DATA ON MANUFACTURE, IMPORT, EXPORT, USES AND RELEASES OF BENZYL BUTYL PHTHALATE (BBP) AS WELL AS INFORMATION ON POTENTIAL ALTERNATIVES TO ITS USE

The technical work on this report has been led by COWI A/S, supported
by IOM and Entec UK Ltd
under framework contract ECHA/2008/2 (specific contract
ECHA/2008/02/SR5/ECA.227)

Revised version of 29 January 2009

PREFACE

The present report is one of three reports including data on manufacture, import, export uses and releases of three phthalates: benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), and bis(2-ethylhexyl) phthalate (DEHP), as well as information on potential alternatives to these phthalates. This report concerns BBP.

The data collection for the three substances has been undertaken under the Specific Contract No ECHA/2008/02/SR1/ECA.224 implementing Framework Contract ECHA/2008/2.

According to Article 58(3) of the REACH Regulation, among the substances identified as presenting properties of very high concern, priority for inclusion in Annex XIV shall normally be given to substances with:

- persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties; or
- wide dispersive uses; or
- high volumes.

Annex XV dossiers have been prepared by Austria and Sweden for the identification of these three phthalates (among other substances) as substances of very high concern (SVHC), in accordance with Article 58 (c), i.e. as substances toxic to reproduction. They have now been placed on the candidate list for consideration for inclusion in Annex XIV.

The overall objective of this project is to provide ECHA with information on the manufacture, import, export, uses and releases of BBP as well as information on the properties and risks of alternative substances and techniques.

The information provided will support ECHA in:

- setting priority of substances on the candidate list for inclusion in Annex XIV;
- defining the conditions related to the entries on Annex XIV such as described in article 58 of the Regulation.

The report has been produced according to a format and structure provided by ECHA. Draft reports have been reviewed and commented on by ECHA and this final report has been accepted by ECHA.

The majority of the work has been undertaken over a period of six weeks during autumn 2008 by COWI A/S (Denmark) supported by IOM (UK) and Entec UK Limited (U.K.).

TABLE OF CONTENT

Executive summary

Benzyl butyl phthalate (hereafter referred to as BBP) is mainly used as plasticiser in PVC flooring. Minor applications include the use as plasticiser in coated leather and textiles, films, sealants, paint and adhesives.

Figure 0-1 illustrates the fate of the BBP sent into circulation in the EU in 2007 i.e. the releases from the use of end-products and disposal represent the total life-time emission of the articles produced in 2007 and not the total emission from end-products in the EU in 2007. The latter would depend on the total amount of BBP accumulated in society and would probably be higher, as the amount of BBP sent into circulation has been decreasing in recent years.

As only two manufacturers exist all figures on manufacture, export and end use are for confidentiality reasons indicated as "maximum values", and the actual figures are somewhat lower.

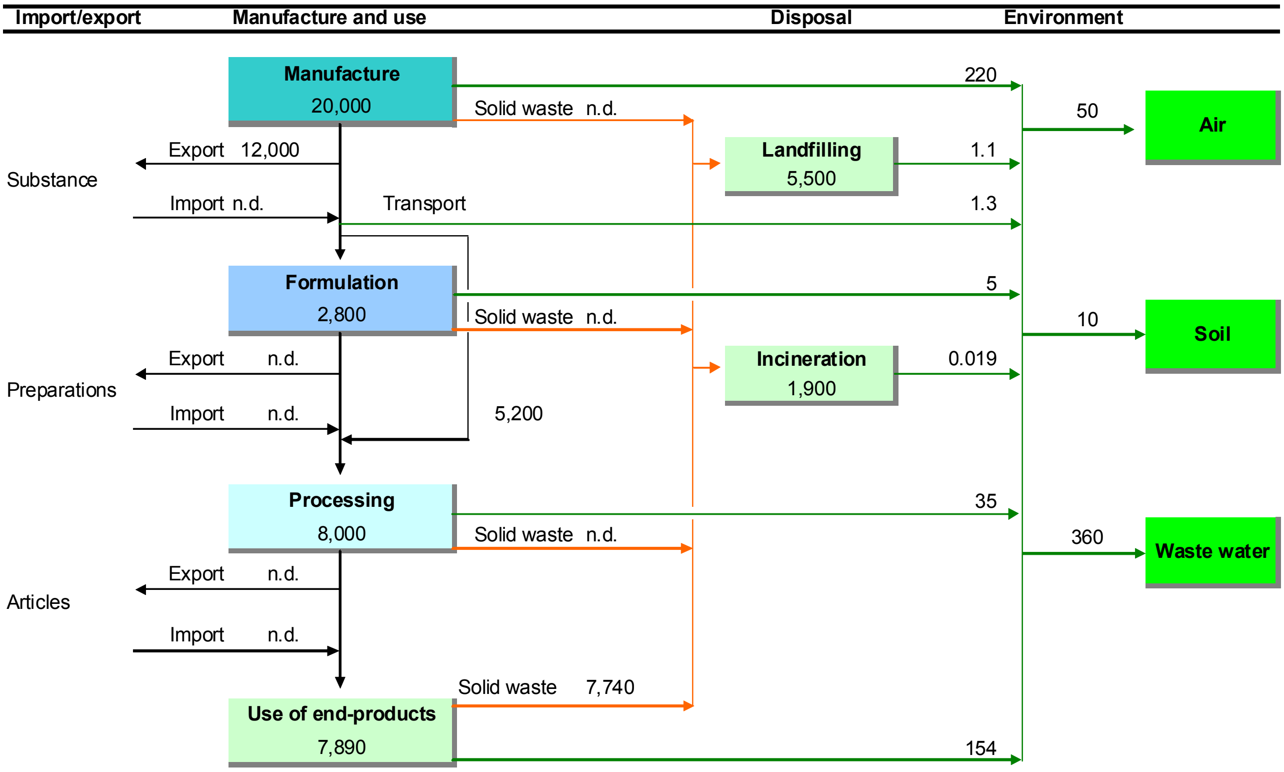

Figure 0-1 Overall flow of BBP sent into circulation in EU society in 2007. Tonnes BBP/year (figures are rounded and higher than actual figures).

According to information retrieved from two manufacturers of BBP in the EU, the total manufactured volume in 2007 was below 18,000 tonnes. The market for BBP has been decreasing over the last decade. During the period 1994-1997, the total reported Western European [1] manufacture of BBP was 45,000 tonnes/year and for 2004 a production volume of 19,500 tonnes/year is reported.

---

[1] The term Western Europe is not defined but is expected to include the countries with market economies before 1990.

The manufactured BBP is further processed in different formulation and processing steps, through which a wide range of end-products are produced as illustrated in the overview flow chart below (Figure 0-2).

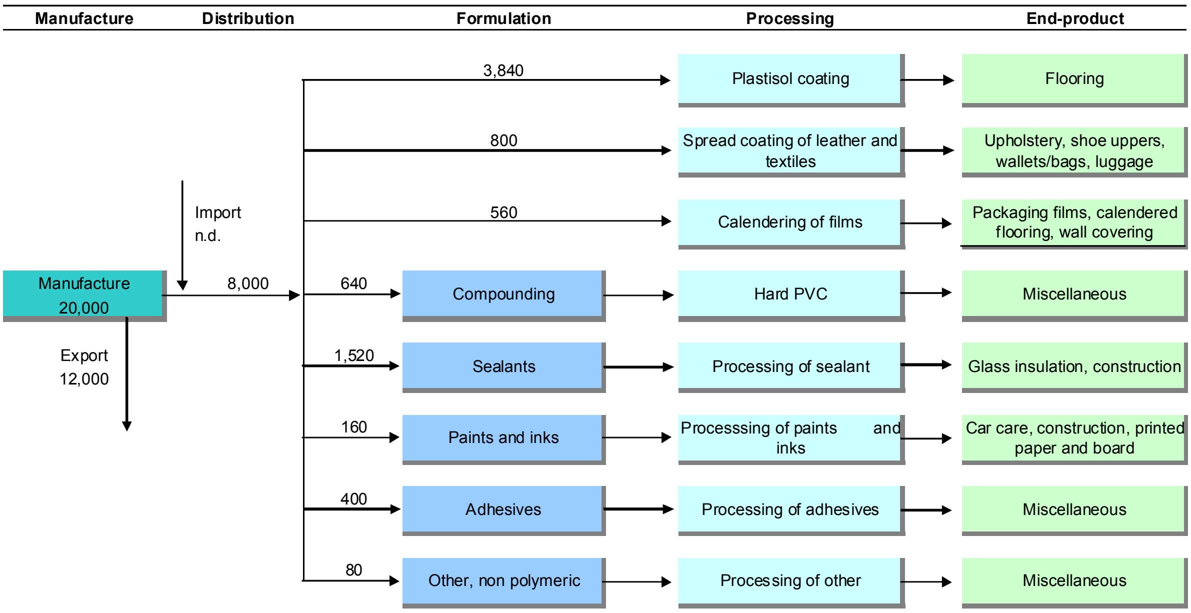

Figure 0-2 Overall flow of BBP through manufacturing processes. Tonnes BBP/year. Figures are rounded and higher than actual figures.

The estimated releases from all activities are summarised in Table 0-1. The emission factors applied in this study are largely derived from the EU Risk Assessment (RAR) for BBP published in 2007. The main releases are to air and waste water. The use of end-products gives rise to the largest releases to the environment with washing of flooring as the largest single source. For releases to the air both processing and end-product uses add significantly to the total with no pronounced major emission source.

Table 0-1 Releases of BBP from manufacturing, formulation, processing, end-products use and disposal in the EU in 2007.

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

Note: Figures are rounded and higher than actual figures.

The decrease in production volumes in recent years reflects the fact that BBP has been replaced for many applications by other substances. A number of previous assessments of, in total, 18 potential alternative substances to phthalates have been reviewed and, on this basis, five alternatives were selected for further assessment in this study. BBP is used in a number of applications and in particular flooring. BBP is used by the flooring industry together with other plasticisers because it adds surface properties to flooring materials that minimise maintenance and give it a prolonged life. When considering alternatives BBP may either be replaced with a substance with similar technical properties or the plasticised PVC flooring may be replaced by another plasticised PVC flooring that may have slightly different functionality.

The main direct alternative to BBP in flooring, and other applications, has been dibenzoate plasticisers, among these dipropylene glycol dibenzoate (DGD), that have some of the same technical properties as BBP. The price of the dibenzoate plasticisers are according to a major manufacturer equivalent to the price of BBP. Furthermore, alkylsulphonic ester (ASE) has been proposed as alternative for different BBP applications.

Alternatively, the flooring (and other PVC 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 in detail to what extent the use of these alternatives can provide exactly the same functionality as BBP, e.g. with regard to processing performance or the need for maintenance of flooring, as the alternatives have mainly been assessed as alternatives to DEHP. Three alternatives, that may not directly substitute for BBP, but may be used for manufacturing of products with nearly the same properties as the BBP containing products are DINP, DEHT and DINCH.

Table 0-2 Applications specifically mentioned by suppliers of selected alternatives

	DGD	ASE	DINP	DEHT	DINCH
Flooring	x		x	x	
Calendered film		x	x	x	x
Spread coated fabric	x	x		x	x
Non polymer applications:					
Adhesives	x	x			x
Paints/lacquers		x			x
Sealants (glass insulation, construction)	x	x	x		

In order to assess the toxicity of the selected alternatives, information on the intrinsic properties, including their human health hazard profile has been collected. On this basis Derived No Effect Levels (DNELs) for critical endpoints have been established tentatively for this study (Table 0-3). It was beyond the scope of this study to compare the alternatives with the health and environmental properties of BBP.

Table 0-3 Tentatively derived No Effect Levels (DNELs) for critical endpoints for selected alternatives

Name	CAS No.	Critical endpoint	DNEL for critical endpoint, mg/kg/day			
			Workers		General population	
			Oral mg/day	Inhalation mgm^{-3}	Oral mg/day	Inhalation mgm^{-3}
DGD	27138-31-4	Developmental	700	71	350	17
ASE	91082-17-6	Liver toxicity (increased liver weight)	8	0.8	4	0.2
DINP	28553-12-0	Developmental	44	4	22	1
DEHT	6422-86-2	Liver toxicity	409	0.08	204	0.02
DINCH	166412-78-8	Kidney toxicity	75	8	38	2

The level of information available on the hazard properties of these potential alternatives varies and is not comparable with that for BBP in all cases. This should be taken into account in making any comparisons of these substances with the hazards/risks of BBP.

With regard to potential environmental hazards and risks of alternatives, a number of existing assessments and databases on hazardous effects have been reviewed. In some cases, PNEC values have been drawn from existing assessments. In others, information on the hazardous properties of the potential alternatives has been provided.

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 DEHP is not straightforward for all substances. However, based on the information presented, the following conclusions can be drawn for two of the substances:

- DGD may possibly be readily biodegradable but the data do not allow a firm conclusion to be drawn. However, the substance is not a PBT substance but does have moderately bioaccumulative properties. Experimental data on aquatic ecotoxicity indicate that the correct environmental classification could be N; R51/53.

- For DINP, the EU risk assessment concluded that there is no need for further information or testing or for risk reduction measures beyond those which are being applied already. It would therefore be reasonable to conclude that use of DINP as an alternative would not introduce significant new risks to the environment (although if there were a large increase in quantities released, this could in theory lead to a change in the risk assessment conclusions).

- Given that alkylsulphonic phenyl esters (ASE) have been the subject of a review of PBT and vPvB properties, the outcome of which was a conclusion that the main constituents are neither PBT or vPvB, it is reasonable to conclude that these substances would not be considered to be a SVHC on the basis of these properties.

No firm conclusions on the relative hazards or risks could be drawn for the other potential alternatives.

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 use of DEHP/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/PVC, but clear conclusions are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments.

Abbreviations and acronyms

AGD	Anogenital distance
AGI	Anogenital index
ASE	Alkylsulphonic phenyl ester
ATBC	Acetyl tri-n-butyl citrate
BBP	Benzylbutylphthalate
BCF	Bioconcentration factor
BHT	Butylated hydroxytoluene
BTHC	Butyryl trihexyl citrate
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
CMR	Carcinogenic, mutagenic, reprotoxic
COMGHA	Acetylated monoglycerides of fully hydrogenated castor oil
DBP	Dibutylphthalate
DBS	Dibutyl sebacate
DEHA	Diethylhexyl adipate
DEHP	bis(2-ethylhexyl) phthalate
BBPA	Tris(2-ethylhexyl) phosphate
DEHT	Di(2-ethylhexyl) terephthalate (identical to DOTP)
DGD	Dipropylene glycol dibenzoate
DIDP	Di-isodecyl phthalate
DINCH	Di-(isononyl)-cyclohexan-1,2-dicarboxylate
DINP	Di-isononyl phthalate
DNEL	Derived No Effect Level
DOP	Di-octyl phthalate (same as DEHP)
DOTP	Di(2-ethylhexyl) terephthalate (same as DEHT)
ECHA	European Chemicals Agency
ECPI	European Council for Plasticisers and Intermediates
ESD	Emission Scenario Document (if nothing else is mentioned, the ESD for plastics manufacturing)
EPA	Environmental Protection Agency
EU	European Union
EuPC	European Plastics Converters
EuPIA	European Printing Ink Association
F_0, F_1, F_2	Parent, first and second generations in multigenerational experiment
GD	Gestational day
IUCLID	International Uniform Chemical Information Database
LDPE	Low density polyethylene
LOAEL	Lowest observed adverse effects level
LOEL	Lowest observed effects level
NACE	Nomenclature Statistique des Activites Economiques
NOAEL	No Observable Adverse Effect Level
NOEL	No observed effects level
PBT	Persistent, Bioaccumulative and Toxic
PND	Post natal day
PNEC	Predicted No Effect Concentrations
PVC	Polyvinyl chloride
QSAR	Quantitative Structure-activity Relationship

RAR	Risk Assessment Report (if nothing else mentioned, the RAR for BBP)
SCENIHR	EU Scientific Committee on Emerging and Newly Identified Health Risks
SVHC	Substances of very high concern
TC NES	EU Technical Committee of New and Existing Chemical
TGD	Technical Guidance Document
TOTM	Tris-2-ethyhexyl trimellitate
UCD	Use Scenario Document (if nothing else is mentioned, the USD for plastics manufacturing)
UK	United Kingdom

1 Information on manufacture, import and export and releases from manufacture

1.1 *Manufacturing sites and manufacturing processes*

The substance benzyl butyl phthalate (hereafter referred to as BBP) is used as a plasticiser in polymer and non-polymer products, with PVC flooring as the main application. BBP has the CAS N^{o} 85-68-7.

Manufacturing sites - Two manufacturers of BBP in the EU (2007) have been identified (Table 1-1). The manufacturers were identified through information from the European Council for Plasticisers and Intermediates (ECPI). Neither of the manufacturers are members of the ECPI.

Table 1-1 Manufacturers of BBP in the EU in 2007

Company	Town of manufacturing site	Country
Ferro	Antwerp	Belgium
Lanxess	Not indicated	Germany

Manufacturing process - According to the EU Risk Assessment Report for BBP from 2007 (hereafter referred to as the RAR) phthalate plasticisers are produced by esterification of phthalic anhydride in closed systems with a surplus of alcohol at temperatures of about 90ºC. The vapour from the process is condensed and returned to the reactor. After virtually complete esterification the surplus alcohol is evaporated off under vacuum at 160ºC. The second step involves the conversion of phthalic acid-monobutylester to BBP via reaction with benzylchloride. This step is slower than the first step. The product is then neutralised, washed and finally filtered. The reaction processes occur in closed systems. Process water is either treated in industrial waste-water treatment plants or discharged to the local municipal waste-water treatment plant. Liquid and /or solid waste fractions like distillation residues and used filter-papers are burned in an industrial combustion plant.

Use descriptors and NACE codes for the process are included in Table 2-1 giving descriptors for all processes.

Manufactured tonnage - Data on manufactured tonnage, releases from the manufacturing site and the distribution of the manufactured tonnage on end-uses (first users) has been obtained by use of a questionnaire sent directly to eight manufacturers of phthalates. All manufacturers have responded with information on manufactured tonnage, whereas only some of the manufactures have provided information on releases and distribution of end-uses.

The total manufactured tonnage in 2007 was below 18,000 tonnes. A significant part of the manufactured tonnage is exported to countries outside the EU. According to ECPI (2008), in Western Europe about one million tonnes of phthalates are produced each year, of which approximately 900,000 tonnes are used to plasticise PVC (polyvinyl chloride). BBP seems to represent less than 1% of the production.

The market for BBP has been decreasing over the last decade. In the period 1994-1997, the total reported Western European manufacture of BBP was 45,000 tonnes/year and for 2004 a production volume of 19.500 tonnes/year was reported (RAR).

No data has been available for estimating the global production of BBP.

1.2 *Import and export of BBP on its own or in preparations*

The substance on its own - BBP is included in the trade statistics from Eurostat in the commodity group "Esters of orthophthalic acid (excl. dibutyl, dioctyl, dinonyl, or didecyl orthophthalates". The date for the commodity groups is shown in Table 1-2. As BBP probably only account for a small part of the commodity group the statistics does not provide much information on extra-EU trade.

According to information from manufacturers less than 12,000 tonnes were exported annually in the period 2005-2007. No data has been obtained on import, but the data in table 1-2 indicates that it will be very small and in any case below about 3,000 tonnes. For the total phthalates in the group, the export was about 20-30 times the import.

Table 1-2 Extra-EU27 import and export of BBP 2005-2007 (t/y)

CN8 code	Name	2005		2006		2007	
		Import	Export	Import	Export	Import	Export
2917 3400	Esters of orthophthalic acid (excl. dibutyl, dioctyl, dinonyl, or didecyl orthophthalates	3,429	93,701	3,129	71,181	no data	no data

Preparations - Data on extra-EU27 import and export of "plasticised poly vinyl chloride, in primary forms, mixed with other substances" retrieved from Eurostat are shown in Table 1-3. The content of BBP is not known, but considering that BBP represents less than the EU manufacturing of phthalates, the statistics cannot be used to indicate import and export of BBP in compounds.

