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

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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 DBP.

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.).

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Executive summary

Dibutyl phthalate (hereafter referred to as DBP) is used for a number of applications. One of the major applications is as plasticiser in polymers, but by itself it is too volatile for PVC applications and it is used as a gelling aid in combination with other plasticisers. The specific applications in polymers are not well described, but include PVC products, fibreglass and rubbers. It is further used as plasticiser for adhesives, paints/lacquers, and grouting agents and as solvent in different small applications. Based on the information obtained only a relatively uncertain distribution between different applications can be established and the indicated distribution should be considered a "best estimate scenario" used for estimating releases; the releases from end-product uses are estimated with high uncertainties. Apart from the use in adhesives, where DBP seems to be widely used for some types, the use of DBP for other applications seems to be very scattered and it is either used for some niche productions (not described in this report) or used as processing aid by some specific manufacturers (e.g. for manufacturing of flooring) where other manufactures use other plasticiser systems for manufacturing of similar products.

Figure 0-1 illustrates the fate of the DBP 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 DBP accumulated in society and would probably be higher, as the amount of DBP 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.

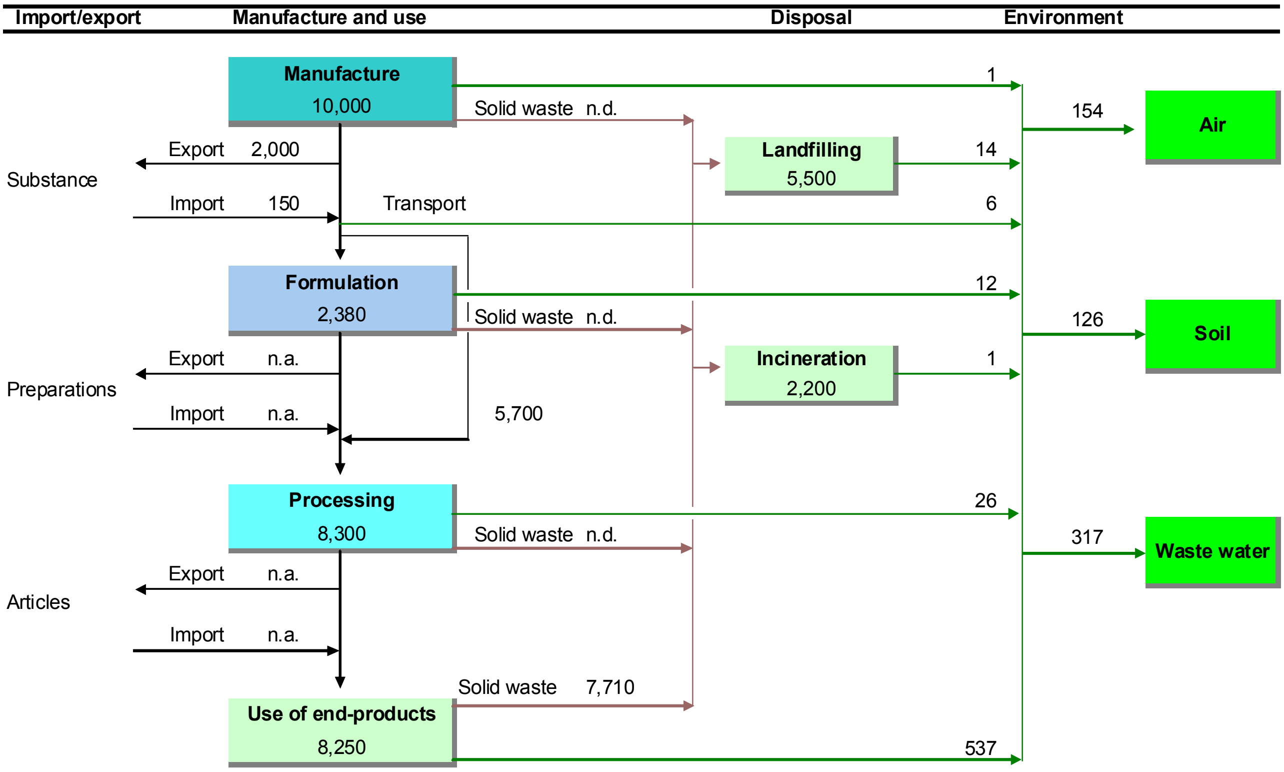

Figure 0-1 "Best estimate scenario" of overall flow of DBP sent into circulation in EU society in 2007. Tonnes DBP/year. (Figures are rounded and higher than actual figures)

According to information retrieved from the two manufacturers of DBP in the EU, the total manufactured volume in 2007 was less than 10,000 tonnes. The market for DBP has been decreasing over recent decades: In 1994 the production volume of DBP in the EU was 49,000 tonnes and in 1998 it was 26,000 tonnes, with an export of 8,000 tonnes. In 2005 DBP was produced by three manufacturers, and the total volume was slightly above 10,000 tonnes.

