annex XIV

- *Sunset date*:
  48 months after the entry into force of the Decision to include the substance in Annex XIV

3.2.2. Review periods for certain uses

Neither the available information for DBP nor the comments following the public consultation of 14 January 2009 provide information that would support defining review periods for any uses in accordance with article 58(1)(d).

ECHA therefore recommends not to include any review periods for uses of DBP.

3.2.3. Exempted (categories of) uses

Recommendation:

ECHA recommends not to include any exemptions for uses of DBP.

Justification:

Exemption for use in artists' paints:
Directive 76/769/EEC sets out the restrictions on the uses of substances as well as specific exemptions to these restrictions. These restrictions (and their exemptions) are incorporated in Annex XVII of the REACH Regulation which will replace the entries in Directive 76/769/EEC from 1 June 2009. The recitals of Directive 76/769/EEC and the directives amending it provide that these restrictions have an objective to protect human health and/or the environment. Directive 76/769/EEC could therefore constitute specific Community legislation imposing minimum requirements relating to the protection of human health and the environment for the use of a substance within the meaning of Article 58(2) of the REACH Regulation.

On this basis, ECHA considers that where an entry in Annex XVII exempts a specific use of a substance from the restrictions, Article 58(2) could be used to exempt that specific use from authorisation in the two following situations:

> i) Annex XVII includes a restriction on a specified use of a substance and this restriction specifies condition(s) under which the restriction does not apply
>
> ii) Annex XVII includes a generic ban on a substance and a specified use is exempted from this generic ban. Such an exemption can be subject to further conditions.

Entries 28 to 30 of Annex XVII provide that all substances classified as CMR (Category 1 and 2) may not be used in substances and mixtures placed on the market for sale to the general public. However, these entries exempt from restriction the use of such substances in artists' paints.

In the draft recommendation published by ECHA on 14 January 2009 ECHA considered that as DBP is one of the CMR substances concerned by entries 28 to 30 of Annex XVII and that recital (80) of the REACH Regulation requires that a proper interaction should be ensured between the provisions of authorisation and restriction, an exemption from the authorisation requirement should be granted pursuant to Article 58(2) of the REACH Regulation for the use of MDA in artists' paints on the basis that this use has been specifically exempted in Annex XVII.

In its opinion of 20 May 2009 ECHA's Member State Committee (the MSC) considered that no exemption should be granted from the authorisation requirement for the use of DBP in artists' paints. This opinion was based on the following considerations.

First, some members of the MSC expressed doubts as to whether the exemption from restrictions of the use in artists paints could be regarded as meeting the criteria for exemption from authorisation set out in Article 58(2) as the exemption to the restriction was based on socio-economic grounds rather than on health and risk considerations.

On this point ECHA considers that in determining whether an exemption to a restriction should benefit from an exemption from the authorisation requirement it is not possible to simply dissociate the exemption from the restriction. The restriction and its related exemptions must be examined as a whole in order to determine whether an exemption under Article 58(2) of the REACH Regulation should be granted.

Second, all members of the MSC considered that an exemption should not be granted for the use of artists' paints on the basis that the exemption from the restriction requirement of that use in entries 28 to 30 of Annex XVII covers a category of substances (i.e., all CMRs) rather than a specific substance (i.e., only DBP or group of specified substances). In the MSC's view an exemption to a restriction covering a wide range of substances may not necessarily meet the requirements from exemption from authorisation under Article 58(2) of the REACH Regulation.

On this latter point ECHA shares the MSC's concern. On the basis of the information available ECHA cannot determine whether such an exemption can be justified under Article 58(2) of the REACH Regulation. ECHA therefore decided on the basis of the MSC's opinion and the deliberations leading to that opinion to amend its recommendation and not propose an exemption from the authorisation requirement for the use of DBP in artists' paints.

ECHA however urges the European Commission to examine on the basis of the information at its disposal whether such exemption should be introduced after all, and to further clarify under what conditions specific exemptions to restrictions set out in Annex XVII should be taken into account when determining exemptions from the authorisation requirement under Article 58(2) of the REACH Regulation.

Exemptions requested by third parties:
During the public consultation on the draft recommendation, ECHA received a number of requests for use-specific exemptions of DBP.

ECHA did not see grounds for recommending general exemptions for DBP for the reasons set out in the "*Responses to comments*" document.

However, with regard to the use of the prioritised substances in medical devices and in primary/immediate packaging of medicinal products ECHA was not in a position to fully assess the possible consequences of the existing Community legislation on the implementation of the provisions in Title VII of the REACH Regulation. In particular in these cases, ECHA urges in its recommendation for the European Commission to examine these requests for exemptions.

3.2.4. Application of authorisation to product and process oriented research and development (PPORD)

Neither the available information for DBP nor the comments following the public consultation of 14 January 2009 provide information that would support introducing exemptions from the authorisation requirement for product and process oriented research and development (PPORD) on the basis of Article 56(3) of the REACH Regulation.

Therefore ECHA does not recommend to exempt the use of DBP in PPORD from authorisation.

3.3 Possible route for authorisation

The substance meets the criteria in Article 57(c) and according to available information it seems to be possible to determine a toxicological threshold in accordance with section 6.4 of Annex I.
Therefore, pursuant to Article 60(2) of the REACH Regulation, if the risk to human health from the use of the substance arising from its toxicity to reproduction is adequately controlled in accordance with Section 6.4 of Annex I and this is documented in the applicant's chemical safety report, an authorisation will be granted ('adequate control route'); if not, pursuant to Article 60(4) of the REACH Regulation, an authorisation may be granted ('socio-economic route').

4. References

EC (2004): European Union Risk Assessment Report, Dibutyl phthalate (DBP). European Commission, JRC, EUR 19840 EN.

COWI, IOM & Entec (2009): Data on manufacture, import, export, uses and releases of Dibutyl phthalate (DBP) as well as information on potential alternatives to its use. Report prepared for ECHA.

RCOM (2009): "*Responses to comments*" document. Document compiled from the commenting period 14.01-14.04.2009.