BBP may be traded in end-product preparations such as sealants, adhesives and paint, but no information is available for estimating the BBP content of the product groups indicated in the statistics.

Table 1-3 EU27-extra import and export of vinyl chloride containing polymers and copolymers in primary form that may contain BBP (t/y)

CN8 code	Name	2005		2006		2007	
		Import	Export	Import	Export	Import	Export
3904.22.00	Plasticised poly "vinyl chloride", in primary forms, mixed with other substances	12,696	118,257	13,593	132,343	13,805	133,138
3904.30.00	Vinyl chloride-vinyl acetate copolymers, in primary forms	4,184	22,737	3,201	27,999	3783	26,335
3904 40.00	Vinyl chloride copolymers, in primary forms (excl. Vinyl chloride-vinyl acetate copolymers)	2,518	96,078	3,065	61,508	3,232	39,139

1.3 *Import and export of articles containing the substance*

BBP may be imported and exported in a range of articles, primarily flooring. As BBP use represents only a minor part of the PVC flooring, import/export statistics on flooring or other articles cannot be interpreted in terms of BBP.

1.4 *Releases from manufacture*

The total estimated releases from the manufacturing of BBP in 2007 are shown in the table below based on a combination of site specific data and the average emissions factors from the RAR (as described below).

Table 1-4 Manufactured tonnage and estimated releases from manufacture in 2007

Manufacturer	Tonnage, 2007	Releases to working environment	Releases to the environment, t/y			
	t/y	t/y	Air	Soil	Waste water	Waste
Total (round)	18,000	n.d.	0.1	0.1	198	n.d.

* Figures in grey cells are based on actual data obtained from manufacturers
n.d. = no data

Working environment - The BBP RAR discusses occupational exposure in detail, and examples of workplace air concentrations are given. The production of BBP usually takes place in closed systems. However, both inhalation and dermal exposure may occur during the production of BBP. Most of the transport is done by railway tanks. The RAR does not provide data to allow total emissions to the working environment to be estimated.

One of the producers of BBP has reported that production occurs in a fully closed system. There is a potential for exposure during sampling, drumming or loading of bulk trucks. Measured BBP concentrations in the most "exposed" area was 0.007mg/m^3. The other producer has not provided information about releases to the working environment, or to other release pathways.

Air - Only partial data for releases to air were reported by producers. As a consequence, emission factors derived from the 1997 BBP RAR release data were used to calculate release estimates for production (total releases to air divided by total production volume in 1997; newest RAR release data were from 1997). Details on site specific data cannot be revealed as these are confidential.

Waste water - Releases were estimated using a combination of site specific data and emission factors derived from the 1997 BBP RAR release data (total releases to waste water divided by total production volume in 1997). Details on site specific data cannot be revealed as these are confidential.

Soil - No site specific data were available on releases to soil. The BBP RAR does not provide emission factors to soil, and thus releases to soil cannot be quantified.

Transport of BBP

Almost all of the phthalates consumed within EU, including BBP, are transported by road tankers. The release during distribution of pure BBP relates to spillage and the cleaning of transport vessels. It is assumed that this release is directed to the waste water system outside the production site. The RAR discusses, based on different information sources, the release due to spillage and cleaning and suggests an emission factor of 0.0065 %. This emission factor is applied here as well and multiplied by the manufactured (of which some is exported) and imported volume.

2 Information on uses and releases from uses

2.1 *Identification of uses*

More than 70% of the BBP is used as a plasticiser in polymer products, mainly PVC for flooring. Plasticisers have the function of improving the polymer material’s flexibility and workability. BBP is one of a number of substances used as plasticiser in PVC and other polymer materials. BBP is, according to industry, an unusual plasticiser because of its chemical asymmetry which results in unique performance properties.

It is used widely by the flooring industry because it adds surface properties to flooring materials that minimise maintenance and give it a prolonged life (ECPI 2008).

The following flow diagram illustrates the relationship between the different processes and the end-product uses described further in this chapter. The indicated quantities are described further in the next section.

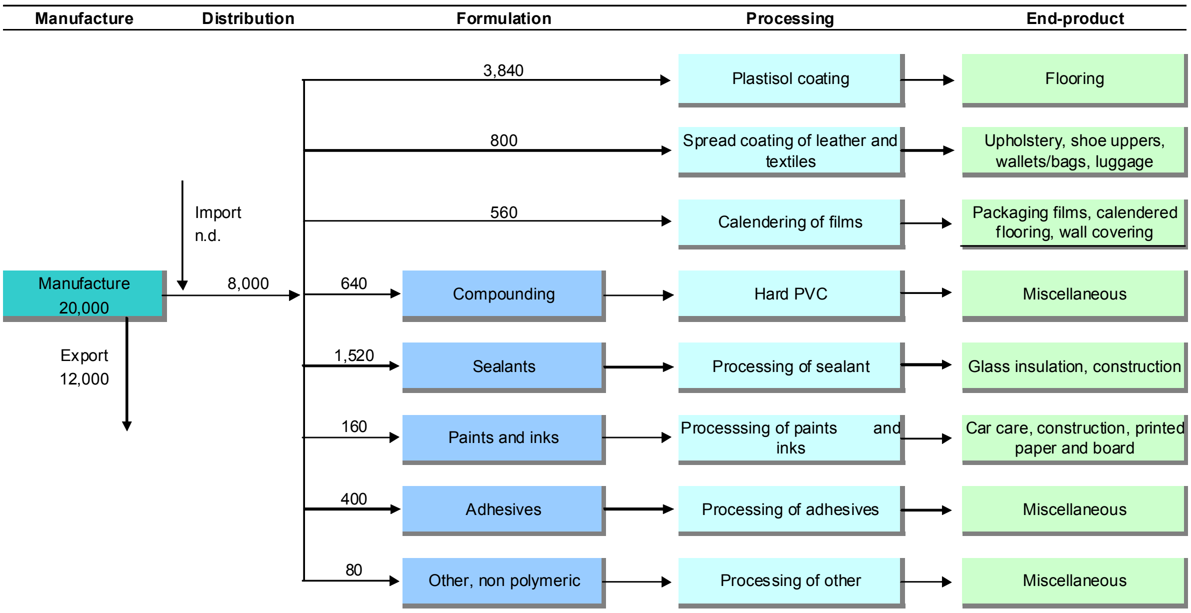

Figure 2-1 Overall flow of BBP through manufacturing processes in 2007. Tonnes BBP/year

2.1.1 Formulation and processing

The plasticised PVC is processed by a number of processes.

Table 2-1 overleaf gives and overview of the identified industry uses of BBP with use descriptor codes and NACE codes presented. A more detailed description of the involved processes is included in section 2.2 on quantification of uses.

Table 2-1 Use descriptors and NACE codes for all involved industrial processes

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
Synthesis of BBP	PROC1 PROC 3	Use in closed process, no likelihood of exposure. Industrial setting; Use in closed batch process (synthesis or formulation) Industrial setting;	SU9	Manufacture of fine chemicals	C20.1.4	Manufacture of other organic basic chemicals
Compounding of polymer	PROC5	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact). Industrial setting	SU12	Manufacture of plastic products, including compounding and conversion	C20.1.6	Manufacture of plastics in primary forms
Formulation of adhesives/sealant	PROC3,4	Use in closed batch process (synthesis or formulation) Industrial setting; Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting;	SU10	Formulation [mixing] of preparations and/or re-packaging	C20.5.2, C20.3.0	Manufacture of glues Manufacture of paints, varnishes and similar coatings, printing ink and mastics
Formulation of lacquers and paint	PROC3,4	Use in closed batch process (synthesis or formulation) Industrial setting; Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting;	SU10	Formulation [mixing] of preparations and/or re-packaging	C20.3.0	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
Formulation of printing ink	PROC3,4	Use in closed batch process (synthesis or formulation) Industrial setting; Use in batch and other process (synthesis) where opportunity for exposure arises. Industrial setting;	SU10	Formulation [mixing] of preparations and/or re-packaging	C20.3.0, C20.5.9	Manufacture of paints, varnishes and similar coatings, printing ink and mastics Manufacture of other chemical products n.e.c.
Calendering of polymer	PROC6	Calendering operations. Industrial setting;	SU12	Manufacture of plastic products, including compounding and conversion	C22.2.1, C22.2.3	Manufacture of plastic plates, sheets, tubes and profiles Manufacture of builders' ware of plastic

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
Spread coating (with plastisol)	PROC10	Roller application or brushing of adhesive and other coating. Industrial or non-industrial setting;	SU5, 12	Manufacture of textiles, leather, fur	C22.2.1	Manufacture of plastic plates, sheets, tubes and profiles
				Manufacture of plastic products, including compounding and conversion	C13.9.9	Manufacture of other textiles n.e.c.
Application of adhesives/sealant	PROC7, 10, 19	Spraying in industrial settings and applications. Industrial setting; Roller application or brushing of adhesive and other coating. Industrial or non-industrial setting; Hand-mixing with intimate contact and only PPE available. Non-industrial setting.	SU6, 19	Manufacture of pulp, paper and paper products Building and construction work	C17.2.9	Manufacture of other articles of paper and paperboard

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
Painting (application of lacquers and paint)	PROC7, 11	Spraying in industrial settings and applications. Industrial setting; Spraying outside industrial settings and/or applications	SU18, 19, 21	Manufacture of furniture Building and construction work Private households (= general public = consumers)	C43.3.4, C31	Painting and glazing Manufacture of furniture
Printing (application of printing ink)	PROC10	Roller application or brushing of adhesive and other coating. Industrial or non-industrial setting;	SU6	Manufacture of pulp, paper and paper products	C22.2.9, C17.2	Manufacture of other plastic products Manufacture of articles of paper and paperboard

*1 Process descriptors extracted from the REACH guidance, chapter R.12: Use descriptor system (ECHA 2008a)

*2 NACE codes and description extracted from: http://ec.europa.eu/comm/competition/mergers/cases/index/nace_all.html

2.1.2 End-product uses

The end-product uses of BBP are as follows (based on ECPI 2008, RAR 2007, suppliers' websites):

- Flooring (both calendered and spread coated flooring);
- Wall covering;
- Coating of leather and textiles (upholstery, shoe uppers, wallets/bags, luggage);
- Packaging films;
- Sealants (polysulphide based, polyurethane based or acrylic-based) for insulating double glazing and other applications;
- Paints for car care and construction (acrylic lacquers and other);
- Inks for paper and board;
- Adhesives (polyvinyl acetate and other);
- Miscellaneous (hard PVC, nitrile rubber and other).

BBP is not permitted for use in toys and childcare articles (Directive 2005/84/EC) or in cosmetics.

2.2 *Quantification of uses*

Information on the distribution of the BBP supply to the various formulation and processing activities has been obtained from manufacturers of the substance. The indicated distribution, together with the distribution indicated in the RAR, is presented in Table 2-2 below.

The data confirms the continued usage of BBP in most of the processes and end-uses mentioned in the RAR, but flooring seems to take up a larger part of the current total, whereas sealant takes up less.

According to CEPE (European Council of producers and importers of paints, printing inks and artists' colours), DEHP, DBP and BBP are no longer used in printing inks by CEPE/EuPIA (European Printing Ink Association) members following its classification as reprotoxic category 2 (CEPE 2007). CEPE brings approximately 85% of this industry together in its membership together whereas EuPIA represents close to 90% of the printing ink manufacturers selling in Europe (EuPIA web site). In the Danish product register a consumption of 0.3 tonnes BBP in inks was registered, but it may be due to non updated registration (see Annex 2). In the Swedish product register, which is more regularly updated, BBP has not been registered in printing inks since 2001 (Annex 2).

In the information obtained from manufacturers, coatings and inks are quantified together.

Table 2-2 Distribution of BBP on "first uses" based on actual data from manufacturers and in 2004 (RAR)

Process	2007 distribution	2004 distribution
	%	% , (RAR)
Formulation and processing (at same site):		
Plastisol coating	48	41
Spread coating of leather and textiles	10	9
Calendering of films	7	6
Processing from compound:		
Hard PVC	8	6
Non-polymeric, processing:		
Processing of sealants	19	31
Processing of coatings and inks	2	4
Processing of adhesives	5	2
Processing of other non-polymeric	1	2
Total processing (rounded)	100	100

2.2.1 Formulation and processing

For chemical products such as adhesives, paints, inks and sealants, "formulation" means the actual manufacture of the products, whereas the application of the products in for example the building industry, paper products industry or similar, is termed "processing".

For polymer products, "formulation" means production of semi-final products, such as PVC compound, which is pre-mixed, extruded PVC granulate ready for production of PVC end-product (e.g. hoses or toys), or plastisol, a pasty mixture (or “paste”) of constituents prepared for spread coating of textiles, or other materials. Here, "processing" is the production of the polymer products themselves (hoses, toys, etc.).

Distinguishing between formulation and processing is, for several of the products, somewhat artificial, as the two processes take place in the same production facility. In this case, the total quantity is here allocated to the processing step (where releases are estimated for all involved processes), and formulation only includes compounding for further processing in other facilities.

The total use of BBP for formulation and processing in shown in Table 2-3 and Table 2-4. The processes are further described below the tables.

Table 2-3 Estimated BBP use for formulation in 2007 and 2004

Process	Amount used (t/y), 2007	% of total , 2007	Amount used (t/y), 1999 *1	Number of sites of use, 1999
Compounding by extrusion	640	23	1,080	83
Non-polymeric, formulation:		0		
Formulation of sealant	1,520	54	6,000	n.d.
Formulation of coatings and inks	160	6	720	n.d.
Formulation of adhesives	400	14	360	n.d.
Formulation of other non-polymeric	80	3	360	n.d.
Total formulation (rounded)	2,800	100	8,520	

*1 Source: RAR 2007.
n.d. No data

Table 2-4 BBP use for processing in 2007 and 2004

Process	Tonnage (t/y), 2007	% of total, 2007	Tonnage (t/y), 2004 *1	Number of sites of use (2004/2006)
Formulation and processing (at same site):				
Plastisol coating for flooring	3,840	48	8,000	9 (in 2006)
Coating of leather and textiles	800	10	1,800	<10
Calendering of films	560	7	1,080	n.d. (few)
Processing from compound:				
Processing of hard PVC	640	8	1,080	n.d.
Non-polymeric				
Processing of sealants	1,520	19	6,000	6 (formulation sites)
Processing of coatings and inks	160	2	720	n.d. (few)
Processing of adhesives	400	5	360	n.d.
Processing of other non-polymeric	80	1	360	n.d.
Total processing (rounded)	8,000	100	19,400	

*1 Source: RAR 2007.
n.d. = No data

Formulation of adhesives, sealants, paints, lacquers and printing inks - Formulation of these chemical products basically consists of mixing of ingredients in a batch or continuous processes.

Calendering - In the calendering of flexible PVC, the polymer mass runs through the gaps between the hot rolls of the calender. A minor part of the PVC flooring production containing BBP, as well as wall covering, is produced by calendaring.

Plastisol applications -"Plastisol" is a pasty liquid obtained by blending (formulating) PVC resin with plasticiser and other ingredients at room temperature.

Paste is spread onto the substrate to be coated (flooring, coated fabric textile, woven glass, etc.) by a knife or a perforated roller. Spread coated products are “fused” (gelled) in tunnel ovens heated with hot air. The energy is supplied by an infrared heating source (IR) and/or hot air (DEHP RAR, 2008). Primarily, a discontinued process is applied, where a length of PVC flooring is produced at a time and rolled up for transport to the next process step (e.g. printing) (BBP RAR, 2007).

Processing (application) of sealants - BBP is used in polysulfide sealants applied for thermopane double glass windows, as well as polyurethane foam sealants and acrylic sealants for consumer/construction use (BBP RAR, 2007). Polysulfide sealants are also currently used widely for various other construction purposes, but this use is not explicitly mentioned in the BBP RAR. On this basis it is assumed that BBP- containing sealants could likely be used in non-industrial settings. Since the BBP RAR was produced, quantities of BBP used for sealants seem however to have decreased, perhaps as a result of substitution after the classification of BBP as reprotoxic category 2. However, this has not been confirmed.

Processing (application) of coatings/paints/lacquers and inks - A small amount of BBP is still used for these purposes. The main function of BBP is to give flexibility to prevent the paints/inks from chipping and flaking from the surfaces they are applied to (BBP RAR, 2007).

Processing (application) of adhesives - A small amount of BBP is used in adhesives. The BBP gives flexibility to the polymer-based adhesives (polyacrylic, polyvinylacetate). It is presumed in the BBP RAR that the BBP is used in dispersion type adhesives used in paper and automobile industry, and for wood and construction purposes. As such, the application of the adhesives could take place partly in industrial settings and partly in consumer/construction settings.

2.2.2 End-product uses

The estimated use of BBP in end-products, by product type, is shown in Table 2-5. The allocation of the EU-manufactured quantities to different product types has been done on the basis of information on the tonnage used for different processes (Table 2-4). No data has been available on import and export of BBP within articles and, for some application areas, the actual quantities for end uses may be significantly different from those indicated. In the absence of import/export data, however, the EU manufacture data are used as best estimate.

According to the RAR, for 2004 it was known that about 8,000 tonnes/annum of the total BBP production was used in flooring and about 6,000 tonnes/annum in sealants while the remaining 5,500 tonnes/annum were not further specified (import/export was not accounted for).

Table 2-5 Estimated BBP tonnage in end-products marketed in the EU27 based on EU manufacture data 2007

End-product use area	Tonnage, t/y				% of
	EU Manufacture	Import	Export	End-product use	total 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

2.3 *Quantification of releases from uses*

2.3.1 Formulation and processing

According to the Emission Scenario Document on Plastic Additives (ESD, 2004), the major releases of phthalates from polymer conversion processes occur initially as gaseous phthalate. Some of this remains in the air as gas or aerosols (small droplets staying in the air), or adsorbs on particles in the air. Other parts are quickly condensed to the liquid form on surfaces and will be washed of when the production equipment is cleaned periodically. There is generally no processing water, except in some case cooling water, which is not in contact with plastic matrix.

The important factors determining the amount of phthalate released to the working environment and the exterior environment are:

- The volatility of the phthalate (the ESD rates DEHP as of medium volatility and BBP as of higher volatility; DBP is among those with higher volatility judged by vapour pressure data from the RAR, as well as from other sources).
- The working temperatures during processing. Higher temperatures imply higher releases due to evaporation.
- The surface area of the PVC exposed to air. For example, calendaring of PVC (with hot rolls) creates a large exposed surface at elevated temperatures (briefly).
- Existence of exhaust air cleaning system. According to the ESD, burners (exhaust gas incineration) are often used resulting in a distinct release reduction (the ESD works with a standard reduction factor of 10, but it may be higher).
- For the working environment: Closed or open production processes, existence of air suction systems.

The ESD works with an approximate ratio between releases for the high, medium and low volatility groups of 5:1:0.2, taking medium volatility - exemplified by DEHP - as the standard of 1. BBP is explicitly mentioned as the example of a high volatility phthalate.

The estimated releases of BBP from formulation and processing in EU27 are shown in Table 2-6 and Table 2-7 below. The further description of background for the estimates for each process is provided below the tables. The releases are based on the processed quantities shown in Table 2-3 and Table 2-4. Release factors used are shown in Annex 1.