The manufactured DBP 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).

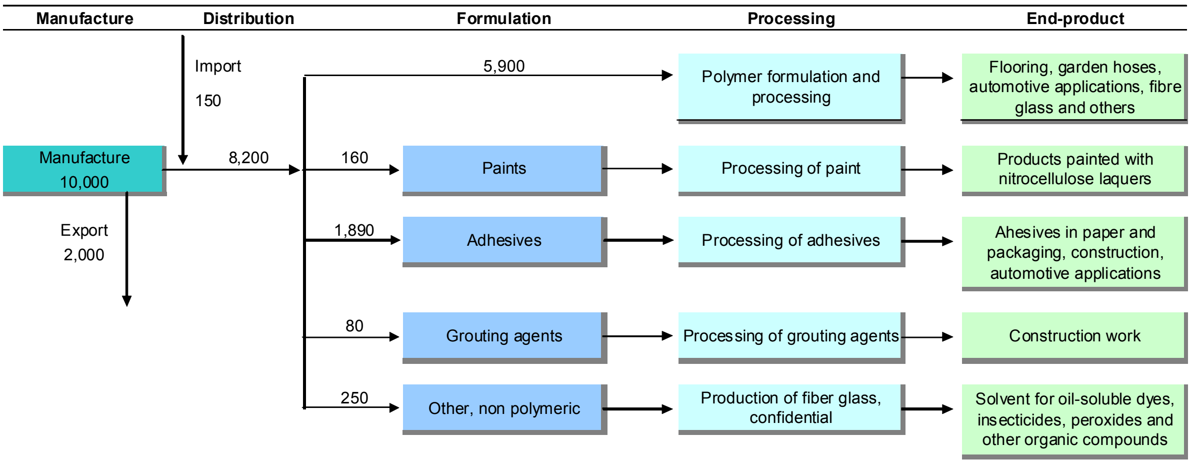

Figure 0-2 **"Best estimate scenario" of the overall flow of DBP through manufacturing processes. Tonnes DBP/year. (Figures are rounded and higher than actual figures)**

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 DBP published in 2004. As the specific processes and end-product uses are not known in detail, the releases have only been estimated with high uncertainty. It is, however, certain that the end-product uses represent the major part of the releases to air, soil and waste water during the entire life-cycle. Manufacture of DBP and disposal both account for a small part of the total releases. For disposal in landfills, however, it is uncertain how much of the DBP may be released over a very long term perspective. Transport of the substance from manufacturing includes all transport activities of the substance on its own, i.e. the tonnage is the sum of the tonnages manufactured and imported.

Table 0-1 **"Best estimate scenario" of releases of DBP from manufacturing, transportation, formulation, processing, end-products use and disposal in the EU in 2007. (Figures are rounded and higher than actual figures).**

Activity	Tonnage handled	Emission to (t/y):		
	t/y	Air	Soil	Waste water
EU manufacture of DBP	10,000	0.1	0.0	0.9
Transportation of substance from manufacturing 1*	12,200	0.0	0.0	6.1
Formulation	2,380	5.2	0.2	6.2
Processing	8,300	6.7	10.3	9.0
End-product uses	8,250	141.0	115.0	281.0
Disposal	7,710	0.9	0.2	13.8
Total releases (round)		154	126	317

*1 The tonnage handled is the sum of EU production and import.

The decrease in production volumes in recent years (to about 15% of the 1994 level) reflects the fact that DBP for many applications has been replaced by other substances. The main marketed all-round alternative to DBP is Di-isobutyl phthalate (DIBP). Di-isobutyl phthalate (DIBP) has application properties very similar to the properties of DBP and may therefore be used to substitute for DBP in most, if not all, of its applications.

Applications specifically mentioned by suppliers of selected alternatives, relevant in the context of DBP, are shown in the following table. DINP is not in itself considered an alternative to DBP, but has been suggested as an alterative together with dibenzoates (among these DGD). The price of alternatives ranges from the same price to slightly higher that DBP.

