1 June 2009

Background document for bis(2-ethylhexyl) phthalate (DEHP)

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:	bis(2-ethylhexyl) phthalate (DEHP)
EC Number:	204-211-0
CAS Number:	117-81-7
IUPAC Name:	bis(2-ethylhexyl) phthalate

2. Background information

2.1. Intrinsic properties

DEHP 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

DEHP is manufactured in the European Union (EU) in a volume of approximately 340,000 tonnes/year in 2007[2] (COWI, IOM & Entec, 2009). The manufacture has decreased dramatically over the last 10 years from 595,000 tonnes/year in EU-15 in 1997[3].

A net export of DEHP on its own at approximately 50,000 tonnes/year in 2007 is estimated (COWI, IOM & Entec, 2009), which is a slight decrease since 2005. In

[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] DEHP Western European production in 2007: 187,000 tonnes (COWI, IOM & Entec, 2009); estimated DEHP Western European production for 2008: 149,000 t (RCOM, 2009)

[3] Note: no information on manufacture in 1997 is available for the 12 current Member States that were not members in 1997 (COWI, IOM & Entec, 2009)

addition, a net export of DEHP in preparations at approximately 10,000 tonnes/year in 2007 is estimated (COWI, IOM & Entec, 2009).

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

2.2.2. Manufacture and uses

2.2.2.1. Manufacture and releases from manufacture

In the EU, seven manufacturing sites have been identified (COWI, IOM & Entec, 2009).

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

- Air: 1 t/y
- Soil: 4 t/y
- Waste water: 220 t/y

2.2.2.2. Uses and releases from uses

The manufactured DEHP is further processed in different formulation and processing steps, through which a wide range of articles and preparations are produced (COWI, IOM & Entec, 2009).

DEHP is indeed one of a number of substances widely used as plasticiser in PVC and non-PVC polymer materials, these being used for producing a range of indoor and outdoor products, including flooring, roofing, wires, cables, hoses, profiles, coated fabrics (such as artificial leather for bags, book covers), medical devices as well as primary packaging of medicinal products and active pharmaceutical substances (COWI, IOM & Entec, 2009; RCOM, 2009).

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 (COWI, IOM & Entec, 2009).

In addition, DEHP is used in a large number of various preparations including adhesives, sealants, rubber, lacquers, paints and printing inks.

DEHP is also used as analytical standard for test and measurement instruments (RCOM, 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 (COWI, IOM & Entec, 2009)

Process	Tonnage (t/y), 2007	% of total, 2007	Number of sites of use (1999)
Formulation and processing (at same site):			
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.
Processing from compound:			
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.
Non-polymeric, processing:			
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	

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 (COWI, IOM & Entec, 2009)

End-product use area	Tonnage, t/y				% of total use
	EU Manufacture	Import	Export	End-product use	
Indoor uses:					
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
Outdoor uses:					
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
Total end-product use (round)	282,000	40,000	37,000	285,000	100

The estimated releases to the environment from all activities are summarised in Table 3. 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 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 (COWI, IOM & Entec, 2009).

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 (COWI, IOM & Entec, 2009).

Table 3 Releases of DEHP 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 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

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

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

As already mentioned under section 2.2.2.1, DEHP is manufactured at seven sites in seven different Member States (COWI, IOM & Entec, 2009).
Then, as already mentioned under section 2.2.2.2, DEHP is used for formulation and processing at a large number of sites in the EU, the number of sites is assumed to be 500 to 1,000. The supply chains related to the polymer uses of DEHP seem to include only few levels while the preparations related supply chains may have more levels.
DEHP is finally used in a very large number of diverse articles and preparations, used ubiquitously in the EU. This indicates a large number of companies involved in different supply-chains of DEHP. Furthermore, users of the end products (articles and preparations) containing DEHP represent several different industry sectors and professional user groups.

In conclusion, DEHP can be found in preparations and articles on the market throughout the EU and involves different and multiple actors in several supply chains.

2.3. Availability of information on alternatives

Information available on alternative substances:
It appears that a number of potential alternative substances to DEHP have been identified that may be applied for different application areas. However, 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 in specified applications.

For many of the large volume applications like flooring or cable/wires, phthalates (mainly DINP) are still the plasticiser of choice (COWI, IOM & Entec, 2009); DINP represents the main alternative to DEHP applied today (COWI, IOM & Entec, 2009). However, for some applications, non-phthalate alternatives are widely used, demonstrating the feasibility of substitution for at least these applications. Non-phthalate alternatives have mainly been applied for applications where there has been a concern as to human exposure to the substance: toys[4], medical products, packaging for food and water beds are examples.