Table 2-6 Estimated BBP releases from formulation

Process	Releases to working environment (t/y)	Releases to the environment (t/y)			
		Air	Soil	Waste water	Waste
Compounding by extrusion	n.d.	0.2	0.1	1.6	n.d.
Non-polymeric, formulation:					
Formulation of sealant	n.d.	0.8	0.2	0.0	n.d.
Formulation of coatings and inks	n.d.	0.0	0.0	0.5	n.d.
Formulation of adhesives	n.d.	0.1	0.0	1.2	n.d.
Formulation of other non-polymeric	n.d.	0.2	0.0	0.2	n.d.
Total formulation (rounded)	n.d.	1.3	0	3.6	n.d.

n.d. No data

Table 2-7 Estimated BBP releases from processing (including releases from formulation where formulation and processing takes place at the same site)

Process	Releases to working environment (t/y)	Releases to the environment (t/y)			
		Air	Soil	Waste water	Waste
Formulation and processing (at same site):					
Plastisol coating for flooring	n.d.	5.0	1.9	5.0	n.d.
Coating of leather and textiles	n.d.	2.0	0.4	2.0	n.d.
Calendering of films	n.d.	0.8	0.3	0.8	n.d.
Processing from compound:					
Processing of hard PVC	n.d.	1.6	0.3	1.6	n.d.
Non-polymeric					
Processing of sealants	n.d.	1.5	0.2	0.0	n.d.
Processing of coatings and inks	n.d.	8.0	0.2	0.1	n.d.
Processing of adhesives	n.d.	0.0	2.0	0.4	n.d.
Processing of other non-polymeric	n.d.	0.2	0.0	0.2	n.d.
Total processing (rounded)	n.d.	19.2	5.3	10.1	n.d.

n.d. No data

Formulation (pre-processing)

Prior to actual processing to produce the desired end product, the raw materials are mixed (formulated) according to a recipe suited for the end product in question.

The Emission Scenario Document (ESD, 2004) describes the common formulation processes as follows (extracts).

Dry blending - This method typically consists of mixing all ingredients in a lidded blender with a high speed rotating agitator which heats the material by friction. Temperatures of 100- 120°C (maximum) are reached and the liquid plasticiser is completely absorbed by the fine PVC powder grain. The hot blend is dropped in a cooling blender (also lidded) for rapid cooling to avoid lumping. During dry-blending the exposure of hot material to open air is small, and the amount of emitted plasticiser vapour is very small (~0.01%).

Plastisol blending - Plastisol blending takes place in stirred vessels at ambient temperatures. To avoid the development of high viscosities by swelling of the PVC particles due to plasticiser uptake, the vessels may be cooled to remove the heat of friction. Any significant emissions of plasticiser at ambient temperatures are excluded.

PVC material containing BBP is primarily formulated and processed to end products in the same facilities (BBP RAR).

General remarks

Working environment, polymer uses - The BBP RAR discusses occupational exposure in some detail, and a few examples of workplace air concentrations of BBP for PVC conversion/formulation processes are given. Generally, the main routes of occupational exposure are anticipated to be inhalation of BBP-gas and, if formed, liquid aerosol, and by dermal uptake of liquid BBP, especially in processes performed at elevated temperatures, and in cases of direct contact during manual loading into process equipment, product sampling and cleaning of the process equipment. Calendering of PVC flooring is given as an example of higher exposure due to elevated temperatures in an open process. As described in detail for another phthalate, DEHP (DEHP RAR 2008), much of the gas emitted in cases of hot processes with BBP will likely rapidly condense to form an aerosol with the consequence that workers will be exposed to both gas and aerosol.

The exposure of workers in the further processes depends on the BBP concentrations generated in the working environment air (exposure via inhalation), on the direct skin contact with surfaces with BBP present (dermal exposure), and in both cases the time span of the exposures. Besides examples of measured workplace air concentrations, the BBP RAR presents model predictions of inhalation and, for some exposure situations, dermal exposure. These data will not be discussed quantitatively here. The data provided in the BBP RAR do not enable quantitative assessment of the amount of BBP released in the working environment.

Air and water releases - For all PVC conversion processes, the RAR uses a split between air releases and releases to waste water of 50%/50%, based on the ESD assumption that while most releases occur initially to air at elevated temperatures, the gaseous BBP is subsequently condensed in the conversion premises resulting in BBP following liquid releases (probably via cleaning processes).

Losses with waste from downstream polymer article production - Losses with waste from downstream article production, such as, for example, PVC film waste from the production of ring binders, or PVC flooring waste from construction of houses, are not quantified in either this study or the RAR. The lack of quantitative inclusion of such losses to waste may result in a slight over-estimation of the amount of product actually applied, and thereby of the releases during the use phase. Ultimately, the full amount of the article will be allocated to waste (in the disposal phase).

Working environment, non-polymer uses - According to the BBP RAR, the formulation (production) of sealants may be done in open or closed mixing processes. In the open process, the workers may be exposed during the mixing of the ingredients. The exposure may be both via inhalation and as dermal exposure (on the skin). The formulation processes for sealants, and probably also for the other non-polymer uses, are generally not performed at elevated temperatures, and therefore air-borne exposure may be lower than during, for example, calendering of PVC flooring.

Losses with waste from processing (application) of non-polymer products - The amount of these products ending up in application waste are not quantified in the BBP RAR. An actual quantification of these losses has not been included in this study either. A rough estimate for a non-industrial setting would be that on average up to 5% of the total amount of paint, sealant and adhesives may be lost as waste during the application steps. This waste consists of un-used remainders in partially used cans and tubes, as well as the thin film of product generally left in empty cans/tubes. In an industrial setting these losses to waste will be smaller due to optimized production procedures. The lack of quantitative inclusion of such losses to waste in this study may result in a slight over-estimation of the product amounts actually applied, and thereby of the releases during the use phase. Ultimately, the full amount of the product will be allocated to waste (in the disposal phase).

Plastisol coating in production of flooring

Air, waste water - Based on EuPC 2006 data obtained for this study, only small quantities of BBP are known to be used in facilities without air cleaning. Two producers in Europe are not accounted for by EuPC, but one of them is believed to have state of the art equipment. In conclusion, BBP RAR factors for facilities with air cleaning systems are used for releases to air and water. The ESD (2004) states that releases from fomulation of plastisol are zero.

Soil – The BBP RAR release factor was used, based on the TGD standard factor.

Coating of leather and textiles (extrusion, according to BBP RAR)

Air, waste water - BBP RAR release factors were used for air and water, based on ESD factors for extrusion and industry data from 1996.

Soil – The BBP RAR release factor was used, based on the TGD standard factor.

Calendaring of flooring and wall covering, and extrusion of film

Air, waste water - Based on information available for this project, an estimated 8% of total BBP consumption is assumed to be used for calendered flooring and wall covering. For these processes, the ESD (2004) air release factors for facilities with air cleaning were used for formulation: 0.025%, plus calendering: 0.125%. For waste water, the same ESD factors apply (for formulation: 0.025%, plus calendering: 0.125%).

The remaining 2% allocated for this application category is assumed to be extruded PVC film produced with on-site formulation. ESD factors for formulation plus extrusion with air cleaning of 0.025% + 0.025% to air, plus the same factors to waste water were used.

Soil – The BBP RAR release factor was used, based on the TGD standard factor.

Compounding and processing of hard PVC
Air, waste water - Compounding: ESD factors were used, assuming large facilities with air cleaning: 0.005% to air and 0.005% to water from raw materials handling, plus 0.025% to air and 0,025% to water from extrusion of the compound.
Processing: ESD factors for injection moulding, assuming smaller facilities with no air cleaning (as in RAR): 0.25% to air and 0,25% to water.

Soil – The BBP RAR release factors were used for both formulation and processing, based on TGD standard factors.

Formulation and processing of sealants
Formulation: Water releases are based on those for one major site in the BBP RAR. Air and soil releases are based on TGD defaults.

Processing: The BBP RAR release factors from the TGD were applied; air releases however were reduced to 0.1% due to low working temperatures. The BBP RAR assumes no releases to water and soil during processing.

Formulation and processing of coatings and inks
Formulation and processing: The BBP RAR uses TGD defaults for formulation and processing, but releases to water from formulation are set at 0.3%, as no water is involved in the formulation process. These factors were also used here.

Formulation and processing of adhesives
The BBP RAR uses the TGD defaults for formulation and processing, stating that emissions to water from processing should be reduced from 1% to 0.1% as no water is utilised in the process, and releases to water from formulation should be 0.3%, as no water is involved in the formulation process either. These factors were also used here.

Processing of other non-polymeric uses
This is reported as confidential use in the BBP RAR. The BBP RAR uses TGD defaults recommended by industry, stating that releases to water from formulation should be 0.3%, as no water is involved in the formulation process.

2.3.2 End-product uses

Releases from the entire service life of end-products are summarised in Table 2-8.

The releases are life-time emissions indicating the ultimate fate of the substance in the end-products i.e. the total of the releases corresponds to the total tonnage of BBP in marketed end-product in 2007 as shown in Table 2.5. The background for the estimates is provided below the table.

In order to make the lifetime emission from the in-service life comparable with the emission from manufacturing and processing (expressed in tonnes per year), the lifetime emission is similarly expressed in t/y, implicitly assuming a steady state situation with constant consumption at the 2007 level. The actual emission in the EU of BBP from end-products in service in 2007 is probably much higher reflecting the higher

BBP consumption in previous years resulting in large quantities of BBP accumulated in end-products in society.

Nearly 100% of the BBP-containing articles are used for indoor applications. Sealants are believed to be mainly used for insulating glazing which may be considered an outdoor use, but the sealant in the glazing is not exposed to the weather and the emissions from the sealant is considered to resemble releases from indoor uses. Therefore no assessment has been performed with respect to direct release to the environment during service life.

Many of the product groups contribute to emissions to air. Flooring accounts for nearly 50% to the total emissions, and the highest concentrations in the indoor environment are expected in rooms with BBP-plasticised flooring, because of the large surfaces from where the substance can be released. Flooring is also considered to be the main source of releases to waste water.

Table 2-8 BBP releases from end-products during their lifetime

End-product use area	Releases to the environment, t/y			
	Air	Soil	Waste water	Solid waste
Flooring	14	0	101	4,175
Film	0.0	0	0	0
Coated fabric, upholstery, shoe uppers, luggage,etc.	6.4	0	16	778
Hard PVC	n.d.	n.d.	n.d.	640
Non polymer applications:				
Sealant	0	0	0	1,520
Paints and ink	1.4	0	0	159
Adhesives	3.6	0	0	396
Other non-polymeric	4.0	4	4	68
Total	29	4	121	7,740

BBP present in end-products is mainly released to the environment during their service-life by the following processes:

- Emission to air by evaporation;
- Leaching and abrasion released to waste water by washing operations for indoor uses.

BBP not released during the life of the end-products will be present in the products at the time of disposal of these products and will be directed either to landfills or incineration.

Flooring and wall covering - Flooring is the largest product group. During use, emissions from flooring are expected due to abrasion, washing and evaporation. ECPI (quoted in the RAR) estimated the loss due to evaporation, arriving at a factor of 0.0016% per year corresponding to a life-time emission factor of 0.032% assuming a service life of 20 years.

According to the RAR, ECPI has estimated phthalate emissions to air and water due to water extraction during washing of flooring. From estimates of the general release of plasticisers from flooring due to water extraction an emission rate of 0.04% per year was calculated. With a service life of 20 years, this corresponds to a life-time emission rate of 0.8%. Abrasion of PVC flooring has been evaluated in the RAR of DEHP (DEHP RAR 2008) on the basis of industrial information. In the RAR a life-time loss (lifetime = 20 years) of 6.2% due to abrasion is assumed and a similar procedure is used herein. This loss is assumed to occur on surfaces that are frequently walked on (50% of surfaces) so the average life-time emission factors for abrasion can be estimated at 3.1%. The particles produced by abrasion are very small particles. The distribution of these particles is unknown, but it is assumed that 50% is removed by wet cleaning and ultimately released to WWTP (RAR 2007). Total releases from flooring can consequently be estimated at 2.35% (0.8% for leaching and 1.55% for abrasion). It is assumed that all BBP emitted to water enters the wastewater treatment system. Wall coverings constitute a very small fraction of the product group "flooring and wall coverings" and the same emission factor is used for the same quantity, although the releases from wall covering to waste water may be lower than for flooring.

Film - Film is assumed mainly to be packaging film. The release factors for air emission would be significantly higher than for flooring, but the lifetime is very short and so the same emission factor as for flooring is applied. The releases to water from the film are assumed to be insignificant.

Coated fabric, upholstery, etc. - Release from coated fabric, upholstery, luggage, and other coated products are estimated in the RAR using the same emission factors as for flooring. Emissions to the air will be determined by the surface area. Coated fabric typically has a thickness of 0.3-0.5 mm whereas the thickness of flooring is typically 1-4 mm. The surface to volume ratio is consequently about 5 times higher for the coated fabric while the service life is typically only half the life of the flooring (10 years for coated fabric vs. 20 years for flooring). A lifetime emission factor 2.5 times the factor for flooring will be applied. Releases to water occur when the products are washed; the abrasion of the products is estimated to be insignificant. The life-time releases to water from the products are assumed to be 2.5 times the life-time emission rate of 0.8% for leaching from flooring.

Hard PVC - The use of BBP in hard PVC plastic is not known and no emission factors have been established.

Sealant - It is assumed that the main use of sealant is for windows. Because the window sealant is closely confined within the window frame, any evaporation of BBP from window sealants to air is, according to the RAR, thought to be negligible and the emission factor is estimated to be 0.

Paints, inks and adhesives - It is assumed that air is the main release compartment for these use categories. BBP is used as a plasticiser in polymers in the cured products, and an emission factor to air is based on the evaporation rate found for flooring. It is assumed that the ink, adhesive or paint thickness is 0.01 mm and that evaporation is therefore a factor of 100 higher than for flooring. This gives a release fraction to air of 0.16% per year (based on the RAR). Assuming a lifetime of 5 years, the lifetime emission will be 0.9%. The RAR does not assume any losses to waste water for these applications.

Other non-polymer products - The actual applications covered by this product category are confidential. According to industry, quoted in the RAR, an emission loss of 5% on a yearly basis is assumed for air, water and soil. The life-time emission factors are similar.

2.4 *Quantification of releases from waste disposal*

The total quantity of municipal solid waste generated in the EU27 around 2005 was estimated by the European Topic Centre on Resource and Waste Management at 254 million tonnes (Skovgaard et al 2008). Of the municipal solid waste generated in 2005 approximately 45% was directed to landfills, 18% was directed to incineration while the remaining 37% was recycled or recovered (Skovgaard et al 2007). However, as recycling/recovery activities addressing flexible PVC as well as other uses of phthalates are few and still rather scarce, it is deemed that in reality all phthalates present in end-products will ultimately be directed to either landfills or incineration. Thus, the figures presented above are here adjusted to 71% to landfills, 29% to incineration and 0% to recycling.

Solid waste incineration

Few data are available regarding emissions of phthalates from waste incineration plants and the presence of phthalates in incineration residues.

A few measurements are available from Denmark, reported in 1994 (Kjølholt et al. 1994). These measurements concern the emissions of phthalates from a Danish municipal solid waste incineration plant equipped with so called "wet" flue gas cleaning technology.

The following concentrations of BBP were measured (Kjølholt *et al.* 1994):

Flue gas: <0.01-0.19 µg/m^2
Clinker: 0.02 - 0.2 mg/kg
Fly ash: <0.02 - 0.44 mg/kg
Flue gas cleaning residue: <0.2 mg/kg
Waste water: 0.02 - 0.04 µg/l

The emission data were used for estimating the total releases of BBP from Danish incinerators in a Danish substance flow analysis for phthalates (Hoffmann 1996) and these data are used in the RAR for BBP for estimating the total emission from incinerators in the EU using a per capita emission approach. In order to be able to reflect the actual changes in the use of the substance, emission factors are estimated for DEHP, DBP and BBP by combining the Danish data with information on European consumption figures for phthalates in the early 1990s. It is roughly assumed that the percentage of the phthalates in the waste resemble the percentage of phthalates marketed in the EU in the early 1990s. In fact the composition of phthalates in the waste are expected to reflect the composition of marketed phthalates some years before, but historic data has not been available.

With improved flue gas treatment on incinerators in recent years, the actual emission factors are probably lower today, but the estimated emission factors are applied as a worst case in the absence of more recent information. The total estimated EU27 emission is on this basis estimated at 0.019 t/y (Table 2-10).

The RAR does not estimate emissions of BBP from incinerations as these are assumed to be very small, which is confirmed by the present estimate.

Table 2-9 Estimated emission factors for DEHP, DBP and BBP from waste incinerators based on data on Danish incinerators in 1994

	DEHP	DBP	BBP
Measured emission factors, g/m3 *1	5.7-17	0.54-9.2	<0.00-0.19
Total emission, kg *2	118	68	1.3
Total phthalates content of waste, tonnes *2	3,000	3,000	3,000
Estimated percentage of total phthalates *3	51	5.5	4.0
Estimated total substance content of waste, tonnes	1,530	164	121
Emission factor, % of content in waste	0.008	0.041	0.001

*1 Source: (Kjølholt et al. 1994)

*2 Phthalate content of incinerated waste in Denmark and estimated emission from Danish incinerators (1994). Source: Danish substance flow analysis for phthalates (Hoffmann 1996).

*3 Percentages of the single phthalates are not estimated in the Danish report. The indicated figures represent the percentages of the substances on the European market around 1994 based on information in the RARs for DEHP, DBP, and BBP

The total release of BBP to waste water from the Danish incinerators was estimated at less than 0.03 kg and releases to waste water from incinerators are considered insignificant and not further discussed.

The total amount of BBP in residues was 0.4 tonnes indicating that less than 1% of the BBP was not destroyed by the incineration.

Landfilling

Municipal landfills are considered to release BBP mainly through leachate water (based on the RAR). The amount of BBP discharged with leachate was estimated as 2.1 tonnes/year in the RAR based on data from the UK and leachate concentrations from Sweden (based on the RAR). The low leachate rate of BBP will probably cause accumulation in the landfill and the future emission from the landfill may therefore be higher. It is not possible based on the available data to estimate how much of the BBP directed to landfill will be released from the landfill before it is ultimately degraded. In the absence of data, the release rate from the RAR will be used, corrected for the decreased amount of BBP brought into circulation in society.

Biological treatment/compost

Phthalates may be present in materials directed to biological waste treatment. In compost produced in Denmark, a concentration of <0.1 mg BBP/kg has been registered, corresponding to total quantity of <1 kg for all compost produced in Denmark (Hoffmann 1996). This quantity will be directed to soil.

Assuming a similar situation in other European countries, the total amount of BBP directed to soil with compost may be roughly estimated as <1 kg * 488.5/5.3 corresponding to <0.1 tonnes BBP/year.

Waste water and sewage sludge
Reported measurements indicate that around 97-100% of BBP present in waste water will be removed by waste water treatment processes (Hoffmann 1996). The figures stated are based on 3 series of measurement undertaken in Denmark covering waste water from a large mixed urban area, an industrial area and a mostly residential areal.

Effluent concentrations <0.05 and <2 µg/l have been reported (Hoffmann 1996). The reported concentrations were close to detection limits in all cases.

Assessment of the amount of waste water generated and directed to waste water treatment in the EU is difficult due to lack of data.

In Denmark the amount of water emitted from municipal waste water treatment plant is estimated to be 611 million m^3 in 2003 corresponding to 115 m^3 per capita per year. This figure includes domestic waste water, industrial waste water and storm water directed to sewage treatment. The figure seems to correspond reasonably well with figures from other EU countries reported in Eurostat (2001).

Assuming an average effluent concentration of <1µg/l a discharge from waste water treatment plants of 115 m^3 per capita per year and a population of 488.5 million persons in 2005 for EU(27) would give a total emission of BBP from waste water treatment plants of <56 tonnes/year Compared with the total of 360 t BBP directed to waste water treatment as estimated in this study it is in accordance with the observation that only a minor part of the BBP is discharged from the plants.

Measurements from Denmark reported by (Hoffmann 1996) indicate that 0.1-18% (average 7%) of the amount of BBP directed to waste water treatment will end up in sewage sludge.

Sludge concentrations between <0.4 and 0.7 mg BBP/kg DS have been reported (Hoffmann 1996). Based on the data reported it may be assessed that mean values would likely be about 0.5 mg BBP/kg dry matter.

If it is assumed that some 7% of the BBP in the waste water is ending up in the sludge, the total amount in sludge would be around 25 tonnes per year.

About 32-35% of the sewage sludge produced in the EU is used for agricultural purposes, while 10% is directed to incineration and the remainder is directed to landfills (Eurostat 2001).

In this assessment waste water is indicated as a release pathway together with soil and air and in order to avoid double counting the terminal release pathways are not included in the summary tables and flow charts.