Table 0-2 Applications specifically mentioned by suppliers of selected alternatives relevant in DBP context

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

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

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 DBP.

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}
DIBP	84-69-5	Developmental	350	35	175	9
DINP	28553-12-0	Developmental	44	4	22	1
DINCH	166412-78-8	Kidney toxicity	75	8	38	2
GTA	102-76-1	Reproductive toxicity	1400	141	700	35
DGD	27138-31-4	Developmental	700	71	350	17

With regard to potential environmental hazards and risks of alternatives, 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 of data sources) amongst the potential alternatives and, as such, drawing definitive conclusions on whether any additional risks for the environment would be introduced if these were to be substituted for DBP is not straightforward for all substances.

- 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).

- 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 but does have moderate bioaccumulative properties. Experimental data on aquatic ecotoxicity indicate that the correct environmental classification would be N; R51/53.

- GTA is easily biodegradable and does not have bioaccumulative properties. The toxicity to aquatic organisms is considered to be low. In conclusion, GTA does from an environmental point of view appear to be an acceptable alternative.

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

Abbreviations and acronyms

AGD	Anogenital distance
AGI	Anogenital index
BBP	Benzylbutyl phthalate
BCF	Bioconcentration factor
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
CMR	Carcinogenic, mutagenic, reprotoxic
DBP	Dibutylphthalate
DEHP	bis(2-ethylhexyl) phthalate
DGD	Dipropylene glycol dibenzoate
DIDP	Di-isodecyl phthalate
DIBP	Di-isobutyl phthalate
DINCH	Di-(isononyl)-cyclohexan-1,2-dicarboxylate
DINP	Di-isononyl phthalate
DNEL	Derived No Effect Level
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)
EU	European Union
EuPC	European Plastics Converters
EuPIA	European Printing Ink Association
EVA	Ethylene vinyl acetate
F_0, F_1, F_2	Parent, first and second generations in multigenerational experiment
GD	Gestational day
GTA	Glyceryl triacetate
IUCLID	International Uniform Chemical Information Database
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
PNEC	Predicted No Effect Concentrations
PP	Polypropylene
PVA	Polyvinyl acetate
PVC	Polyvinyl chloride
RAR	Risk Assessment Report (if nothing else mentioned, the RAR for DBP)
SCENIHR	EU Scientific Committee on Emerging and Newly Identified Health Risks
SVHC	Substances of very high concern
TGD	Technical Guidance Document
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 dibutyl phthalate (hereafter referred to as DBP) is used as a plasticiser or solvent in various polymer and non-polymer products.

DBP has the CAS N° 84-74-2.

Manufacturing sites - Three manufacturers of DBP in the EU in 2005 have been identified (Table 1-1). The manufacturers were identified through a questionnaire sent to European manufacturers of phthalates based on a list drawn up by the European Council for Plasticisers and Intermediates (ECPI). None of the manufacturers are members of ECPI. One of the manufacturers ceased the production in 2006 and today DBP is only produced by two of the manufacturers.

Table 1-1 Manufactures of DBP in the EU in 2005

Company	Town of manufacturing site	Country
Proviron	Hemiksem	Belgium
Zak (Zakłady Azotowe Kędzierzyn SA)	Kędzierzyn-Koźle	Poland
DEZA a.s.	Otrokovice	Czech Republic

Manufacturing process - According to the Annex XV dossier, DBP is produced by the reaction of phthalic anhydride with n-butanol in the presence of concentrated sulphuric acid as a catalyst. Excess alcohol is recovered and recycled and the di-n-butyl phthalate is purified by vacuum distillation and/or activated charcoal.

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) have been obtained by use of a questionnaire sent directly to eight manufacturers of phthalates. All manufacturers have responded with information on manufactured tonnage and information on releases, whereas only one of the manufacturers has provided information on the further use of DBP.

The total manufactured tonnage in 2005, 2006 and 2007 is confidential but in 2005 it was more than 10,000 tonnes per year and in 2007 it was less than 10,000 tonnes per year. A significant part of the manufactured tonnage is exported to countries outside the EU. According to ECPI (2008), in Western Europe [1] about one million tonnes of phthalates are produced each year, of which approximately 900,000 tonnes are used to

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

plasticise PVC (polyvinyl chloride). DBP seems to represent less than 1% of the production.