It has also to be noted that 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.

Table 4 shows applications which have been specifically mentioned by suppliers of a non-exhaustive selection of alternatives to DEHP. It has to be noted that:

- 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 (COWI, IOM & Entec, 2009);
- the alternative substances listed in the table may probably be used for other applications as well (COWI, IOM & Entec, 2009).

[4] DEHP is not allowed anymore in toys and childcare articles in EU (RCOM, 2009)

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

	DINP[5]	DEHT[6]	BTHC[7]	DINCH[8]	ASE[9]
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[10]	X		x	x
Toys	x[9,11]	X		x[9]	x
Automotive	x				
Non polymer applications:					
Adhesives	x[9]			x	x
Printing inks	x[9]			x	x
Sealants (glass insulation, construction)	x				x

Note: DIDP – Di-isodecyl phthalate (CAS # 68515-49-1) and Di-(2-propylheptyl) phthalate (DPHP, CAS # 53306-54-0) are also alternatives to DEHP. These are C10 di-esters with increased permanency and are used in applications such as wire and cable, film and sheet, coated fabric, automotive, and non-polymer applications such as sealants (RCOM, 2009)

Therefore, 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 DEHP is not straightforward for all substances (COWI, IOM & Entec, 2009). Furthermore, the technical and economic feasibility may need further assessment for specific applications. 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 DEHP with other plasticisers, the soft PVC may also be replaced with other materials. However, comparison of DEHP-containing 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 may be 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 (COWI, IOM & Entec, 2009).

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

[10] RCOM, 2009
[11] toys which cannot be placed in the mouth only (RCOM, 2009)

In the specific case of resilient flooring, it appears three materials have been assessed as alternatives to DEHP-containing 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 COWI, IOM & Entec, 2009). However, it appears that the suitability of cork and linoleum as alternatives is a matter of discussion, and in particular their technical and economic feasibility (RCOM, 2009).

As for wall coverings, it appears that 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-containing PVC for wall covering applications (cited in COWI, IOM & Entec, 2009).

Therefore, the available information on alternative materials shows that for many applications of DEHP-containing 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 conclusions are complicated by the fact that not all relevant 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 (COWI, IOM & Entec, 2009).

To conclude on the information available on alternatives, there appears to be information available on alternative substances to DEHP and alternative materials to polymers containing DEHP for many of the uses. Furthermore the available information indicates substitution of DEHP is already ongoing for certain uses.
On the other hand, some of the information available 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 is a change from a polymer containing DEHP to totally different materials.

2.4. Existing specific Community legislation relevant for possible exemption

It is noted that DEHP 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[12] 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., 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 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 DEHP in concentrations lower than 0.5% is permitted.

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

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 DEHP 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 DEHP 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[13], motor fuels, mineral oil products intended for use as fuel and fuels sold in closed systems. Use of DEHP in these products therefore does not need to be exempted from authorisation under Article 58(2) of the REACH Regulation.

However, the use of DEHP 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) DEHP 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 DEHP 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 DEHP 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.

[13] 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.

3. Conclusions and justification

3.1. Prioritisation

The volume of DEHP manufactured in the EU was approximately 340,000 tonnes in 2007; the use in the EU is estimated to approximately 280,000 tonnes in 2007.

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 (assumed to be 500 to 1,000). DEHP is used in a very large number of diverse articles and preparations. 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.

Furthermore, 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.

Given the very high volumes used and the ubiquitous wide dispersive uses of DEHP in preparations and in articles, ECHA recommends to include DEHP 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. Many 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.

Furthermore, the available information indicates that, even though substitution has already started for some specific applications, the preparation of the analysis of alternatives may require some time for many applications of DEHP, in particular the assessment of the risks of alternative substances and the technical feasibility of alternative materials.

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 DEHP 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 DEHP.

3.2.3. Exempted (categories of) uses

Recommendation:

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

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 DEHP 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 DEHP 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 DEHP 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 DEHP 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.

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

ECHA did not see grounds for recommending general exemptions for DEHP 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 DEHP 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 DEHP 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

EC (2008): European Union Risk Assessment Report, Bis(2-ethylhexyl) phthalate (DEHP). European Commission, JRC, EUR 23384 EN.

COWI, IOM & Entec (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.
Report prepared for ECHA.

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