Summary
The releases from the main waste operations are shown in Table 2-10 below. Compared to the estimated releases during the use of the end-product, the releases from waste disposal are small.

Table 2-10 Releases of BBP from main solid waste operations

	Tonnage (t/y)	Releases to the environment, t/y		
		Air	Soil	Waste water
Incineration	1,900	0.019	0.00	0.0
Landfilling	5,500	0.000	0.24	0.9
Total		0.019	0.24	0.9

3 Information on alternatives

3.1 *Identification of alternative substances and techniques*

3.1.1 Identification of alternative substances

Following the classification of BBP as toxic to reproduction (Repr. Cat. 2), BBP 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 previous chapter.

BBP can be used to replace a small portion of the primary plasticiser for products that need a slight reduction in gelation or fusion temperature. The BBP is typically used together with other phthalate plasticisers like DEHP or DINP. It is used widely by the flooring industry because it adds surface properties to flooring materials that minimise maintenance and give it a prolonged life (ECPI 2008b). One of the manufacturing benefits of using BBP is that it allows PVC transformers to operate with less energy input than with many similar plasticisers (ECPI 2008b). BBP depresses the melting temperatures of the crystallites, thus promoting fusion at lower processing temperatures.

For the use of BBP in sealant for insulation glass a manufacturer has pointed out the two main benefits of using BBP: its compatibility with the polysulphide base and its lower cost compared to other phthalates (Inform 2003).

Alternatives may be considered at three levels:

- Alternative substances that have similar processing properties and provide similar end-product properties, i.e. that it allows PVC transformers to work with less energy input and adds surface properties to flooring materials that minimise maintenance;

- Alternative plasticiser/polymer systems that can be used for production of end-products with nearly similar properties, but having other processing properties with the implication that processes have to be changed;

- Alternative materials/solutions that can provide the same overall product service, but with different end-product properties.

Plasticisers that are recommended (by industry or in the literature) as substitutes for BBP in different applications

When considering suitable alternatives that can be used without process changes, considerations have to include the plasticiser's compatibility with the polymer, process constraints (speed, temperature, viscosity, etc.) the efficiency (amount of plasticiser required to achieve the desired flexibility), ease of processing and cost-effectiveness.

Dibenzoates - According to Cadogan (2006) and Patric (2006) BBP has mainly been replaced by benzoates. Dibenzoates were specifically mentioned as alternatives to BBP in sealants in a Danish review of alternatives to phthalates in non-PVC products (COWI 2000). The summary results of the review are shown in Table 3-2.

Many dibenzoate plasticisers are marketed as substance blends.

On request one manufacturer of dibenzoates has provided information on dibenzoates particularly suitable as alternatives to BBP (Table 3-1).

Table 3-1 Applications of dibenzoates from Genovique as alternatives to BBP (Genovique 2009)

Applications	Genovique Product 1	Genovique Product 2	Bulk Pricing compared to BBP
Flooring	Benzoflex 2088	Benzoflex 9-88	Equivalent
Calendered Film	Benzoflex 9-88	Benzoflex 2088	Equivalent
Spread Coated Fabric	Benzoflex 2088	Benzoflex 50	Equivalent
Adhesives	Benzoflex LA-705	Benzoflex 2088	Equivalent
Paint/lacquers	Velate 375	Benzoflex 9-88	Equivalent
Sealants - Glass	Benzoflex 2088	Benzoflex 9-88	Equivalent
Sealants - Construction	Benzoflex 2088	Benzoflex 9-88	Equivalent

Benzoflex 2088:	Diethylene glycol dibenzoate (61-69%), dipropylene glycol dibenzoate, triethylene glycol dibenzoate
Benzoflex 9-88:	Dipropylene glycol dibenzoate (89%), propenyl propyl benzoate, dipropylene glycol monobenzoate, propylene glycol dibenzoate, propylene glycol monobenzoate
Benzoflex LA-705:	Proprietary benzoate esters (76-80%), dipropylene glycol dibenzoate
Benzoflex 50:	Diethylene glycol dibenzoate (45%), dipropylene glycol dibenzoate (45%), , diethylene glycol monobenzoate, dipropylene glycol monobenzoate, propenyl propyl benzoate, propylene glycol dibenzoate.
Velate 375:	Proprietary benzoate esters (76-82%), dipropylene glycol dibenzoate

Dipropylene glycol dibenzoate (DGD; CAS No 27138-31-4) is together with diethylene glycol dibenzoate (CAS No 120-55-8) one of the main constituents of dibenzoate plasticisers.

Environmental and health assessment of DGD was done by Stuer-Lauridsen et al. (2001). At the time of the assessment there were not sufficient data to describe the human toxicity of the substance and the data availability was insufficient for calculating PNECs or providing other indications of ecotoxicity for the assessment of environmental risks of DGD.

In a health, environmental and technical/economic assessment of DEHP alternatives for thee application areas, The Toxics Use Reduction Institute (TURI 2006) at University of Massachusetts Lowell investigated DGD as alternatives to DEHP in resilient flooring. For technical/performance criteria and environmental criteria, DGD had a high scoring, but data were not available for essential health effects.

No IUCLID data sheet is available for DGD and probably very little information will be available. The substance has been selected for further evaluation.

Alkylsulphonic phenyl ester (ASE) - According to information from BASF for this study alkylsulphonic phenyl ester (CAS N^o 91082-17-6, ASE, trade name Mesamoll) can replace BBP in many applications. ASE is a general purpose plasticiser with good gelling behaviour and saponification resistance. It is compatible with many types of polymers including PVC and polyurethanes (Lanxess 2008). The product is not specifically marketed as alternative to BBP, rather as alternative to DEHP.

A Danish study (Nilsson et al. 2002) demonstrated the feasibility of ASE as alternative to DEHP in waterbeds. A health and environmental assessment identified as critical parameters that it was not demonstrated (at the time of the study) whether the alternative had endocrine disrupting properties and that the substance was not easily degradable in the water environment. The main constituents have recently been assessed and are not considered as PBT by the TC NES Subgroup on Identification of PBT and vPvB Substances (ECB 2008). The constituents do not meet the P/vP criteria based on screening data, but they meet the screening B (bioaccumulative) criteria. This substance contains impurities, which may meet the P/vP and B/vB criteria based on screening data; however, these impurities are present in such low concentrations that they are not considered to be of concern at present due to a very limited potential for environmental release from the current production and use within the EU. The substance has been selected for further evaluation.

Table 3-2 Identified alternatives to non-PVC products (COWI 2000)

Chemical name	Printing inks	Paint and lacquer	Adhesives	Sealants	Rubber	Moulding agents
Acetyl tri-n-butyl citrate (CAS 77-90-7)	x					x
Dioctyl sebacate (CAS 122-62-3)	X		x			
Dibutyl sebacate (CAS 109-43-3)	X	x				x
Tricresyl phosphate (CAS 78-32-0)					X	
2,2,4-Trimetyl1,3-pentandiol diisobutyrate (CAS 6846-50-0)	x	x	X	X		x
Epoxidized soybean oil (CAS 8013-07-8)	x	x	x	x		
Epoxidized linseed oil (CAS 8016-11-3)		x	x			
Diphenyl-2-ethylheyl phosphate (CAS 1241-94-7)	X	X			X	
Di-isononyl adipate (CAS 33703-08-1)	X	X	X		X	
Di-(2-ethylhexyl) adipate * (CAS 103-23-1)	X	X	X	x	X	x
1,2,3-Propantriyl triacetate (CAS 102-76-1)	X		X			
Tricresyl phosphate [without ortho-compounds] (CAS 78-32-0)		X				
Triphenyl phosphate (CAS 115-86-6)		X				
Tri(2-ethylhexyl)phosphate (CAS 78-42-2)		X	x	X		x
Diethylen glycol dibenzoate (CAS 120-55-8)			X	X		
Triethylen glycol dibenzoate (CAS 120-56-9)			X	X		
Dipropylen glycol dibenzoate (CAS 27138-31-4)			X	X		
Butyl diglycol acetate (CAS 124-17-4)				X		
Silicone oils (CAS 63148-62-9)				X		
Diphenyl cresyl phosphate (CAS 26444-49-5)				X	X	
Benzyl-(2-ethylhexyl) adipate (CAS 58394-64-2)					X	

X Substitutes proposed by market actors.
x: Substances registered in the Danish Product Register as used in the specified applications, but not proposed by market actors.
*: Synonyms often used: dioctyl adipate.

Alternative plasticiser/polymer systems

Besides replacing BBP with another plasticiser, end-products may be produced using other plasticiser/polymer systems although this may be at the expense of some of the properties of the plasticiser.

Alternatives to DEHP for applications where both DEHP and BBP are used would therefore be considered as possible alternatives to BBP, though again not all properties may be matched. For this reason studies of alternatives to DEHP and to phthalates more generally (including BBP) will be reviewed for the selection of potential alternatives to BBP. For flooring, the main use of BBP, many products are produced without BBP. In a Danish investigation in 2001, BBP was found in 2 out of 5 investigated floorings whereas other floorings included DEHP or DINP/DIDP only (Pors and Fuhlendorff 2001). Also for spread coating of leather and textiles and calendering of films, end-products manufactured with the use of DEHP (or alternatives to DEHP) may substitute for products manufactured with the use of BBP. Use of substitutes may imply some process changes e.g. that the process has to take place at higher temperatures and with higher energy input. Most assessments of alternatives to phthalates have focused on alternatives to DEHP (with a volume of more than 20 times the volume of BBP), and it has not been possible to identify any assessments of the costs and feasibility of replacement of BBP. It has not been assessed in detail to what extent the use of these alternatives can provide exactly the same functionality as BBP, e.g. with regard to need for maintenance of flooring, as the alternatives have mainly been assessed as alternatives to DEHP.

A large number of substances are used as plasticisers in PVC, in other polymers and in non-polymer applications. Some of the most common application areas are described at the web site of the Plasticiser Information Centre (http://www.plasticisers.org/), an initiative of the European Council for Plasticisers and Intermediates (ECPI). For others the description of the plasticisers refers to websites of the manufacturers or to previous assessments.

A number of non-phthalate alternatives are today marketed for and applied in applications where the risk of human exposure is particularly high and where there has been consumer attention to substituting the phthalates in PVC: toys and childcare, medical devices, food packaging and water mattresses. Alternatives marketed specifically for these products groups include among others adipates, citrates, carboxylates, alkylsulphonic acid ester and castor oil derivatives.

A number of alternatives to DEHP (and other phthalates) in PVC applications have been evaluated in previous studies as summarised in Table 3-3. In the table it is indicated whether the assessments include a health assessment (H), an environmental assessment (E) and a technical/economic assessment (T). Three of the studies included all three aspects. None of the substances are included in the List of Dangerous Substances (Directive 67/548/EEC).

For the European Commission, Postle et al. (2000) investigated alternatives to phthalates in toys and children care articles, while Nielson et al. (2002) supported by the Danish EPA, investigated an alternative to DEHP in water mattresses.

In a recent study from the USA, the Toxics Use Reduction Institute (TURI 2006) at the University of Massachusetts Lowell has investigated a number of alternatives to DEHP for three application areas: resilient flooring, wall coverings and medical devices for neonatal care. For the Danish EPA, Stuer-Lauridsen *et al.* 2001 undertook a health and environmental assessment of a number of substances without a technical assessment while Karbæk (2003), also for the Danish EPA, made a technical assessment of alternatives to phthalates in medical devices.

Most recently the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2008) has made a health assessment of the safety of medical devices containing DEHP-plasticised PVC or other plasticisers on neonates and other groups possibly at risk.

The main results of these assessments are briefly reviewed in the following in order to select the most relevant alternatives for the more detailed assessment in this study

Table 3-3 Alternatives to DEHP and other phthalates assessed in studies cited

Chemical group	Substances assessed	Abbreviation	CAS N^{o}	Stuer-Lauridsen *et al.* 2001	Postle *et al.* 2000	TURI 2006	Nilsson *et al.* 2002	Karbæk 2003	SCENIHR 2008
Coverage *1				H;E	H;E;T	H;E;T	H;E;T	T	H
Phthalates	Di-isononyl phthalate	DINP	68515-48-0 28553-12-0		x	x		x	x
	Di-isodecyl phthalate	DIDP	68515-49-1 26761-40-0			x			
Terephthalates	Di(2-ethylhexyl) terephthalate	DEHT/DOTP	6422-86-2			x			x
Adipates	Diethylhexyl adipate	DEHA	103-23-1	x	x	x		x	x
Citrates	Acetyl tri-n-butyl citrate	ATBC	77-90-7	x	x			x	x
	Butyryl trihexyl citrate	BTHC	82469-79-2			x			x
Phosphate esters	Tris(2-ethylhexyl) phosphate	BBPA	298-07-7	x					
	2-ethyhexyl diphenyl phosphate		78-42-2	x					
Trimellitate esters	Tris-2-ethyhexyl trimellitate	TOTM	3319-31-1	x		x		x	x
Alkylsulphonic acid esters	O-toluene sulfonamide		88-19-7	x					
	Alkylsulphonic phenyl ester	ASE	91082-17-6				x		
Butane esters	2,2,4-trimethyl1,3-pentandioldiisobutyrate		6846-50-0	x					
Epoxy esters and epoxidized oils	Epoxidised soy-been oil		8013-07-8	x				x	
Benzoates	Dipropylene glycol dibenzoate	DGD	27138-31-4	x		x		x	
Carboxylates	Di-(isononyl)-cyclohexan-1,2-dicarboxylate	DINCH	166412-78-8			x			x
Castor oil derivatives	Acetylated monoglycerides of fully hydrogenated castor oil	COMGHA	736150-63-3						x
Polyesters	Polyadipates		-	x					
Sebacates	Dibutyl sebacate	DBS	122-62-3	x				x	

*1 Includes human health assessment (H); environmental assessment (E); technical/economic assessment (T)

SCENIHR evaluation of health risk of alternatives in medical devices

BBP is generally not used in medical devices, but the assessed alternatives may also be relevant as alternatives for some BBP applications and reference to the assessment is therefore included.

The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has assessed a number of alternatives for use in medical devices. The Committee obtained access to toxicity data for eight possible alternative plasticisers and compared their toxicity with that of DEHP. The alternative plasticisers were evaluated for their potential toxicity and ranked according to toxicity and leaching. The SCENIHR assessment is considered the most up-to-date and comprehensive for these eight alternatives and the human toxicity evaluation of these substances.

To compare the toxicity, a short summary of the potential genotoxicity, the carcinogenicity, repeated dose toxicity and reproductive toxicity were summarised (Table 3-4). In this table (as well as in Table 3-5) the NOAEL is shown as the lowest effects in male or female rat. Available information on the leaching behaviour of alternative plasticisers was sparse, but in general appears to be of the same order of magnitude as that of DEHP. The margin of exposure for DEHP in neonate seems to be very low. For blood transfusion peak values up to 22 mg/kg bw/day have been estimated showing a dose 4 times higher than the NOAEL of DEHP.

Table 3-4 NOAEL of DEHP compared with some alternative plasticisers. The critical endpoint is shown to indicate that, for some of the chemicals, it is different from reproductive effects (SCENIHR 2008)

Plasticiser	NOAEL mg/kg bw	Reproductive Toxicity	Critical endpoint	Exposure Range (neonates) µg/kg bw/day
DEHP	4.8	Yes	Reproduction	42-2300
ATBC	100	No	Decreased bw	
COMGHA	5000	No data	Decreased bw	
BTHC	250	No	Liver weight	
DEHA	200	Yes	Foetotoxicity	
DINCH	107	No	Kidney*	
DINP	15 (88)	No/Yes	Liver	
DEHT/DOTP	500-700	No	Developmental	
TOTM	100	Yes	Reproduction	

bw: body weight

* Kidney effects in male rats due to alpha-2-u macroglobulin, a mechanism not relevant to man

According the SCENIHR, considering similar leaching rates, the margin of safety of other plasticisers will be least 20 times higher for most alternatives. The toxicological profile of DEHP and the alternative plasticisers with respect to repeated dose toxicity, genotoxicity, carcinogenicity and maternal toxicity in Table 3-5.

Table 3-5 Comparison of the toxicological profiles of DEHP and potential alternatives to its use (SCENIHR 2008)

Plasticiser	Repeated dose Toxicity, NOAEL mg/kg bw/day	Genotoxicity	Carcinogenicity	Maternal toxicity mg/kg bw/day
DEHP	29 (male rat)	Negative	LOAEL 320 (male rat)	LOAEL 750 (rat)
ATBC	100	Negative	Negative	NOAEL 100 (rat)
COMGHA	5000	Negative	No data	No data
BTHC	250	Negative	Negative	NOAEL
DEHA	200	Negative	NOAEL 1250	NOAEL 400 (rat)
DINCH	107	Negative	Negative	NOAEL 1000 (rat)
DINP	15 (88)	Negative	Kidney	LOAEL 750 (rat)
DEHT/DOTP	500-700	Negative	Negative	NOAEL 458 (rat)
TOTM	100	Negative	No Data	NOAEL

The SCENIHR concludes that DEHP causes the most severe effects on reproduction in animal studies evaluating toxicity. DEHA, DINP, and TOTM also caused reproductive toxicity, but in doses more than 20 times higher than that of DEHP. COMGHA and TOTM could not be evaluated for all endpoints due to lack of data.

Regarding the alternatives, for some compounds sufficient toxicological data were available to indicate a lower hazard compared to DEHP. However, a risk assessment of these alternative plasticisers could not be performed by SCENIHR due to a lack of human exposure data. For others, information on the toxicological profile was inadequate to identify the hazard. This limits the proper evaluation of the potential to replace DEHP by alternative plasticisers. The risks and benefits should be carefully evaluated for each individual medical device and each medical procedure in which the alternative needs to be used.

Health, environmental and technical/economic assessment of DEHP alternatives for three application areas

The Toxics Use Reduction Institute (TURI 2006) at the University of Massachusetts Lowell investigated a number of alternatives to DEHP for three application areas: Resilient flooring, wall coverings and medical devices for neonatal care. In the context of BBP alternatives to DEHP in flooring are the most relevant.

The Institute identified and assessed four plasticiser alternatives and three material alternatives to DEHP/PVC in flooring. Each of the plasticiser alternatives assessed (DEHA, DINP, DGD and DEHT) exhibited according to the authors equal or better environmental health and safety profiles compared to DEHP. They also exhibited comparable costs and performance characteristics, though industry was reported to feel that cost is a limiting factor in the lower end industrial and commercial resilient flooring markets. In addition, it is likely that some processing modifications would be required in order to switch to an alternative plasticiser. This could require initial additional capital input by industry.

Health and environmental assessment of a number of alternatives
Stuer-Lauridsen *et al.* (2001) assessed, for the Danish EPA, eleven substances and two materials identified as potential substitutes to phthalates. The study included a health and environmental assessment whereas the technical assessment was undertaken in a parallel study (COWI 2001).

The compounds for which ecotoxicity data were available (only data for the aquatic environment were available) showed relatively high acute ecotoxicity, which in all cases would lead to an environmental hazard classification. The adipate (see the table below for details of the specific substances) would be 'Very toxic' (R50/53), epoxidised soybean oil would be classifiable as 'Toxic' (R51/53), and o-acetyl tributyl citrate, di(2-ethylhexyl) phosphate and tri(2-ethylhexyl) phosphate would be classified as 'Harmful' (R52/53). For the trimellitate and the sebacate, the low aqueous solubility in combination with persistence and bioaccumulation potential would reportedly lead to a classification as 'May cause long term effects in the aquatic environment' (R53). Several substances show limited degradability in the environment (the trimellitate and possibly both phosphates). Some had an estimated high bioaccumulation potential (citrate, trimellitate, dibenzoate and sebacate). The trimellitate and the dibenzoate possibly combine both these environmentally undesired properties. The authors emphasised that this was based on estimated values for bioaccumulation, which again were based on estimated octanol-water partition coefficients. It is possible that these compounds to some extent hydrolyse in the environment. Bioaccumulation would then be considerably lower. Measured bioaccumulation for the adipate and the two phosphates were below the criteria for when substances are considered to bio-accumulate.