The market for DBP has been decreasing over the last decade. In 1998 the production volume of DBP in the EU was estimated at 26,000 tonnes, of which 8,000 tonnes was thought to be exported outside the EU (RAR). Already at that time there was a clear decreasing trend in the production of DBP from a level of 49,000 t/y in 1994.

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

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

The substance on its own - DBP is in the trade statistics from Eurostat included in the commodity group "dibutyl orthophthalates". The group changed CN8 code from 2006 to 2007, but the name of the group is still the same. The steep increase in the export from 2006 to 2007 is remarkable and may be due to some misreporting because of the changes in CN8 codes.

Apart from DBP, the group may include Di-isobutyl phthalate (DIBP), a substance that is marketed as an alternative to DBP. No data are available on the distribution between the two substances. In the product registers of the Nordic countries (SPIN 2008) the total registered quantities of DIBP is approximately the same as for DBP(as shown in Annex 2).

In any case the data demonstrate that the import of DBP on its own is small and less than 156 tonnes in 2007.

According to questionnaire replies only about 100 tonnes were exported by the manufacturers, but export may be undertaken by others. Considering that the reported export is increasing and twice the reported production volume of DBP in 2007 it seems more likely that DIBP takes up the major part of the reported export, and the export of DBP on its on will, with a view to the information from manufacturers, roughly be assumed to account for approximately half of the export at the 2005-2006 level corresponding to around 2,000 tonnes.

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

CN8 code	Name	2005		2006		2007	
		Import	Export	Import	Export	Import	Export
2917 3100	DIBUTYL ORTHOPHTHALATES	182	4,382	298	4,881		
2917 3410	DIBUTYL ORTHOPHTHALATES					156	15,377

Preparations - DBP may be exported in polymer compounds. 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 DBP is not known, but considering that DBP represents less than 1% of the EU manufacturing of phthalates, the statistics cannot be used to indicate import and export of DBP with compounds.

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

Table 1-3 EU27-extra import and export of vinyl chloride containing polymers and copolymers in primary form that may contain DBP (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*

DBP may be imported and exported in a range of articles. As DBP is used only for a minor part of the products within the different commodity groups, the import/export of DBP cannot be determined on the basis of the registered import or export of articles.

1.4 *Releases from manufacture*

The total reported releases from the manufacturing of DBP in 2007 are shown in the table below based on the manufacturer's reply to the questionnaire.

Table 1-4 Manufactured tonnage and reported releases from manufacture in 2007 by manufacturing site

Manufacturer	Tonnage, 2007	Releases to working environment	Releases to the environment and waste, t/y			
	t/y	t/y	Air	Soil	Waste water	Waste
Site 1	Confidential	n.d.	0.0002	n.d.	0.2	n.d.
Site 2	Confidential	n.d.	0.08	n.d.	0.7	n.d.
Total (round)	10,000		0.1	0.0	0.9	n.d.

* Figures in grey cells are based on actual data obtained from manufacturers

n.d. = no data

Working environment - The DBP RAR discusses occupational exposure in detail, and examples of workplace air concentrations are given. The production of DBP usually takes place in closed systems. However, both inhalation and dermal exposure may occur during the production of DBP. Such exposures may occur from "breathing" of the system at elevated temperatures, during system leaks, filling of road and rail tankers, drumming, cleaning of tanks, during service and maintenance, transfer, and process sampling. Most of the transport is done in tanks, and drumming only happens occasionally. The RAR does not provide data to allow total emissions to the working environment to be estimated.

The manufacturers of DBP contacted during this study report possible exposures during the filling of drums, during the release of pumps, during disposal of rinsing water in between production campaigns, and during sampling from the production. Personal protection equipment has to be worn during working hours. No quantitative information on exposure was reported.

Transport of DBP on its own
Almost all of the phthalates consumed within the EU, including DBP, are transported by road tankers. The release during distribution of pure DBP relates to spillage and the cleaning of transport vessels. It is assumed that this release occurs 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 0.05 % which is considerably higher than the emission factors for this activity applied in the RAR for DEHP (2008) and the RAR for BBP (2007). However, this emission factor is applied here as well and multiplied by the manufactured volume (of which some is exported) and the imported volume.

