1 June 2009

Background document for benzyl butyl phthalate (BBP)

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:	benzyl butyl phthalate (BBP)
EC Number:	201-622-7
CAS Number:	85-68-7
IUPAC Name:	benzyl butyl phthalate

2. Background information

2.1. Intrinsic properties

BBP 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

BBP is manufactured in the European Union (EU) in a volume of approximately 20,000 tonnes/year in 2007 (COWI, IOM & Entec, 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 (COWI, IOM & Entec, 2009).

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

2.2.2. Manufacture and uses

[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

2.2.2.1. Manufacture and releases from manufacture

In the EU, two manufacturing sites have been identified.

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

- Air: 0.1 t/y
- Soil: no data
- Waste water: 220 t/y

2.2.2.2. Uses and releases from uses

BBP is either processed, mainly as plasticiser in polymers, and in particular in PVC for floorings, or formulated as component in preparations (e.g. printing inks, adhesives and sealants, paints).

More than 70% of the BBP is used as a plasticiser in polymer products, mainly PVC for flooring; other uses are for polymers used for coating of leather and textiles, for calendering of films COWI, IOM & Entec, 2009) or primary/immediate packaging of medicinal products and active substances (RCOM, 2009).

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; however, BBP is, according to industry, an unusual plasticiser because of its chemical asymmetry which results in unique performance properties (COWI, IOM & Entec, 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, paints, coatings and inks are the main products (COWI, IOM & Entec, 2009).
BBP is also used as analytical standard for test and measurement instruments (RCOM, 2009).

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

Table 1 BBP use for processing in 2007 (COWI, IOM & Entec, 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	

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 (COWI, IOM & Entec, 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

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

The main releases are to air and waste water. For releases to the air, both processing and end product uses add significantly to the total with no pronounced major emission source (COWI, IOM & Entec, 2009).

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.

The use of end products gives rise to the largest releases to the environment with washing of flooring as the largest single source.

Table 3 Releases of BBP from manufacturing, formulation, processing, end-products use and disposal in the EU in 2007 (COWI, IOM & Entec, 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

n.d. No data

Note: Figures are rounded and higher than actual figures.

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

As already mentioned in above sections, BBP is manufactured at two sites in the EU (COWI, IOM & Entec, 2009).

BBP is then either processed, mainly as plasticiser in polymers, or formulated. As far as the polymer uses of BBP are concerned, it appears from the available information that the related supply chains include only few levels. Indeed, 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. On the other hand, the preparations related supply chains may be much more complex, with a higher number of levels and more actors (COWI, IOM & Entec, 2009). It has to be noted that 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.

Finally, users of the end products (articles and preparations) containing BBP represent several different industry sectors and professional user groups, which are probably widespread in the EU.

In conclusion, according to available information, the supply chain of BBP is considered as relatively complex, as it involves different types of industries and activities with a large number of actors throughout EU.

2.3. Availability of information on alternatives

The decrease in production volumes in recent years reflects the fact that BBP has been replaced for many applications. Although it has not been investigated whether suitable alternatives exist for all applications of BBP, there is not either information on specific difficulties in substituting BBP in certain applications (COWI, IOM & Entec, 2009).

Information available on alternative substances:
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 (COWI, IOM & Entec, 2009).

According to the information available, 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 (COWI, IOM & Entec, 2009).

As far as flooring applications are concerned, BBP adds, as mentioned above, 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 (COWI, IOM & Entec, 2009). Therefore, if BBP 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 BBP for different applications will then depend on a range of performance criteria and on how critical the specific properties offered by BBP are for those. 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).

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 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 (COWI, IOM & Entec, 2009).

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 (COWI, IOM & Entec, 2009); a non-exhaustive list of the most probable alternatives for the main uses of BBP is provided in Table 4 (COWI, IOM & Entec, 2009).

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

	DGD[2]	ASE[3]	DINP[4]	DEHT[5]	DINCH[6]
Flooring	x		x	x	
Calendered film		x	x	x	x
Spread coated fabric	x	x	x[7]	x	x
Non polymer applications:					
Adhesives	x	x	X[6]		x
Paints/lacquers		x	X[6]		x
Sealants (glass insulation, construction)	x	x	x		

Note: Isodecyl Benzoate is also mentioned as an alternative plasticiser for non-PVC applications (RCOM, 2009)

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 (COWI, IOM & Entec, 2009).

However, 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 the possible 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 BBP is not straightforward for all substances (COWI, IOM & Entec, 2009).

Thus, further investigations would be needed in order to assess the suitability of the possible alternative substances.

Information available on alternative 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-containing 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-containing PVC, but clear conclusions are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments (COWI, IOM & Entec, 2009).

To conclude on the information available on alternatives, there appears to be information available on alternative substances to BBP and possible alternative

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

[7] RCOM, 2009

materials to polymers containing BBP for several of the uses. Furthermore the available information indicates substitution of BBP 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. 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 BBP provides to certain end products (e.g. affecting their maintenance or longevity).

2.4. Existing specific Community legislation relevant for possible exemption

It is noted that BBP 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., 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 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 BBP 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 BBP 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 BBP 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 BBP in these products therefore does not

[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.

need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

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

BBP is manufactured in the EU in a volume of approximately 20,000 t/y. A net export of approximately 12,000 tonnes is estimated. Thus, the use in the EU is estimated to be approximately 8,000 t/y.

Even though 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 preparations and articles 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 of preparations and articles containing BBP. As BBP is not chemically bound in 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.

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

3.2. Recommendation for Annex XIV entry

3.2.1. Transitional arrangements

Based on the available information, 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 BBP, the preparation of the analysis of alternatives may require some additional time for other uses, and in particular to conclude whether or not the transfer to alternatives is feasible. This is the case, for instance, where the identified potential alternative may have an impact on the specific properties that BBP confers to certain end products affecting, e.g., the maintenance.

Furthermore, some of the uses and potentially affected user groups are the same as for DEHP, which further supports the setting of 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 BBP 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 BBP

3.2.3. Exempted (categories of) uses

Recommendation:

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

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 BBP 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 BBP 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 BBP 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 BBP 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 BBP.

ECHA did not see grounds for recommending general exemptions for BBP 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 BBP 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 BBP 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 is possible to determine a toxicological threshold. Therefore, 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 in accordance with Article 60(2) (‘adequate control route’); if not, an authorisation may be granted in accordance with Article 60(4) (‘socio-economic route’).

4. References

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

COWI, IOM & Entec (2009): Data on manufacture, import, export, uses and releases of Benzyl butyl phthalate (BBP) 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