The evaluation of risks to humans or the environment (see Table 3-7) indicated that none of the five assessed substances (diethylhexyl adipate, o-acetyl tributyl citrate, di(2-ethylhexyl) phosphate, tri(2-ethylhexyl) phosphate, and tri-2-ethylhexyl trimellitate) reached concentrations in the aquatic environment which exceeded the predicted no-effect level for the aquatic environment in general. For the adipate, the study concluded that there may be a risk for the sediment compartment due to the sorptive properties of the substance combined with low degradability. The risk to the aquatic environment from o-toluene sulfonamide, epoxidised soybean oil, diisobutyrate and dioctyl sebacate could not be calculated due to lack of data.

Table 3-6 Human health and environmental properties of the investigated substances and materials (Stuer-Lauridsen *et al.* 2001)

Name of substance or material	CAS No.	Humans			Environment		
		Acute and local effect (A/L)	CMR[d]	Sensitisation	Persistence	Bioaccumulation	Aquatic Toxicity
Diethylhexyl adipate (DEHA)	103-23-1	○/○	(○)[a]	○	○	○	● very toxic
O-acetyl tributyl citrate (ATBC)	77-90-7	○/○	○ M, R	○	● (inherent)	(●)	● (harmful)
Di(2-ethylhexyl) phosphate (DEHPA)	298-07-7	●/●	○	○	● (conflicting)	○	● harmful
Tri(2-ethylhexyl) phosphate	78-42-2	(○)/●	○ M, C	-	●	○	● harmful
Tri-2-ethylhexyl trimellitate (TOTM)	3319-31-1	●/○	○	○	●	(●)	-
O-toluene sulphonamide	88-19-7	-/-	(○)[c]	-	(●)	○	-
2,2,4-trimethyl 1,3-pentandiol diisobutyrate	6846-50-0	-/-	-	-	-	-	-
Epoxidised soybean oil	8013-07-8	-/○	○	○	○	-	● toxic
Dipropylene glycol dibenzoate (DGD)	27138-31-4	-/-	-	-	-[b]	(●)[b]	-[b]
Dioctyl sebacate (DBS)	122-62-3	●/(○)	○	○	-	(●)	-
Polyadipates	-	-/-	-	-	- (persistent)	- (unlikely)	- (unlikely)
PU (MDI) - Polyurethane	101-68-8	●/●	(○)	●	- (persistent)	- (unlikely)	- (unlikely)
LDPE - Low density polyethylene	9002-88-4	-/-	-	-	- (persistent)	- (unlikely)	- (unlikely)

Key parameters: acute and local effects, carcinogenicity(C), genetic toxicity (M), reproductive toxicity (R), sensitisation, persistence, bioaccumulation and aquatic toxicity. If data are not available for all parameters or only from non standard test results a tentative assessment is given (shown in parentheses). For the materials an evaluation is given based on general polymer properties. The symbols:

● identified potential hazard
○ no identified potential hazard, and
– no data available.

a Foetotoxicity (reduced ossification) has been identified as the most sensitive effect in a developmental toxicity study.

b QSAR estimates by Danish EPA leads to the classification N; R50/53 (May cause long term effects in the aquatic environment).

c A test on reproductive effects performed on a product containing OTSA as impurity attributes effect to OTSA. No substance specific data available.

d C,M,R indicated that the effect is investigated but no effects are seen

The risk to humans was investigated with exposure scenarios assessing direct exposure to products, e.g. tubes for haemodyalisis, milk tubes, and teething rings, and in relation to workplace scenarios. The selected workplace scenario considered aerosol generation in connection with production of flooring and wall coverings using a process temperature of 200°C and eight exposure events per day. The estimated concentrations in workplace air for the adipate in this scenario were 104 times the concentration, which has been shown to result in more pronounced reactions of workers with an allergy or asthma case history. For the two phosphates the estimated concentrations in workplace air were lower than reported concentrations from inhalation studies in the reviewed literature. As no no-effect levels have been established for this type of exposure, the risk cannot be evaluated.

In relation to indirect exposure from the environment, the estimated concentration was compared to the Acceptable Daily Intake (ADI) with food. For the sebacate the worst case exposure was expected to exceed the suggested ADI. For the trimellitate the exposure is expected to get close to or exceed the suggested group ADI.

In a scenario where the exposure of children to teething rings was calculated, the citrate did reach 37% of a preliminary ADI of 1 mg/kg bw/day. A closer investigation of the exposure conditions and better data on effects may change this evaluation.

Table 3-7 Evaluated risks to humans or the environment. The estimated exposure of humans is compared to the Acceptable Daily Intake (ADI). (Stuer-Lauridsen *et al.* 2001)

Substance	CAS no.	Ratio of dose to ADI		Ratio of PEC to PNEC		Remarks (ADI in mg/kgbw/d)
		Consumer from products	Humans via environment	Water	Sediment	
Diethylhexyl adipate	103-23-1	○	○	○	●	ADI 0.3
O-acetyl tributyl citrate	77-90-7	(○)[a]	(○)	○[b]	○[b]	Preliminary ADI 1.0[c]
Di(2-ethylhexyl) phosphate	298-07-7	○	○	○	○	Group ADI 0.05
Tri(2-ethylhexyl) phosphate	78-42-2	○	○	○	○	Group ADI 0.05
Tri-2-ethylhexyl trimellitate	3319-31-1	(○)	○	○[d]	○[d]	Assigned ADI 0.05
O-toluene sulfonic acid amide	88-19-7	(○)	(○)	-	-	Assigned ADI 0.05
2,2,4-trimethyl 1,3-pentandiol diisobutyrate	6846-50-0	-	-	-	-	No effect and exposure data
Epoxidised soybean oil	8013-07-8	-	-	-	-	No exposure data
Dipropylene glycol dibenzoate	27138-31-4	(○)	(○)	-	-	Assigned ADI 0.05
Dioctyl sebacate	122-62-3	○	●	-	-	Group ADI 0.05

The symbols: ● ratio >1 (identified potential risk), ○ ratio <1 (no identified potential risk), and –no data available.

[a] Dose reaches 37% of preliminary ADI in teething ring scenario.
[b] Tentative estimate based on only one ecotoxicity study.
[c] Preliminary ADI from Nikiforov (1999)
[d] Data set comprise only two acute values and one chronic NOEC value.

Parentheses show an assigned ADI. Predicted environmental concentrations in the aquatic environment (PEC) are compared to predicted no-effect concentrations (PNEC). "Worst case" scenarios were used.

Substances selected for further assessment

The following alternatives that may directly replace BBP for some applications have been selected for further analysis.

- Dipropylene glycol dibenzoate (DGD); CAS N^o 27138-31-4.
- Alkylsulphonic phenyl ester (ASE); CAS N^o 91082-17-6.

The available assessments show that a number of potential alternatives to DEHP exist, which may be suitable to replace DEHP in different application areas and for some applications these alternatives may also be used for producing products that can replace BBP containing products e.g. PVC flooring. Only a few of the alternatives have undergone a comprehensive environmental and health assessment combined with an assessment of the economic and technical feasibility of substitution. For some critical applications, non-phthalate alternatives are widely used, demonstrating the feasibility of substitution for at least these applications, but for many of the large volume applications such as flooring, phthalates (mainly DINP) are still the plasticisers of choice.

It has not been possible to conduct a comprehensive assessment of all substances within the constraints set by time and resources available for this project and, for this reason, a limited number of substances have been selected, representing the most used alternatives and some alternative substances that, based on the previous studies, seem to be promising from a health and environmental perspective. The non-consideration of the other substances in the more detailed assessment of human health and environmental effects (sections 3.2 and 3.3) and the technical and economic feasibility of alternatives (section 3.4) should not be interpreted as concluding that these substances may be no suitable and acceptable alternatives to DEHP or BBP.

The following substances are selected for the more detailed assessment:

- Di-isononyl phthalate (DINP), CAS N^o 68515-48-0, 28553-12-0;
- Di(2-ethylhexyl) terephthalate (DEHT); CAS N^o 6422-86-2;
- Di-(isononyl)-cyclohexan-1,2-dicarboxylate (DINCH); CAS N^o 166412-78-8;

Table 3-8 Applications specifically mentioned by suppliers of selected alternatives

Application area	DGD	ASE	DINP	DEHT	DINCH
Flooring	x		x	x	
Calendered film	x	x	x	x	x
Spread coated fabric	x	x		x	x
Non polymer applications:					
Adhesives	x	x			x
Paints/lacquers	x	x			x
Sealants (glass insulation, construction)	x	x	x		

* Applications that may particularly relevant in relation to BBP

Information sources:

DGD	Covered by different BENZOFLEX types. (see Table 3-1)
ASE	Mesamoll® and Mesamoll II from Lanxess http://www.experts4additives.com/pma/en/applications/others/application_examples/adhesives/
DINP	Jayflex ® from ExxonMobil Chemical http://www.exxonmobilchemical.com/Public_Files/Oxo/Plasticisers/Worldwide/jayflex_broch_EN.pdf
DEHT	Eastman 168 Plasticiser from Eastman Chemical Company http://www.eastman.com/products/producthome.asp?product=71045700
DINCH	HEXAMOLL® DINCH from BASF. http://www.hexamoll.com/icms/basf_6/en/dt.jsp

3.1.2 Identification of alternative techniques

Besides the replacement of BBP with other plasticisers, the soft PVC may be replaced with other materials. For non-polymer applications, primarily in sealants, coatings and adhesives alternative techniques or totally different materials are not considered relevant alternatives for most applications and will not be assessed

Alternative materials proposed or assessed in selected previous studies for two relevant areas – flooring and coated fabric – are listed in Table 3-9.

Table 3-9 Alternative materials to soft PVC by application area

Application	Proposed by TNO 2002 as cited in Annex XV dossiers	Assessed in TURI 2006	Assessed in Postle *et al.* 2000	Proposed in Stuer-Lauridsen *et al.* 2001
Flooring	Linoleum, rubber, polyolefins, wood and textile (sometimes different functionalities)	Natural Linoleum, cork, polyolefin, polyethylene/limestone blend, rubber	n.a.	
Tarpaulins	Polyurethane, ethylene propylene rubber, rubber coated cotton, polyethylene and polypropylene	n.a.	n.a.	
Coated fabrics	Polyurethane for artificial leather. Paper for wall paper. Polyethylene for foils and acrylates	n.a.	n.a.	Polyurethane based on diphenylmethane-4,4'-diisocyanate (MDI) monomer

n.a. Not assessed

Comparison of DBB/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, as for a comprehensive comparison it is necessary to include many other technical aspects and environmental parameters. For a full comparison of the materials it is thus necessary to compare the materials in a life cycle perspective taking also into account e.g. the life-span of the materials, the energy consumption by manufacturing and the maintenance of materials.

The assessment will here focus on the main application area, flooring.

Alternative materials for flooring

The Toxics Use Reduction Institute (TURI 2006) investigated a number of alternatives materials for three application areas of DEHP: Resilient flooring, wall coverings and medical devices for neonatal care. The Institute identified and assessed in detail three material alternatives to DEHP/PVC in resilient flooring based on an initial screening of five materials. The alternatives may also be considered alternatives to BBP/PVC although the comparison of properties may by slightly different. The BBP/PVC flooring has the advantage compared to DEHP/PVC flooring that maintenance is easier. Of the three materials assessed as alternatives to DEHP/PVC, cork and linoleum appeared according to the authors to have equal or better environmental, health and safety, performance and cost profiles. The summary for the comparison of flooring materials is shown in Table 3-10 and the results of the assessment of the alternative materials are provided in Table 3-11.

Table 3-10 Resilient flooring material prioritization summary (TURI 2006)

Material	Performance			Availability (No. of suppliers/mfgr) *1	Cost (purchase & install.) $/sf *1	Environmental		Comments
	Maintenance / Durability	Lifespan (years)	Colors/ Patterns			Hazards	Benefits	
DEHP/PVC	Clean with water and ammonia when needed. Many require routine stripping and wax reapplication.	25+	Many	Many	$3-8	Ref.	Ref.	
Natural Linoleum	Dust mop, vacuum or sweep with a broom to remove grit and dust from the surface	40+	Many patterns and colors	Many	$3-6	Outgases linseed oil VOCs	Rapidly renewable, decomposes in dump, may be compostable	
Cork	Sweep or vacuum floor frequently. Wet maintenance is entirely forbidden. Recoat with polyurethane 4-8 yrs or when floor starts to show wear	80+	Limited solid colors	Many	$6 - $11.50	Some manufacturers use urea formaldehyde binders	Rapidly renewable, biodegradable at end of useful life	
Polyolefin (Stratica)	Sweep or vacuum floor frequently; mop with water when necessary			Many	$6.50/sf	Petrochemical based	Low VOC, solvent free adhesive, limited recycling	
Polyethylene / Limestone (LifeLine)	Moist or wet-cleaning method with mildly alkaline cleaner should be used	30-50		Despite printed literature, does not appear to be available in the US	$5-$6	Installed with a regular acrylic based adhesive	Recycled during production, disposed of by burning and used as an energy waste since contains no PVC	Not currently available in the US
Rubber	Sweep or vacuum to remove loose dirt, spot clean and use damp mop			Many	$3-10	Some outgas of VOCs – varies between differing products	Recyclable but no infrastructure to take back	Limited colors and prints; more of a niche product for high traffic industrial & commercial installations

*1 sf: square foot = 0.093 m^3; mfgr = manufacturer

Table 3-11 Alternative materials assessment summary for resilient flooring (TURI 2006)

Assessment Criteria		DEHP/PVC Reference	Comparison of Materials to DEHP/PVC		
			Linoleum	Cork	Polyolefin
Performance Criteria	Color/Pattern Choices	Large	=	-	=
	Ease of Maintenance	Easy	=	=	=
	Recyclable	Yes	-	-	=
Cost	Purchase and Installation Cost	\$2 - \$10/ft2	=	=	=
	Expected Lifespan of Material	25+ years	+	+	+
Environmental Criteria	Derived from Sustainable Material	No	+	+	=
	Use Environmentally Preferred Materials for Installation	Possible	=	+	=
	Energy Use/ GHG emissions (mfg)	Ref .	+	?	=
	Biodegradable/ Compostable	No	+	+	=
Human Health Criteria	Emissions of VOCs • Manufacture • Installation • Use	Yes (M, I, U)	=	=	= (M, I) + (U)

Comparison Key: + Better - Worse ? Unknown = equal

Life cycle assessments (LCA) of PVC and alternative materials

In a study for the European Commission, Baitz et al. (2004) compiled an overview of the publicly available information on LCA on PVC and competing materials, for a variety of applications. Approximately 100 LCAs related to PVC were identified, of these only 30 included comparisons at the application level.

For applications of soft PVC in flooring the study concludes:

- Most flooring application studies conclude that linoleum has comparable or slightly fewer environmental impacts compared to PVC flooring of equivalent quality in the production phase. One study states that wooden flooring tends to have lower impacts than PVC and linoleum, but is more demanding in the use and maintenance phase. All analysed studies claim the importance of the use phase due to detergent or chemical use in cleaning and maintenance. One study concentrates on the use phase and suggests that PVC might have advantages over linoleum in this phase and that the demand seems to be strongly dependent on the context of the individual application (private use, professional use, industrial use). Therefore, the use phase should be analysed in more detail to obtain a representative judgement. There is little LCA information about carpeting, a main a, within this application.

Conclusion

The available studies demonstrate that for the application of DEHP/PVC in flooring alternative materials exist at similar prices and the same is assumed to also be true for BBP/PVC used for flooring. Many of the materials seems to have equal or better environmental, health and safety, performance and cost profiles that DEHP/PVC, but clear conclusion are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments.

The available studies demonstrate the complexity in the evaluation of alternative materials, however, more in depth investigations could not be conducted within the limits of time and resources available for this study. The further assessment of alternatives will therefore focus on alternatives to BBP at a substance level.

3.2 *Human health effects*

For the assessment of the human health effects of the selected alternatives, preliminary DNELs (Derived No Effect Levels) have been derived for workers and the general population for oral exposure and exposure by inhalation; these are considered the most relevant exposure routes for the main applications of DEHP. The DNELs have been derived using the REACH guidance document "Chapter R.8: Characterisation of dose [concentration]-response for human health" (ECHA 2008b).

It should be noted that the time and resources available for the derivation of these preliminary DNEL values has been much less than has typically been used for the derivation of (no-)effect values for DEHP, e.g. in the context of the RAR. Furthermore, the derivation of these endpoints for DEHP involved extensive review and scrutiny in EU technical committees. Care should therefore be taken in drawing conclusions based on a comparison of the effect data derived in this study for the alternatives with the effect data for DEHP.

3.2.1 Dipropylene glycol dibenzoate (DGD)

The toxicity information about DGD is primarily derived from MSDSs and product information from two manufacturers of Benzoflex® 9-88, a plasticizer for adhesives, caulks, flooring and paints, containing 88 - 100% DGD. Both companies (Velsicol Chemical Corporation and Genovique Specialities™ Corporation) refer to the same test data.

Acute toxicity - Benzoflex® 9-88 has low acute toxicity by the oral, dermal and inhalation route.

Irritation - No dermal reaction was reported following a single semi-occlusive application of Benzoflex® 9-88 to intact rabbit skin for 4 hours. A single instillation of Benzoflex® 9-88 into the eye of the rabbit elicited transient very slight conjunctival irritation only.

Sensitising properties - No allergic skin reaction was reported in guinea pigs after repeated skin contact (intradermal and topical) using the Magnusson and Kligman method.

Repeated dose toxicity - Decreased body weight gain and liver, spleen and caecum effects were reported in rats given up to 2500 mg/kg/day in their diet for 13 weeks. The non-toxicologically significant NOEL was judged to be 1000 mg/kg/day. All treatment related changes showed evidence of, or complete, recovery after 4 weeks without treatment.

No effects were reported in dogs administered up to 1200 mg/kg/day Benzoflex® 9-88 in their diet for 90 days.

Mutagenicity - Benzoflex® 9-88 did not induce mutagenic activity in bacteria (*Salmonella* or *E. coli*) or mammalian cells (mouse lymphoma). This material did not induce clastogenic activity (chromosome aberrations) in Chinese hamster lung (CHL) cell in vitro.

Carcinogenicity - No carcinogenicity studies have been identified.

Reproductive toxicity - No reproductive toxicity studies are referred to in the information from the manufacturers. However, in a letter of 9 November 2006 from Velsicol to EPA regarding the status for the HPV submission for DGD, Velsicol refer to the company's response of 27 February 2002 to EPA's comments from 28 January 2008 regarding the robust summary submission for DGD. EPA suggests that the NOAEL for the moist sensitive developmental effects should be 250 mg/kg bw/day based on developmental delay indicated by incomplete ossification of sternebrae. In the response letter Velsicol argues and concludes that the NOAEL for all aspects of pre-natal development should be 500 mg/kg/day with increase in cervical ribs being of greater toxicological significance than transient incomplete ossification of 5th/6th sternebrae, as the assessment of foetal ossification on day 20 only represents "a snapshot in time" (Velsicol 2006).

Estrogenic activity - Benzoflex® 9-88 did not induce vaginal cornification at doses up to 2000 mg/kg/day for 7 days, by oral gavage, in ovariectomized adult rats. Benzoflex® 9-88 did not increase uterine weight or uterine weight to final body weight ratio at doses up to 2000 mg/kg/day for 7 days, by oral gavage, in ovariectomized adult rats. According to the information from Genovique, this demonstrates that 9-88 does not exhibit estrogenic activity up to and including the maximum tolerated dose (MTD).