2 Information on uses and releases from uses

2.1 *Identification of uses*

DBP is a specialist, fast fusing plasticiser. By itself it is too volatile for PVC applications and it is used in PVC as a gelling aid in combination with other high molecular weight plasticisers (ECPI 2008b, BASF 2008a). The gelling agent is the agent which reacts fastest with the PVC.

Current uses of DBP, according to actual information obtained from industry or product registers are listed below. In general it has been very difficult to obtain specific information on uses from manufacturers and suppliers of the DBP.

- Gelling aid in combination with other plasticisers in plastics. DBP is used in PVC (manufacturer information). It has not been possible to obtain very specific information on the uses, but the following applications are mentioned by different sources: floor coverings (BASF 2008a), automotive uses (manufacturer information) and garden hoses (RAR). In a Danish investigation in 2001, DBP was found in a concentration of 1.5% in one out of 5 investigated floorings (Pors and Fuhlendorff 2001). The European Plastic Converters (EuPC), has in a survey by their members not indentified any use of DBP, and assume that DBP today is used by relatively few companies for different niche purposes. In a substance flow analysis of DBP (and other substances) in Germany for 1995 it is mentioned that polymer applications are mainly PVC, but no information on product types is provided (Leisewitz and Schwarz 1997).

- Rubbers (manufacturer information). The RAR specifies that DBP is used in some polychloroprene rubber and nitrile rubber, but not in all polychloroprene (neoprene) or nitrile rubbers. New information on actual uses has not been obtained.

- DBP is used extensively in the adhesives industry to plasticise polyvinyl acetate (PVA) emulsions (ECPI 2008b). The low viscosity and compatibility of DBP make it suited for PVA-based adhesives for bonding cellulosic materials. According to the RAR the most important uses of the adhesives are for paper and packaging, wood building and automobile industry.

- Epoxy resins (manufacturer information). Probably same application that in the RAR is mentioned as "solvent in the production of fiber glass". More specific information on this application has not been obtained. The usage of DBP in epoxy based fibreglass is e.g. described in Feldman et al. (1983).

- In the coatings industry as a primary plasticiser-solvent for nitrocellulose lacquers (ECPI 2008b).

- Grouting agents, used to reduce water leakages in tunnels, sewer systems, buildings etc. (RAR). DBP contents as high as 30-60% are (were) found in polyurethane foams used in grouting applications for water control in tunnels, sewer systems, buildings etc. (RAR). No actual confirmation of this application has been obtained. In the Norwegian product register a consumption of 3-5 tonnes DBP for "filling agents" was registered until 2003, but none of the Nordic product registers have any registering of the use of fillers sealants or similar products.

- Other applications:

    - Solvent for many oil-soluble dyes, insecticides, peroxides and other organic compounds (ECPI 2008b);

    - Antifoam agent and as a fibre lubricant in textile manufacturing (ECPI 2008b);

    - Used in compounding flavours (ZAK 2008);

    - Printing inks, polishing agents, corrosion inhibitor materials (Danish product register, Annex 2);

    - Use in PP (polypropylene) catalytic systems (comment to Annex XV dossier);

    - One application described in the confidential part of the report.

According to the American Chemistry Council (quoted in CERHR 2001), in the US DBP is used mainly as a coalescing aid in latex adhesives. DBP is also used as a plasticiser in cellulose plastics and as a solvent for dyes. Although there was limited use of DBP in PVC during the 1970s and 1980s, it was around 2000 not used as a plasticiser in PVC in the USA (CERHR 2001).

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

According to CEPE (European Council of producers and importers of paints, printing inks and artists' colours), DEHP, BBP and DBP 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 DBP in inks was registered, but it may be due to non-updated registration (Annex 2). In the Swedish product register, which is more regularly updated, DBP has not been registered in printing inks since 2001. (Annex 2). It is on this basis assumed that the use in inks is very small (if any) and inks are included in the "other, non-polymeric" product group.

The flow chart below illustrates the "best estimate scenario" for the flow of DBP through the different process and the resulting end-products. It has not been possible to obtain comprehensive quantitative updated information on the use of DBP for the different uses from manufacturers and suppliers and the available information does not allow real estimates of the distribution between the different use areas to be made. It is, however, deemed that the distribution between applications most likely is different from the 1997 distribution used in the RAR, but the updated distribution is highly uncertain. The background for the distribution is discussed further in the following sections.