Table 3-12 Human health effects of dipropylene glycol dibenzoate

Name of substance	Dipropylene glycol dibenzoate	
Abbreviation	DGD	
CAS No.	27138-31-4	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Endpoint	Value	Reference
LD$_{50}$, (oral, rat)l	5,131 mg/kg	Genovique (2008)
LD$_{50}$ (dermal, rat)	> 2,000 mg/kg	Genovique (2008)
LC$_{50}$ (inhal.), species unknown	> 200 mg/L	Genovique (2008)
Endpoint	NOAEL mg/kg bw	Reference
Reproductive toxicity	No data	-
Developmental toxicity	500 mg/kg bw/day	Velsicol (2006)
Maternal toxicity	No data	-
Repeated dose toxicity, NOEL, oral	1000 mg/kg bw/day	Genovique (2008)
Genotoxicity	Negative	Genovique (2008)
Carcinogenicity	No data	-
Critical endpoint	Developmental toxicity (increase in cervical ribs)	Velsicol (2006)
Preliminary DNELs	DNEL for critical endpoint, mg/kg/day	Remarks
Workers, oral	700 mg/day	Default assessment factors
General population, oral	350 mg/day	
Workers, inhalation	70.52 mg/m^3	
General population, inhalation	17.39 mg/m^3	

3.2.2 Alkylsulphonic phenyl ester (ASE)

The toxicity information in this section is derived from the IUCLID data sheet (IUCLID 1999).

Acute toxicity - APS/ASE has a low acute toxicity. The oral LD$_{50}$ in rats is in the range 26380-31650 mg/kg. No toxic effects were observed following application of a dermal dose of 1055 mg/kg or following intraperitoneal administration of 5275 mg/kg. No skin irritation was observed in experiments with rabbits in human volunteers and no eye irritation was observed in experiments with rabbits.

Repeated dose toxicity - In a 25 day repeated dose experiment in rats, APS/ASE was administered in the diet at concentrations of 3000 and 10000 ppm, equivalent to doses of 360 and 1230 mg/kg/day respectively. There was a significant increase in liver weight in the higher dose group but no other toxic effects were observed.

In a 90 day experiment in rats, APS/ASE was administered in the diet at concentrations of 750, 3000 and 12000 ppm in the diet, equivalent to doses of 55.4, 228.0 and 985.2 mg/kg/day in males and 68.7, 282.6 and 1488.5 mg/kg/day in females. In the high dose group there was a reduction in body weight gain and increased feed in females and increased water consumption in males. There was a significant increase in liver weight in all dose groups and an increase in kidney weight in the high dose group. No histopathological effects or effects on haematology or clinical chemistry were observed apart from an increase in thromboplastin time (ie reduced blood clotting) in the high dose group.

In a 43 day experiment, rats received 100 ppm APS/ASE in their diet, equivalent to a dose of 7.5 mg/kg/day. An accumulation of the test substance was observed in fat tissue but not in the liver. In a 28 day experiment, rats received 1000 ppm APS/ASE in their diet, equivalent to a dose of 75 mg/kg/day. An elimination half time of 15 days was calculated for fat tissue. In a 49 day study at the same dose, no accumulation of APS/ASE was observed in the liver.

In a six week study in which rats were dosed by gavage to give an average daily dose of 530 mg/kg/day, no effects were observed on behaviour or organ histopathology and there was no substance related alteration in oxygen consumption.

In a one year study in which rats were dosed by gavage twice a week to give an average dose of 265 and 530 mg/kg/day, no effects were observed on weight gain, organ histopathology, haematology or skeletal tissue.

Genotoxicity/carcinogenicity - APS/ASE gave negative results in the Ames test with Almonella typhimurium with and without metabolic activation and in an *in vitro* cytogenic assay with V9 cells. No carcinogenicity assays have been conducted.

Reproductive/developmental toxicity - No effects on fertility were observed in female rats exposed to a dose of 530 mg/kg/day by oral gavage for six weeks. There are no developmental toxicity data.

Table 3-13 Human health effects of alkylsulphonic phenyl ester

Name of substance	Alkylsulphonic phenyl ester	
Abbreviation	APS/ASE	
CAS No.	91082-17-6	
Endpoint	Value	Reference
LD$_{50}$	26380-31650 mg/kg (oral)	IUCLID
NOAEL mg/kg bw		
Reproductive toxicity Female fertility: NOAEL Male fertility: Developmental toxicity:	 530 mg/kg/day no information no information	IUCLID
Repeated dose Toxicity, LOAEL	55.4 mg/kg bw/day	IUCLID
Genotoxicity	Negative (limited data)	IUCLID
Carcinogenicity	No data	IUCLID
Critical endpoint	Liver toxicity (increased liver weight)	LOAEL 55.4 mg/kg/day
Preliminary DNEL	DNEL for critical endpoint	Remarks
Workers, oral	7.76 mg/day	Default assessment factors, x5 for LOAEL rather than NOAEL
General population, oral	3.88 mg/day	
Workers, inhalation	0.78 mgm^{-3}	
General population, inhalation	0.19 mgm^{-3}	

3.2.3 Di-isononyl phthalate (DINP)

The toxicity of DINP is reviewed in the DINP RAR (2003) and most of the following text is summarised from the DINP RAR.

Acute toxicity - DINP has a low oral, dermal and inhalation toxicity.

Irritation - Overall, DINP may be considered as a very slight skin and eye irritant, with effects reversible in short time (within 24 and 48 hours, the eye irritation completely subsided in all tested rabbit eyes).

Sensitising properties - These have not been demonstrated for any of the phthalates. However, one out of two Buehler tests with DINP gave a weak positive response. On the other hand, a patch test in humans gave a negative response.

Repeated dose toxicity - A number of repeated dose toxicity studies using rats, mice, rabbits, primates and dogs have been reviewed. In the conclusion for repeated dose toxicity the following is stated in the DINP RAR: "...for effects on the liver and kidneys, a NOAEL of 88 mg/kg/d is determined in rats regarding results found in a chronic/carcinogenic study (Aristech, 1994 cited in DINP RAR)". One mechanism by which DINP causes liver toxicity in rodents is peroxisome proliferation which is believed to be of little relevance to human risk assessment and hence the DINP RAR focussed on liver endpoints that were independent of peroxizome proliferation. Another study cited by the DINP RAR (Lington et al., 1997)) reported a dose-related increase in relative organ weights of liver and kidney in both male and female rats with a clear NOAEL of 15(males)-18(females) mg/kg/day. In addition to the increased liver and kidney weights at the LOAEL of 152(females)-184(males) mg/kg/d, males had increased incidences of spongiosis hepatis and serum levels of alkaline phosphatase and transaminases. Spongiosis hepatis, which is a focal degeneration of parasinusoidal cells, presumably not related to peroxisome proliferation, was also seen in 5 males in the Aristech study (Moore, 1998 cited in DINP RAR). The NOAEL/LOAEL for spongiosis hepatis are the same in the two studies as for the increases in liver and kidney weights.

After the DINP RAR was finalised, the Chronic Hazard Advisory Panel on DINP of the US Consumer Product Safety Commission reported its risk characterisation using spongiosis hepatis as the critical endpoint [CSTEE/2001/12-Add. 3 - Report to the U.S. Consumer Product Safety Commission by the Chronic hazard advisory panel on di(isononyl) phthalate (DINP) – June 2001]. The CPSC have calculated the benchmark dose corresponding to a 5% response for this effect to be 12 mg/kg/d based on the Exxon study and 15 mg/kg/d on the Aristech study. The CSTEE considers the approach as scientifically sound and supports the use of the benchmark dose for spongiosis hepatis as the starting point of the risk characterisation.

Mutagenicity - DINP has been tested for gene mutations in bacteria and mammalian cells in vitro, for unscheduled DNA synthesis in hepatocytes, and for chromosomal aberrations in vitro and in vivo. DINP has also been studied for cell transforming activity in seven experiments with Balb/c-T3 cells. It was recorded as positive in one experiment, had non-significant doubtful activity in three experiments and was negative in three experiments.

Carcinogenicity - In chronic/carcinogenicity studies with DINP, significant increases of liver tumours were seen in rats and mice. However, it was demonstrated that DINP induced hepatic peroxisome proliferation in rodents, but not in monkeys. Further evidence for species differences in the hepatic peroxisome proliferator response is presented by Hasmall et al. (Arch. Toxicol., 73, 451-456, 1999; not included in the DINP RAR). In vitro, DINP induced beta-oxidation, DNA synthesis and suppression of apoptosis in cultured rat hepatocytes, but had no effect on these parameters in cultured human hepatocytes. Carcinogenic responses in rats and mice have little relevance for humans.

In two studies using Fischer rats there were clear increases in the incidences of mononuclear cell leukaemia. IARC has categorised MNCL as “an unclassified leukaemia with no known human counterpart” and substances which increase MNCL frequency as “not classifiable as to carcinogenicity in humans” (IARC, 1990 cited in DINP RAR).

In the Exxon combined chronic toxicity/carcinogenicity study (Lington et al., 1997 cited in DINP RAR), malignant tubule cell carcinomas were seen in 2 and 4 males of the high dose and high dose recovery groups, respectively. Non-neoplastic histopathological findings in the male kidneys were consistent with hyaline droplet nephropathy. A retrospective study of these changes identified a dose-dependent increase in the accumulation of α2u-globulin in specific regions of male rat kidneys only (Caldwell et al., 1999). Thus, there are good reasons to regard these kidney tumours to be caused by the species and sex-specific α2u-globulin mechanism which, is not relevant for humans (DINP RAR).

Reproductive toxicity - In mice, a very high dose (>5g/kg bw/d) led to a decrease in testicular weight with abnormal/immature sperm forms and uterus/ovaries atrophy in a 13-week study. A NOAEL of 276 mg/kg bw/d for testicular effects was reported in a 104-week chronic rat study based on a reduced testicular weight at 742 mg/kg. In the developmental studies, visceral and skeletal variations increased on litter basis at 1,000 mg/kg/d, leading to a NOAEL of 500 mg/kg bw/d. A decrease of mean offspring body weight was observed following parenteral administration of DINP in the one and two-generation study from the lowest dose tested (LOAEL of 159/mg/kg bw/d).

A study by Gray et al. (2000 cited in DINP RAR) that investigated the effects of several phthalates on neonatal rats found evidence that DINP might have anti-androgenic potency. However, the reported changes (occurrence of female-like areolas/nipples in infant males) were slight and this was only seen at a very high dose (750 mg/kg from gestational day 14 to postnatal day 3). In this respect DINP was about an order of magnitude less active than DEHP and BBP. There has been a proposal by the US National Toxicology Program that further testing be carried out in this area.

Table 3-14 Human health effects of Di-isononyl phthalate

Name of substance	Di-isononyl phthalate	
Abbreviation	DINP	
CAS No.	28553-12-0	
Endpoint	Value	Reference
LD$_{50}$	>10000 mg/kg	NICNAS 2007
NOAEL mg/kg bw		
Reproductive toxicity: NOAEL mouse	Effects on male fertility: 742 mg/kg/day	DINP RAR
Developmental toxicity: LOAEL rat	159 mg/kg bw/day – decreased pup weight	DINP RAR
Repeated dose Toxicity, NOAEL rat	88 mg/kg bw/day ; liver and kidney toxicity	DINP RAR
Genotoxicity	Unlikely to be genotoxic	DINP RAR
Carcinogenicity	Cancers observed in rodents unlikely to be relevant to humans	DINP RAR
Critical endpoint	Developmental toxicity	Dose: 159 mg/kg/day : LOAEL in rats
Preliminary DNELs	DNEL for critical endpoint, mg/kg/day	Remarks
Workers, oral	44.5 mg/day	Default assessment factors plus x5 for LOEL rather than NOEL. The DINP RAR takes repeated dose toxicity as critical endpoint – the calculated DNELS based on the NOAEL in a 2 year study would be double those calculated on the basis of developmental effects.
General population, oral	22.3 mg/day	
Workers, inhalation	4.45 mgm^{-3}	
General population, inhalation	1.11 mgm^{-3}	

3.2.4 Di(2-ethylhexyl) terephthalate (DEHT)

SCENIHR (2008) have recently reviewed the toxicity of DEHT and the following review is based on their report.

Acute toxicity - Acute toxicity data are mainly reported for rats and, mice. LD$_{50}$ was >5000 mg/kg and 3200 mg/kg bw in oral studies and >20 ml/kg for dermal toxicity in guinea pigs.

Repeated dose toxicity - In a 90 day (GLP) study in rats fed DEHT in their diet, the NOEL was 0.5% in the diet equivalent to 277 and 309 mg/kg bw for males and females, respectively; the NOAEL was 1% or 584 and 617 mg/kg bw for males and females, respectively. Slight increases in relative liver weight (maximum about 11%) were seen at the 1% dose level. No adverse effects on the testes were found at any dose (Barber & Topping 1995 - cited by SCENIHR).

In a 21 day (GLP) study in rats, the NOEL was 0.5% in the diet or 487 and 505 mg/kg bw for females and males respectively and the NOAEL was 1.2% or approx: 1000 and 1100 mg/kg bw for males and females, respectively. DEHT caused only slight peroxisome proliferation at 2.5%, whilst DEHP caused a moderate increase at 1.2% and a marked increase at 2.5% in this study (Topping et al. 1987 - cited by SCENIHR). The effect seen at the 2.5% exposure level was believed to be secondary to significant decreases in food intake and body weight reduction.

Two other repeated dose studies, one in SD rats with oral feeding at levels of 0.1 and 1% for 2 weeks, the other with inhalation (6h per d for 10 days) of 46.3 mg/m3 revealed no signs of toxicity; the NOEL for these studies were the highest tested doses.

Mutagenity and Genotoxicity - No evidence for genotoxicity was found in assays assessing mutagenicity, i.e. gene mutation in bacterial (Ames test) or mammalian (CHO / hgprt) system. DEHT did not induce chromosomal aberrations in mammalian cultured cells with or without an exogenous metabolic activation system. The results for mono(ethylhexyl)terephthalate (MEHT) in the Ames assay were also negative (Barber 1994 cited by SCENIHR).

Carcinogenicity - Data from a chronic 104 weeks oral study indicate a NOEL for carcinogenicity of 12,000 ppm in the diet (highest dose tested), equivalent to 666 mg/kg/day in males and 901 mg/kg/day in females.

The NOEL for chronic toxicity in the study was 1500 ppm equivalent to 79 mg/kg/day in males and 102 mg/kg/day in females.

Reproduction/ developmental toxicity - In a two generation reproductive toxicity study following OECD guideline 416, DEHT was given to 30 male and 30 female rats at doses of 0, 0.3, 0.6 and 1% in the diet (approx. 0, 150-200; 300-400; 500-700 mg/kg/day for males, and 0, 250-300, 500-600, 800-1000 mg/kg/day for females). The F0 animals received DEHT for at least 70 days before mating and until termination; the F1 generation received diets following weaning (following PND 22) and for at least 70 days before mating. Reproductive parameters were unaffected by DEHT. Mean maternal body weight was reduced in the 1% group throughout gestation and lactation and throughout the F1 generation. No critical histopathological changes were observed: The NOAEL for reproductive toxicity was concluded to be 1% in the diet.

Oral developmental toxicity - *Study 1* following OECD guideline 414: Groups of 25 pregnant rats received DEHT doses of 0, 0.3, 0.6 and 1% in the diet (approx. 0, 226, 458, or 747 mg/kg/day) from GD 0 to GD 20. There was no evidence of embryotoxicity, foetotoxicity or effect of treatment on the number of viable foetuses. No visceral or skeletal anomalies were attributed to the treatment. Changes in maternal body weight were seen at the highest exposure level. The NOAEL for maternal toxicity was 0.6 % (458 mg/kg/day). The NOAEL for developmental toxicity was 1% (747 mg/kg/day).

Study 2: 10 Controls and 8 pregnant rats received DEHT from GD14 to PND3 by gavage at 0 and 750 mg/kg bw, and their male offspring were examined for several parameters of demasculinization: No changes in AGD, testes weight, testes descent, testes lesions, presence of areolas/nipples or vaginal pouches, reproductive organs weights, reproductive malformations or mating behaviour were noted. In contrast, DEHP also assessed in the same study, yielded adverse effects at this dose (750 mg/kg bw) (Gray et al. 2000).

Study 3 following OECD guideline 414: Groups of pregnant mice received DEHT at doses of 0, 0.1, 0.3 and 0.7% in the diet (approx. 0, 197, 592, or 1,382 mg/kg/day) from GD0 to GD18. Changes in maternal weights were seen in the mid and high exposure animals, and the NOEL for maternal toxicity was 0.1% (197 mg/kg bw); the NOEL for developmental toxicity was 0.7% (1,382 mg/kg).

Table 3-15 Human health effects of di(2-ethylhexyl) terephthalate

Name of substance	Di(2-ethylhexyl) terephthalate	
Abbreviation	DEHT	
CAS No.	6422-86-2	
Endpoint	Value	Reference
LD_{50}	>5000 mg/kg (rat, oral)	SCENIHR 2008
NOAEL mg/kg bw		
Reproductive toxicity	No (NOEAL 800-1000 mg/kg/day)	- " -
Developmental toxicity	No (NOAEL rat 750 mg/kg/day)	
Repeated dose Toxicity, NOAEL oral NOEL inhalation	584 mg/kg bw/day rat - liver toxicity 46.3 mgm-3 (6 hrs/day)	- " -
Genotoxicity	Negative	- " -
Carcinogenicity	NOEL 666 mg/kg/day (rats)	- " -
Maternal toxicity	LOAEL 750 (rat)	- " -
Critical endpoint	Developmental	- " -
Preliminary DNELs	DNEL for critical endpoint, mg/kg/day	Remarks
Workers, oral	409 mg/day	Based on ingestion NOEL and default assessment factors
General population, oral	204 mg/day	
Workers, inhalation	0.078 mgm^{-3}	Based on inhalation NOEL and default assessment factors
General population, inhalation	0.020 mgm^{-3}	

3.2.5 1,2-Cyclohexanedicarboxylic acid, diisononylester (DINCH)

SCENIHR (2008) have recently reviewed the toxicity of DINCH and the following review is based on their report.

Acute toxicity - DINCH has very low acute toxicity, the LD50 dose for DINCH in the rat is >5000 mg/kg bw after oral, and > 2000 mg/kg bw after dermal administration.

Repeated dose toxicity - 28 day study. The 28 day toxicity study (dosing 0-600-3000-15,000 ppm in the diet corresponding to 0-64/66-318/342-585/1670 mg/kg bw for males/females, respectively) was followed by a 14 days recovery period. The highest dose induced gamma-glutamyltransferase serum level and degenerated epithelial cells in the urine. The NOAEL was 318 mg/kg bw for males and 342 mg/kg bw for females. The 90 repeated dose toxicity study was performed with doses of 1500-4500-15000 ppm in the diet which equated to 107/128, 325/389, and 1102/1311 mg/kg bw for male/female animals, respectively.

There was no effect on mortality, clinical signs or haematology. Alterations in clinical pathology included increases in serum gamma-glutamyl transferase and in blood and urine stimulating hormone (TSH). Increases were observed in liver and thyroid weights and thyroid follicles showed hyperplasia/hypertrophy. Alpha 2- microglobulin accumulation in the kidney tubules was also observed but the mechanism thought to be rat-specific and not relevant for man. In the liver, enzyme induction of phase I and phase II enzymes was observed. The increased gamma-glutamyltransferase and TSH value, increases in liver and thyroid gland, as well as the thyroid hypertrophy/hyperplasia suggest a common pathogenesis of enzyme induction process. This is not considered an adaptive rather than adverse effect.

In the testes there was a significant increased mean relative weight in all 3 dose groups with no dose-response relationship.

Based on kidney effects the NOAEL was 1,500 ppm (107.1 mg/kg/day) in male and 4,500 ppm (389.4 mg/kg/day) in females. Thyroid hyperplasia/trophy was also observed in the two generation study with a NOAEL of 100 mg/kg/day.

Mutagenity and genotoxicity - DINCH has been evaluated for mutagenicity, both in bacterial (*Salmonella typhmurium/Escherichia coli* reverse mutation assay) and mammalian cell tests (In vitro mutation test in CHO cells), with negative results. It was non-clastogenic in tests conducted *in vitro* (chromosome aberration assay in Chinese hamster V79 cells) and *in vivo* (Micronucleus assay bone marrow cells mouse). DINCH is considered as non-genotoxic.

Carcinogenicity - In a two year combined chronic toxicity/carcinogenicity study (doses 40, 200, 1,000 mg/kg bw/day) also the thyroid was identified as target organ. Thyroid weight was increased in both sexes with follicular cell hyperplasia and the presence of follicular adenomas. The effect was considered due to secondary mechanisms via liver enzyme induction which is considered not relevant for humans. The NOAEL was 40 mg/kg in males and 200 mg/kg in females. Similar to the short term study transitional epithelial cells of the urinary tract were present in the urine. These were temporarily present and considered as adaptive as no histopathological lesions were observed in the kidneys at 12 and 24 moths.

Reproductive toxicity

Prenatal development studies - In a study in rabbits DINCH was orally administered from day 6 to day 29 of gestation with doses of 100, 300, and 1,000 mg/kg bw/day. There was no evidence of maternal toxicity, influence on gestation parameters, developmental effects in pups or teratogenic effects. The NOAEL was determined as the highest dose investigated, 1,000 mg/kg bw/day.

No effects were observed in a study in rats. The dosing of the mothers was from day 6 - 19 post coitum. The NOAEL was equal to the highest dose administered being 1,200 mg/kg bw/day.

In a pre- and postnatal developmental study DINCH was administered orally to the mother animals from day 3 post coitum to day 20 post partum (750 and 1,000 mg/kg bw/day). The offspring (all males and 3 females) was raised to days 100-105 post partum and then evaluated. The results indicated that there was no toxicity in F1 progeny with a NOAEL of 1,000 mg/kg/day but the AGD ($p<0.05$) and AGI ($p<0.01$) were significantly decreased in the male high dose group (1,000 mg/kg bw/day), respectively AGD 7% and AGI 8% below the control group. Also in females of the high dose group the AGI was significantly reduced by 8%. The AGI was also in females significantly ($p<0.05$) decreased. The limited (7-8% change compared to controls) were not considered of biological significance as other corresponding parameters were not affected like testes descendance, preputial separation, vaginal opening, testes weight and histology, and sperm parameters. Also in females the AGI was decreased to the same extent, contradicting the AGI to be an effect of impaired androgen dependent development. In addition, in the two generation study no effects were noted (but AGD and AGI not determined).

Two generation study - The two generation study was performed with continuous dietary administration (doses 0-100-300-1000 mg/kg bw/day). The animals remained in the same dosing group as their parents. Evaluated were sexual maturation of the F1 generation, and sperm parameters of the F0 and F1 generation. There were no effects on fertility and reproductive performance, and no substance related effects on the F1 and F2 generation. In the F0 parents an increase in gamma glutamyltransferase in females, decreased total bilirubin in females, and increased liver, kidney and thyroid weight in both males and females was observed at the highest dose investigated (1000 mg/kg bw). For the F1 parents similar effects were noted including thyroid weight increase with thyroid hypertrophy/hyperplasia. The NOAEL for fertility and reproductive performance was 1000 mg/kg bw for both F0 and F1 parents, and 1000 mg/kg bw for developmental toxicity in F1 and F2 pups.

Table 3-16 Human health effects of 1,2-cyclohexanedicarboxylic acid, diisononylester

Name of substance	1,2-Cyclohexanedicarboxylic acid, diisononylester	
Abbreviation	DINCH	
CAS No.	166412-78-8	
Endpoint	Value	Reference
LD50	>5000 mg/kg (rat, oral)	SCENIHR 2008
NOAEL mg/kg bw		
Reproductive toxicity	No effects on fertility at 1000 mg/kg/day - rat	- " -
Developmental toxicity	No effects on development at 1000 mg/kg/day - rat	- " -
Repeated dose Toxicity, NOAEL	107.1 mg/kg bw/day - kidney	- " -
Genotoxicity	Negative	- " -
Carcinogenicity	Benign thyroid tumours, NOAEL 200 mg/kg/day	- " -
Critical endpoint	Kidney toxicity	107.1 mg/kg bw/day - NOEL rat
Preliminary DNEL	DNEL for critical endpoint	Remarks
Workers, oral	75.0 mg/day	Default assessment factors
General population, oral	37.5 mg/day	
Workers, inhalation	7.5 mgm^{-3}	
General population, inhalation	1.87 mgm^{-3}	

3.2.6 Summary for health effects

The derived preliminary DNELs for critical endpoints are summarised in the following table.

Table 3-17 Preliminary Derived No Effect Levels (DNELs) for critical endpoints

Name	CAS No.	Critical endpoint	DNEL for critical endpoint, mg/kg/day			
			Workers		General population	
			Oral mg/day	Inhalation mgm^{-3}	Oral mg/day	Inhalation mgm^{-3}
DGD	27138-31-4	Developmental	700	71	350	17
ASE	91082-17-6	Liver toxicity (increased liver weight)	8	0.8	4	0.2
DINP	28553-12-0	Developmental	44	4	22	1
DEHT	6422-86-2	Liver toxicity	409	0.08	204	0.02
DINCH	166412-78-8	Kidney toxicity	75	8	38	2

3.3 *Environmental effects*

This section provides a review of the environmental hazards and risks associated with selected alternatives. The approach adopted has been as follows:

1) For those substances where there was a risk assessment available and/or relevant information derived in other studies, we have included PNEC values for the substances/compartments of interest.

2) If information on agreed (or provisionally agreed) classification and labelling in relation to environmental effects was available, this data has been included.

3) Where there was no such information available, we referred to relevant databases (e.g. HSDB, DOSE, Ecotox, material safety data sheets) in order to obtain information on environmental hazard properties of the potential alternatives. Note that the original studies have not been reviewed and so reference is made only to the databases concerned.

We have deliberately avoided drawing conclusions on possible PNEC values or possible classification and labelling where these have not already been agreed. This is because of the resources and timescales available for this work and, more importantly, because the derivation of such values relies upon having a base set of information on environmental hazard properties which in some cases is not available for the potential alternatives. Derivation of PNECs would require a degree of reliability of the values that is not deemed to be warranted [2].

3.3.1 Dipropylene glycol dibenzoate (DGD)

The table below describes the environmental hazard properties of DGD. No comprehensive hazard or risk assessment reports exist for this substance.

Most of the relevant studies have been collected by the US EPA and summarised in the High Production Volume Information System (HPVIS), which is therefore used as the main data reference for DGD (HPVIS 2009).

DGD is not on EU's list of 194 substances with known or suspected endocrine disrupting properties.

Based on QSAR calculations, the Danish EPA proposes DGD to be classified N; R50/53. Genovique (2009) proposes Benzoflex 9-88 to be classified N; R51/53.

---

[2] For example, a simple review of available data on DINP could lead one to conclude that it is appropriate to derive a PNEC value for water (e.g. based on reported LC_{50} values for aquatic organisms in the US EPA Ecotox database), whereas the comprehensive EU risk assessment for this substance concluded that a PNEC could not be derived because NOEC values could not be derived from the available data.

Table 3-18 Hazard properties for DGD

Name of substance	Dipropylene glycol dibenzoate	
Abbreviation	DGD	
CAS No.	27138-31-4	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	LC50, 96 h (fish, *P. promelas*) = 3.7 mg/l (DGD) EC50 48h (*D. magna*) = 19.3 mg/l (Benzoflex 9-88) EC$_r$50 72h (*S. capricornutum*) = 4.9 mg/l (Benzoflex 9-88) QSAR, DGD: LC50 (fish, *P. promelas*) = 0.82 mg/l (most sensitive organism)	HPVIS (2009) HPVIS (2009) HPVIS (2009) DK QSAR (2009)
Sediment	Unknown	
Soil	EC50 (earthworm, *E. foetida)* >1000 mg/kg NOEL = 1000 mg/kg (Benzoflex 9-88)	HPVIS (2009)
Atmosphere	Halflife by photodegradation = 0.282 days (predicted by the AOPWIN model) Fugacity level III model calculations show that max. 0.73 % of emitted will enter the atmosphere.	HPVIS (2009) HPVIS (2009)
STP	EC50, bacteria (*P. putida*) >10 mg/l (Benzoflex 9-88). No inhibitory effects on activated sludge respiration at conc. up to 100 mg/l	Genovique (2008)
Secondary poisoning	Unknown	
Bioaccumulation	Log BCF (calculated) = 2.28 - 2.74 Log Pow = 3.9 (Benzoflex 9-88)	DK QSAR (2009) Genovique (2009)*
Persistence	A study (1998) on benzoflex 9-88 conducted according to OECD 301D showed aerobic biodegradation in 5 days = 30 % of ThOD. It is therefore concluded that DGD is not readily biodegradable. Another study (1998) on anaerobic biodegradation according to USEPA Method 796.3140 showed biodegradation in 60 days = 46 %. DGD is therefore considered ultimately biodegradable under anaerobic conditions. A third study (1997) on benzoflex 9-88 conducted according to OECD guideline 301B showed 85 % biodegradation in 28 days. The test substance is therefore found to be readily biodegradable. In two older studies (1974 and 1982) not conducted according to guidelines DGD/benxoflex 9-88 was found to be easily biodegradable. The halflife in water by hydrolysis is calculated by QSAR to be 77.9 days.	HPVIS (2009) HPVIS (2009) HPVIS (2009) HPVIS (2009) DK QSAR (2009)
Risk assessment conclusions	None identified	

* Confidential information.

3.3.2 Alkylsulphonic phenyl ester (ASE)

The table below describes the environmental hazard properties of ASE.

Table 3-19 Hazard properties for ASE

Name of substance	Sulfonic acids, C10-21-alkane, phenyl esters (alkylsulphonic phenyl esters)	
Abbreviation	ASE	
CAS No.	91082-17-6	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	Unknown	
Sediment	Unknown	
Soil	Unknown	
Atmosphere	Unknown	
STP	Unknown	
Secondary poisoning	Unknown	
Bioaccumulation / persistence	“The main constituents of sulphonic acids, C10-21-alkane, Ph esters are not considered as PBT. They do not meet the P/vP criteria based on screening data but they meet the screening B criteria. This UVCB substance contains impurities, which may meet the P/vP and B/vB criteria based on screening data. These impurities are, however, present in such low concentrations (0.005-0.008% w/w each; sum conc. of all < 1% w/w) that they are not considered to be of concern at present due to a very limited potential for environmental release from the current production and use within the EU. This conclusion applies, unless a substantial increase in environmental release occurs in future. Assessment of ecotoxicity was not carried out during this assessment.”	ECB (2008)
Risk assessment conclusions	None identified	

3.3.3 Di-isononyl phthalate (DINP)

The table below describes the environmental hazard properties of DINP based on the EU risk assessment report.

The risk assessment concluded that there is no need for further information or testing or for risk reduction measures beyond those which are being applied already.

Table 3-20 Hazard properties for DINP

Name of substance	Di-isononyl phthalate	
Abbreviation	DINP	
CAS No.	68515-48-0 28553-12-0	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	Tentatively concluded that DINP does not cause adverse chemical effects towards the aquatic ecosystem. No PNEC derived.	ECB (2003)
Sediment	Tentatively concluded that DINP has no adverse effects towards benthic organisms. No PNEC derived.	ECB (2003)
Soil	$PNEC_{soil}$ = 30mg/kg dw	ECB (2003)
Atmosphere	No PNEC could be determined.	ECB (2003)
STP	Does not have any effects upon microorganisms at or above water solubility. No PNEC could be derived.	ECB (2003)
Secondary poisoning	$PNEC_{oral}$ = 150 mg/kg food	ECB (2003)
Bioaccumulation	BCF = 4,000 for secondary poisoning; 840 for humans exposed via the environment.	ECB (2003)
Persistence	Readily biodegradable (but some isomers resistant to degradation). Half lives as follows: Surface water = 50d Sediment = 3,000d Soil = 300d	ECB (2003)
Risk assessment conclusions	At present no need for further information or testing or risk reduction measures beyond those which are being applied already (for the aquatic compartment, the terrestrial compartment, the atmosphere, microorganisms in sewage treatment plant as well as secondary poisoning).	ECB (2003)

3.3.4 Di(2-ethylhexyl) terephthalate (DEHT)

The table below describes the environmental hazard properties of DEHT. No EU risk assessment has been conducted for this substance.

Table 3-21 Hazard properties for DEHT

Name of substance	Di(2-ethylhexyl) terephthalate	
Abbreviation	DEHT, DOTP	
CAS No.	6422-86-2	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	0.28 mg/l ChV (60 day)	TURI (2006)
Sediment	Unknown	
Soil	Unknown	
Atmosphere	Unknown	
STP	Unknown	
Secondary poisoning	Unknown	
Bioaccumulation	Calculated BCF of 1,400,000 but measured values for related substances (e.g. DEHP) have much lower BCF values.	HSDB (2008)
	BCF = 25	TURI (2006)
Persistence	No data reported.	HSDB (2008)
Risk assessment conclusions	None identified	

3.3.5 1,2-Cyclohexanedicarboxylic acid, diisononylester (DINCH)

The table below describes the environmental hazard properties of DINCH.

Table 3-22 Hazard properties for DINCH

Name of substance	Di (isononyl) cyclohexane-1,2-dicarboxylate	
Abbreviation	DINCH	
CAS No.	166412-78-8	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	Acute: 96h LC_{50} fish, 48h EC_{50} aquatic invertebrates, 72h EC_{50} aquatic plants all > 100 mg/l Chronic: 21d NOEC invertebrates ≥ 0.021 mg/l	BASF (2007)
	Fish LC_{50} > 100 mg/l	TURI (2006)
Sediment	Unknown	
Soil	14d LC_{50} soil dwelling organisms > 1000 mg/kg 21d NOEC terrestrial plants > 1000 mg/kg	BASF (2007)
Atmosphere	Unknown	
STP	180 min EC_{20} > 1000 mg/l	BASF (2007)
Secondary poisoning	Unknown	
Bioaccumulation	BCF = 189	BASF (2007)
Persistence	Biodegradable	BASF (2007)
Risk assessment conclusions	None identified	

3.3.6 Summary for environmental effects

With regard to potential environmental hazards and risks of the investigated alternatives to BBP, a number of existing assessments and databases on hazardous effects have been reviewed.

It is evident from the data reviewed that there is a wide variability in the level of information available (and validity regarding the alternative substances and, as such, in the feasibility to draw definitive conclusions on the nature and level of risks for the environment associated with the substitution of DBP by one of the alternatives. However, based on the information presented, the following conclusions can be drawn:

- DGD may possibly be readily biodegradable but the data do not allow a firm conclusion to be drawn. However, the substance is certainly not a PBT but does have moderately bioaccumulative properties. Experimental data on aquatic ecotoxicity indicate that the correct environmental classification would be N; R51/53.

- For DINP, the EU risk assessment concluded that there is no need for further information or testing or for risk reduction measures beyond those which are being applied already. It would therefore be reasonable to conclude that use of DINP as an alternative would not introduce significant new risks to the environment (although if there were a large increase in quantities released, this could in theory lead to a change in the risk assessment conclusions).

- Given that alkylsulphonic phenyl esters (ASE) have been the subject of a review of PBT and vPvB properties, the outcome of which was a conclusion that the main constituents are neither PBT or vPvB, it is reasonable to conclude that these substances would not be considered to be a SVHC on the basis of these properties.

No firm conclusions on the relative hazards or risks could be drawn for the other potential alternatives.

3.4 *Technical and economic feasibility and availability*

The technical feasibility of replacing BBP for different applications depends on a range of performance criteria, including inter alia material compatibility, temperature performance, volatility, migration and permanence of the alterative plasticiser, its efficiency, tensile strength, and hardness. The use of alternative plasticisers may imply some changes in processing and material composition and may require some research and development as well as changes in process technology.

BBP adds, as mentioned above, according to industry surface properties to flooring materials that minimise maintenance and give the materials 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.

Direct alternatives

The main direct alternative to BBP in flooring, and other applications, has been dipropylene glycol dibenzoate (DGD) which has some of the same technical properties as BBP (see Table 3-1). Further, alkylsulphonic ester (ASE) has been proposed as alternative for different BBP applications.

For the most applied alternatives, dibenzoate plasticisers, the bulk price of the plasticisers are according to a main manufacturer equivalent to the price of BBP (Genovique 2009, see table Table 3-1).

Indirect alternatives

BBP is typically used together with other plasticisers and the BBP can, also, be replaced by other phthalates and non phthalate plasticisers although it may be at the expense of some of the properties. 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.

It has not been investigated in detail whether alternatives exist for all applications of BBP; the industry has not indicated any applications for which the substitution of BBP would be particularly difficult.

The selected alternatives used for the present environmental, health and technical assessment are all today marketed for a number of applications as shown in Table 3-8. The alternatives may quite well also be applied for other applications, but it is noted that the plasticisers are considered by the suppliers as particularly suitable for the indicated applications.

Noting that the price of alternatives may be one of the main determining factors for the substitution of BBP for all major applications the assessment will focus on the costs of substitution.

As the concentration of plasticisers in the polymer matrix can be up to 40% of the product by weight, the price of the alternatives will highly influence the price of the final product. For application areas with high price competition like flooring or roofing even slightly more expensive plasticisers would find difficulty gaining widespread acceptance.

The plasticisers typically do not replace each other on a one-to-one basis. Some plasticisers are more efficient, and therefore less is required to achieve the same level of hardness of the plastic product.

Table 3-23 presents estimates of plasticiser costs based on data obtained from industry sources in the US, and includes estimated substitution factors, which allow for a normalised comparison of costs based on how they are used to create a comparably flexible product. It is considered that the price of alternatives relative to DEHP would not be significantly different on the EU market whereas the absolute prices varies.

It has not been possible to find any comparison to BBP/DEHP mixture and the normalised costs in relation to DEHP can only be used as indicative for the incremental costs of substitution.

Table 3-23 Costs of selected alternatives normalised to the cost of DEHP

	Costs of substance €/kg *1	Substitution factor *1	Normalised cost in percentage of DEHP
DEHP	1.19	1	100
DINP	1.26	1.06	112
DIDP	1.31	1.1	121
DEHT	1.26	1.03	109
DINCH	1.55	unknown	n.d
ASE	n.d.	n.d	n.d

*1 US market in 2006 (TURI 2006) calculated from \$/lb using €/\$ =1.297 and kg/lb =2.204

References

Afshari, A., L. Gunnarsen, P.A. Clausen and V. Hansen. 2004. Emission of phthalates from PVC and other materials. Indoor Air 14: 120-128.

Baitz, M. , J. Kreißig, E. Byrne, C. Makishi, T. Kupfer, N. Frees, N. Bey, M.S. Hansen, A. Hansen, T. Bosch, V. Borghi, J. Watson and M. Miranda. 2004. Life Cycle Assessment of PVC and of principal competing materials. PE Europe GmbH and others for the European Commission.

BASF. 2007. BASF Safety data sheet according to Regulation (EC) No.1907/2006; HEXAMOLL* DINCH, 13.11.2007.

BBP RAR. 2007. European Union Risk Assessment Report: Benzyl butyl phthalate (BBP). Institute for Health and Consumer Protection, European Chemicals Bureau, Ispra

Cadogan, D. Plasticisers of Today and Tomorrow - Alternatives. D. Cadogan. European Council for Plasticisers and Intermediates. Presentation at 2º Congresso Brasileirodo PVC Sao Paulo 19-20 June 2006.

CAS number: 91082-17-6. TC NES Subgroup on Identification of PBT and vPvB Substances. European Chemicals Bureau, Ispra. http://ecb.jrc.ec.europa.eu/documents/PBT_EVALUATION/PBT_sum082_CAS_91082-17-6.pdf

CEPE. 2007. European Council of producers and importers of paints, printing inks and artists' colours. Comments to Annex XV dossiers.

Christensen, C.L., L. Høibye and E. Hansen. 2008. Forbrug af phthalater i Danmark i historisk perspektiv [Consumption of phthalates in Denmark in a historical perspective]. COWI for the Danish Environmental Protection Agency. In publication. (In Danish)

Clausen P.A., V. Hansen , L. Gunnarsen L, A. Afshari, and P. Wolkoff . 2004. Emission of di-2-ethylhexyl phthalate from PVC flooring into air and uptake in dust: emission and sorption experiments in FLEC and CLIMPAQ. *Environ Sci Technol*. 38(9): 2531-2537.

COWI. 2000. Kortlægning og vurdering af substitutionsmuligheder for phthalater i udvalgte produkter [Survey and assessment of substitution options for phthalates in selected products]. Environmental Project No 560. Danish Environmental Protection Agency, Copenhagen. (In Danish)

CSTEE. 2001. Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate. Scientific committee on toxicity, ecotoxicity and the environment. Opinion expressed at the 27th CSTEE plenary meeting Brussels, 30 October 2001. http://ec.europa.eu/food/fs/sc/sct/out120_en.pdf

DEHP RAR. 2008. European Union Risk Assessment Report: bis(2-ethylhexyl)phthalate (DEHP). Institute for Health and Consumer Protection, European Chemicals Bureau, Ispra.

Dictionary of Substances and Their Effects (DOSE, 3rd Electronic Edition), Royal Society of Chemistry, 2005.

DINP RAR. 2003. European Union Risk Assessment Report: 1,2-benzenedicarboxylic acid, di-C8-10- branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP). Institute for Health and Consumer Protection, European Chemicals Bureau, Ispra.

DK QSAR. 2009. The Danish (Q)SAR Database by the Danish EPA and maintained by the Danish QSAR group at the National Food Institute, DTU. Can be accessed from the homepage of the Danish EPA (www.mst.dk/kemikalier/stoflister+og+databaser/)(or directly at http://130.226.165.14/index.html) or from ECB's website (http://ecbqsar.jrc.ec.europa.eu/).

ECB. 2008. Results of the evaluation of the PBT/vPvB properties of: Substance name: Sulphonic acids, C10-21-alkane, Ph esters EC number: 293-728-5. TC NES Subgroup on Identification of PBT and vPvB Substances. European Chemicals Bureau.

ECB. 2008. Summary fact sheet, PBT working group (PBT list no. 82), TC NES subgroup on identification of PBT and vPvB substances, results of the evaluation of the PBT/vPvB properties of Sulphonic acids, C10-21-alkane, Ph esters (EC number: 293-728-5, CAS number: 91082-17-6), 2 March 2008.

ECHA. 2008a. Guidance on information requirements and chemical safety assessment. Chapter R.12: Use descriptor system. May 2008 (version 1.1). European Chemicals Agency, Helsinki.

ECHA. 2008b. Chapter R.8: Characterisation of dose [concentration]-response for human health. May 2008 (version 1.1). European Chemicals Agency, Helsinki.

Ecotox. 2008. Ecotox database (http://cfpub.epa.gov/ecotox/index.html), accessed November 2008.

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

ESD. 2004. Emission Scenario Document on Plastic Additives. 2004. Organisation for Economic Co-operation and Development, Paris.

Eurostat. 2001. Waste water in European countries. Statistics in focus. Environment and energy and . Theme 8 - 14/2001. Eurostat, Luxemburg.

Genovique. 2008. Benzoflex 9-88, Material Safety Data Sheet as of October 1, 2008. Genovique Specialties Corporation, USA.

Genovique. 2009. Personal communication with Mike Watson, Genovique Specialties Corporation, Rosemont, Illinois, January 2009. Includes confidential information on Benzoflex 9-88.

Hoffmann. 1996. Massestrømsanalyse for phthalater [Substance flow analysis for phthalates]. Miljøprojekt nr. 320. Danish Environmental Protection Agency, Copenhagen. (In Danish)

HPVIS. 2009. High Production Information System/OPPT/US EPA. Accessed via OECD's eChemPortal (http://webnet3.oecd.org/echemportal/) on 5 January.

HSDB. 2008. Hazardous Substances Data Bank (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB), accessed November 2008.

Inform. 2003. Inform. ECPI newsletter issue 8, 2003. http://www.ecpi.org/upload/documents/document32.pdf

IUCLID. 1999. IUCLID Dataset. Substance ID. 91082-17-6. European Commission, European Chemicals Bureau.

Karbæk, K. 2003. Evaluation of plasticisers for PVC for medical devices. Environmental Project Nr. 739 2002. Danish Environmental Protection Agency, Copenhagen.

KemI. 2008. PVC. Website of the Swedish Chemicals Inspectorate. http://www.kemi.se/templates/Page.aspx?id=3734

Kjølholt, J., H.V. Andersen, C. Poll, C.D Thomsen. and N.V. von Freiesleben.1994. Miljøbelastning fra affaldsbehandlingsanlæg - Identifikation, miljøvurdering og prioritering af miljøbelastende stoffer i restprodukter og emissioner. [Environmetal load from waste treatment facilities - Identification, environmental assessment and prioritization of environmental pollutants in residues and emissions] Environmental project No. 269. Danish Environmental Protection Agency, Copenhagen. (In Danish)

Lanxess. 2008. Mesamoll®. Date sheet. http://techcenter.lanxess.com/fcc/emea/en/products/datasheet/Mesamoll_e.pdf?docId=78076&gid=2082&pid=780

Little, J., Y. Xu, E.C. Hubal and P.A. Clausen. 2008. Exposure to phthalate emitted from vinyl flooring and sorbed to interior surfaces, dust, airborne particles and human skin. Indoor Air 2008, 17-22 August 2008, Copenhagen, Denmark - Paper ID: 606

Miljøstyrelsen. 2004. Punktkilder 2003 [Point sources 2003]. Det nationale program for overvågning af vandmiljøet; Fagdatacenterrapport. Orientering fra Miljøstyrelsen Nr. 16/2004. (In Danish)

NICNAS. 2007. Human Health Hazard Assessment. Diisobutyl phthalate (DIBP) (CAS No 84-69-5) (Draft for comment). National Industrial Chemicals Notification and Assessment Scheme - NICNAS, Sydney.

Nilsson, N.H., J. Lorenzen and O.C. Hansen. 2002. Substitution af phthalatblødgjort PVC-vandmadras hos Akva Waterbeds [Substitution of phthalate softened PVC water mattress by Akva Waterbeds]. Environmental Projekt Nr. 739 2002. Danish Environmental Protection Agency, Copenhagen. (In Danish)

Patric, S.G. 2005. Practical Guide to Polyvinyl Chloride. Rapra Technology

Pors, J. and R. Fuhlendorff, R. 2001. Analyserapport - Phthalater og organiske tinforbindelser i produkter med PVC. [Analyis report - phthalates and organic tin compounds in PVC products]. MILJØ-KEMI for the Danish EPA.

Postle, M., C. Corden, M. van den Berg and T. Sanderson. 2000. The availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles. RPA and Ritox for the European Commission.
SCENIHR. 2008. Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticiser s on neonates and other groups possibly at risk. Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). European Commission, Brussels.

Skårup S. L. Skytte. 2001. Forbruget af PVC og phthalater i Danmark 2000 og 2001 [The consumption of PVC and phthalates in Denmark 2000 and 2001]. Kortlægning af Kemiske Stoffer i Forbrugerprodukter. Danish Environmental Protection Agency, Copenhagen. (In Danish)

Skovgaard, M., A.Villanueva, F.M. Andersen, H. Larsen and S. Isoard. 2007. Environmental outlooks: Municipal waste. ETC/RWM Working paper 2007/1. European Topic Centre on Resource and Waste Management, Copenhagen.

Skovgaard, M.; N. Hedal, A. Villanueva, F.M. Andersen, H. Larsen and S. Isoard, S. 2008. Municipal waste Management and Green house gasses. ETC/RWM Working paper 2008/1. European Topic Centre on Resource and Waste Management, Copenhagen.

Stuer-Lauridsen, F., S. Mikkelsen, S. Havelund, M. Birkved and L.P. Hansen. Environmental and health assessment of alternatives to phthalates and to flexible PVC. Environmental Project No. 590 2001. Danish Environmental Protection Agency, Copenhagen.

Thornton, I.; D. Butler, P. Docx, M. Hession, C. Makropoulos, M, McMullen, M. Nieuwenhuijsen, A. Pitman, R. Rautiu, R. Sawyer, S. Smith, D. White, P. Wilderer, S. Paris, D. Marani, C. Braguglia and J. Palerm. 2001. Pollutants in Urban waste water and sewage sludge. Directorate-General Environment, European Commission, Brussels.

TURI. 2006. Five chemicals study. Toxics Use Reduction Institute (TURI), University of Massachusetts Lowell, for the Commonwealth of Massachusetts. Chapter on alternatives to DEHP available at:
http://www.turi.org/library/turi_publications/five_chemicals_study/final_report/chapter_7_dehp#7.3

UCD. 1998. Draft Use Category Document on plastic additives. Revised by the Department of Environment (UK), Building Research Establishment (BRE), 1998. [As cited in DEHP RAR, 2008]

Xu, Y., J. Park, P.A. Clausen, V. Kofoed-Sørensen and J. Little. 2008. Characterizing emissions of phthalate plasticiser from vinyl flooring in a specially-designed chamber. Indoor Air 2008, 17-22 August 2008, Copenhagen, Denmark - Paper ID: 688.

Disclaimers

Third Party Disclaimer

Any disclosure of this report to a third party is subject to this disclaimer. The report was prepared at the instruction of, and for use by, our client named on the front of the report. It does not in any way constitute advice to any third party who is able to access it by any means. Entec excludes to the fullest extent lawfully permitted all liability whatsoever for any loss or damage howsoever arising from reliance on the contents of this report. We do not however exclude our liability (if any) for personal injury or death resulting from our negligence, for fraud or any other matter in relation to which we cannot legally exclude liability.

Annex 1: Applied emission factors

Table A-1 Applied emission factors for BBP releases from manufacturing (if actual emissions are not reported)

	Emission factor, %			
	Air	Soil	Waste water	Waste
Manufacturing	0.0006	n.d.	1.1	n.d.

Table A-2 Applied emission factors for BBP releases from formulation

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Compounding by extrusion	n.d.	0.030	0.01	0.255	n.d.
Non-polymeric, formulation:					
Formulation of adhesives/sealant, rubber	n.d.	0.05	0.01	0.001	n.d.
Formulation of lacquers and paint	n.d.	0.025	0.01	0.3	n.d.
Formulation of printing ink	n.d.	0.025	0.01	0.3	n.d.
Formulation of ceramics	n.d.	0.25	0.01	0.3	n.d.

n.d. no data

Table A-3 Applied emission factors for BBP releases from processing

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Formulation and processing (at same site):					
Plastisol coating for flooring		n.d.	0.130	0.05	0.130
Coating of leather and textiles		n.d.	0.255	0.05	0.255
Calendering of films		n.d.	0.135	0.05	0.135
Processing from compound:					
Processing of hard PVC		n.d.	0.250	0.05	0.250
Non-polymeric					
Processing of sealants		n.d.	0.1	0.01	0.001
Processing of coatings and inks		n.d.	5	0.15	0.05
Processing of adhesives		n.d.	0.01	0.5	0.1
Processing of other non-polymeric		n.d.	0.25	0.01	0.3

Table A-4 Applied emission factors for BBP releases from end-products

	Emission factor, %			
	Air	Soil	Waste water	Waste
Flooring	0.32	0.00	2.35	97.33
Film	0.32	0.00	0.00	99.68
Coated fabric, upholstery, shoe uppers, luggage,etc.	0.80	0.00	2.00	97.20
Hard PVC	n.d.	n.d.	n.d.	100.00
Non polymer applications:				
Sealant	0.00	0.00	0.00	100.00
Paints and ink	0.90	0.00	0.00	99.10
Adhesives	0.90	0.00	0.00	99.10
Other non-polymeric	5.00	5.00	5.00	85.00

ANNEX 2: Data from the Nordic product registers

Data from the Nordic product registers were retrieved from the SPIN database as part of the data collection process. Product registers exist in Norway, Denmark, Sweden and Finland. (Spin website: http://195.215.251.229/DotNetNuke/default.aspx).

The substances covered by the product registers differ among the countries and is briefly described below as background for the interpretation of the data.

Substances covered by the product registers
In Sweden the declaration requirements are based on the customs tariff codes, so that as a general rule they apply to all chemical products (substances and preparations). The Swedish register therefore contains more products than those that are classified as dangerous according to EU legislation. In Sweden, substances that are not classified as dangerous and that make up less than 5 per cent of a product may be omitted from the declaration.

In Norway, declaration is mandatory for all products to which the Regulations relating to the classification, labelling, etc. of dangerous chemicals (the Chemical Labelling Regulations) apply. These regulations implement EU directives on the classification, labelling, etc. of chemicals in Norwegian legislation. It means that declaration is only mandatory for products in which one of the substances is included in the list of dangerous substances. For declared products all constituents of the product is registered, whether or not the substances are included in the list of dangerous substances.

In Denmark, like in Norway, the declaration is mandatory for products including dangerous substances, but the requirements also apply to all solvents, pesticides, biocides and cosmetics. Information on all constituents is required for products for which declaration is mandatory. Denmark has complete information on composition for the majority of products. Until 2004 declaration was not mandatory for products marketed before April 1 1983, and for this reason e.g. fuels were generally not declared.

In Finland, like in Norway and Denmark, the declaration is mandatory for products including dangerous substances. Additional requirements apply to pesticides and chemicals that cause danger, although they are not classified. The information on the composition of products is registered from the safety data sheets. Complete information on the exact composition is consequently not necessarily given. There are no data from Finnish reports in these tables, noted for each relevant product group as "n.a." (Not available).

Exemptions
All four countries exempt products that come under legislation on foodstuffs and medicinal products from mandatory declaration. Furthermore, the duty to declare products to the product registers does not apply to cosmetic products in Sweden, Norway and Finland. There is also a general exemption from the duty to declare chemicals in Sweden, Finland and Norway, if the quantity produced or imported is less than 100 kg per year. This means that small volumes of chemicals (e.g. laboratory chemicals or pharmaceuticals) may escape registration.

In addition, there is no requirement to declare solid processed articles to any of the registers. Thus, the duty to declare products to the registers does not include chemicals in textiles, chipboard, etc.

Update of product register data

In Sweden and Norway the quantities, the classification, the codes for areas of use and the codes for product types of products are updated every year, and trends can therefore be followed for both substances and products.

Updating of the other information given by the company at registration, such as composition and physical properties, is supposed to take place whenever these conditions are altered.

In Finland the quantitative data are quite up-to-date as the Finnish product register has only been collecting information on quantities since year 2001.

In Denmark, there is no systematic updating of quantities of products. The companies are obliged to send in any new information regarding their products whenever changes occur. If companies fail to fulfil their obligations, a result might be that products that have been discontinued still remain on the lists. For the present analysis the Danish product register has contacted companies who have declared the use of the substances and updated the declared quantities on this basis.

Registered consumption

The registered consumption of the substances in the Nordic product registers is shown in Table **A2-1, A2-2, A2-3 and A2-4** below. The registers in Norway, Denmark and Finland mainly include products containing dangerous substances.

Table A2-1 Use of benzyl butyl phthalate (BBP) in products in Denmark.

DENMARK Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Binding agents - for binding together the individual constituents in the product	0.4			1.1			
Binding agents for paints, adhesives etc. (see also adhesives)					2.9	2.9	3.9
Adhesive hardeners					0.1	0.1	
Adhesives (see also Binding agents)	10.9	0.1	0.2	0.5	0.0	0.0	0.3
Resins for 1- and 2-comp. hardening adhesives					0.0	0.0	
Other adhesives					0.2	0.2	
Paint, lacquers and varnishes	14.9	8.7	25.5	18.4	9.3	14.2	45.8
Covering lacquers					0.5	1.3	
Protection lacquers					2.9	3.2	
Primer					1.6	1.4	
Anticorrosive paints					1.4	1.4	
Other paint, lacquers and varnishes					0.1	0.1	
Writing ink	0.0	0.0	0.0	0.1	0.1	0.1	0.1
Printing inks	0.3	0.3	0.3	0.4			0.6
Casting materials	0.2	2.7	2.7		7.0	7.0	
Serigraphy inks					0.2	0.5	
Other printing inks					0.1	0.1	
Filling materials (see also Fillers; Insulation materials)	47.8	46.7	46.7	65.0	19.2	8.4	79.3
Padding materials					40.1	40.1	
Stopping material					0.4	0.4	
Tightening materials (putty)					28.5	28.6	

DENMARK Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Binding agents - for binding together the individual constituents in the product	0.4			1.1			
Binding agents for paints, adhesives etc. (see also adhesives)					2.9	2.9	3.9
Adhesive hardeners					0.1	0.1	
Adhesives (see also Binding agents)	10.9	0.1	0.2	0.5	0.0	0.0	0.3
Resins for 1- and 2-comp. hardening adhesives					0.0	0.0	
Other adhesives					0.2	0.2	
Paint, lacquers and varnishes	14.9	8.7	25.5	18.4	9.3	14.2	45.8
Covering lacquers					0.5	1.3	
Protection lacquers					2.9	3.2	
Primer					1.6	1.4	
Anticorrosive paints					1.4	1.4	
Other filling materials					2.0	2.0	
Surface treatment of paper and other non-metallic materials							0.1
Hardeners							2.0
Other and unknown function					155.3	100.2	100.4
Polishing agents							0.1

Table A2-2 **Use of benzyl butyl phthalate (BBP) in products in Sweden.**

SWEDEN Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y	1999 t/y
Softeners for plastic, rubber, paint and adhesive	691.0	642.0	733.0	512.0	540.0			609.0
Plastic construction materials	6.0	57.0	57.0					
Paint and varnish Volatile organic thinner Decorative/protection Industrial use	2.0	2.0	2.0	2.0				
Paint and varnish Volatile organic thinner Decorative/protection Other (including road-, art-,furniture-, autopaint)	0.0			0.0	3.0			
Paint and varnish Water based Decorative/protection Other (including ship-, road-, art-,furniture-, autopaint)					1.0			
Tightening materials (putty)	1.0	13.0	8.0	40.0	44.0			
Padding (filling) materials				2.0	2.0			
Adhesives Water based Industrial use				2.0				
Adhesives Based on organic thinners Industrial use				0.0				
Adhesives Hardener for adhesive Industrial use				0.0				
Paints, varnishes						2.0	2.0	3.0
Printing inks						0.0	0.0	0.0
Other paints, aqueous						1.0	1.0	1.0
Other paints and varnishes, solvent-based						0.0	0.0	0.0
Adhesives (cyanoacrylates)						0.0	0.0	0.0
Adhesives, glues						16.0	5.0	11.0

SWEDEN Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y	1999 t/y
Lubricants						0.0	0.0	0.0
Caulking compounds						1.0	2.0	2.0
Sealing compounds						37.0	30.0	24.0
Anti-corrosive paints								4.0

Table A2-3 Use of benzyl butyl phthalate (BBP) in products in Norway.

NORWAY Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Paint and varnish Volatile organic thinner Decorative/protection Industrial use	3.6						
Paint and varnish Volatile organic thinner Decorative/protection Bottom paint for boats and ships	0.4						
Paint and varnish Volatile organic thinner Decorative/protection Other (including road-, art-,furniture-, autopaint)	0.0	0.3	1.0				
Paint and varnish Volatile organic thinner Active corrosion inhibitor Industrial use		0.0					
Paint and varnish Volatile organic thinner Decorative/protection Industrial use		3.4	2.8				
Paint, lacquers and varnishes				4.4	5.0	7.2	6.9
Paint and varnish Water based Decorative/protection Industrial use			0.5				
Stopping material	0.0	0.1	0.1				
Tightening materials (putty)	0.1	0.2	0.1				
*None indicated *Code M05249*		0.6					
Filling materials (see also Fillers; Insulation materials)				7.0	5.6	5.5	5.6
Adhesives (see also Binding agents)							0.1

Table A2-4 Use of benzyl butyl phthalate (BBP) in products in Finland.

FINLAND **Product group**	**2006 t/y**	**2005 t/y**	**2004 t/y**	**2003 t/y**	**2002 t/y**	**2001 t/y**	**2000 t/y**
Cleaning and washing agents						n.a.	
Pharmaceuticals						n.a.	
Lubricants						n.a.	
Dyestuff, pigments						n.a.	n.a.
Plastic additives and auxiliaries							n.a.
Laboratory chemicals							n.a.
Adhesive and binding materials							n.a.
Building materials and additives							n.a.
Fillers							n.a.
Other use							n.a.

ANNEX 3: CONFIDENTIAL INFORMATION

[Not included in published report]