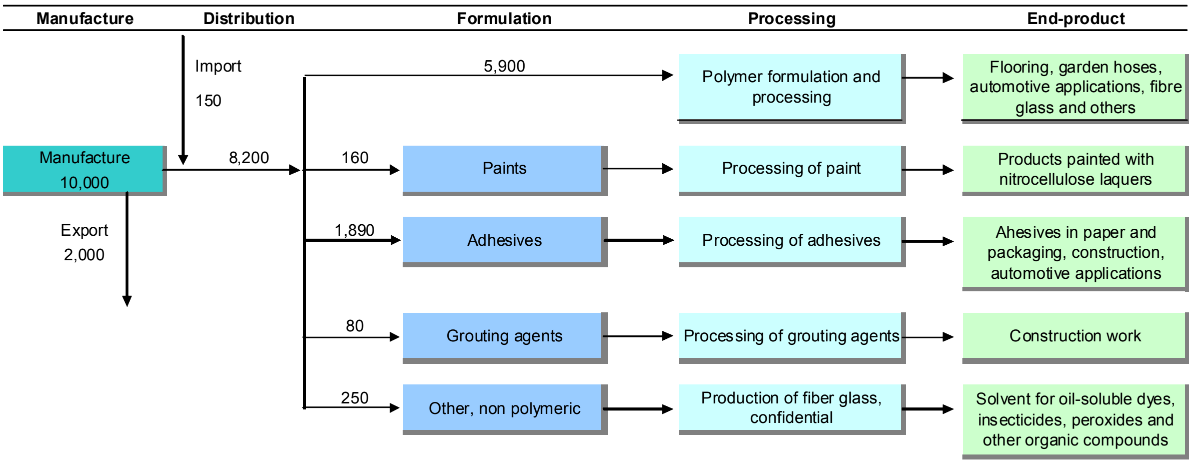

Figure 2-1 Scenario of overall flow of DBP through manufacturing processes in 2007. Tonnes DBP/year. Regarding tonnages, see next section.

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 DBP 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 DBP	PROC1	Use in closed process, no likelihood of exposure. Industrial setting;	SU9	Manufacture of fine chemicals	C20.1.4	Manufacture of other organic basic chemicals
	PROC 3	Use in closed batch process (synthesis or formulation) Industrial setting;				
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
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
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 Manufacture of plastic products, including compounding and conversion	C22.2.1 C13.9.9	Manufacture of plastic plates, sheets, tubes and profiles Manufacture of other textiles n.e.c.

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
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;	SU18, 19, 21	Manufacture of furniture	C43.3.4, C31	Painting and glazing
		Spraying outside industrial settings and/or applications		Building and construction work		Manufacture of furniture
				Private households (= general public = consumers)		

*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

DBP ends up in a large number of end-products. Apart from adhesives, where DBP seems to be widely applied, it seems to be used in a small number of the products only, within each product type. e.g. it might be used in some PVC floors, in some rubber products, in some lacquered products, etc., but it is not possible to point at some specific major end-product uses.

Current uses of DBP are as follows:

- Products of PVC. The specific products are not known but garden hoses, floor coverings and automotive uses have been mentioned;
- Products with epoxy resins. Probably some fibreglass products, but specific applications are not known;
- Rubber products of polychloroprene rubber and nitrile rubber. The specific products are not known;
- Adhesives (of PVA) in building industry, packaging, vehicles, textile and paper sizing;
- Products coated with nitrocellulose lacquers (applications not further specified, but nitrocellulose lacquers are applied e.g. in the automotive industry and for furniture and musical instruments).
- In textiles (used as an antifoam agent and as a fibre lubricant in textile manufacturing);
- Printed products (originating from the use as softener in printing inks - the application is probably very small today);
- Miscellaneous products: polishes, oil-soluble dyes, insecticides, flavours.

2.2 *Quantification of uses*

Information on the distribution of the DBP supply to the various formulation and processing activities has been obtained from one manufacturer representing only a minor part of the market. The distribution indicates that polymer applications is still the major application area, but other information indicates that some of the non-polymer applications, in particular in adhesives, have not decreased so steeply and may make up a larger part of the volume used today.

Table 2-2 DBP distribution of on use categories scenario for 2007 and 1997 distribution as reported in RAR

Product group	Distribution on uses in percentage	
	2007 scenario	RAR 1997
In polymers (PVC, PVA, rubbers)	69	75
Fiber class (epoxy based)	2	confidential included in other non polymeric
Non-polymer applications		
Printing inks	0	7
Adhesives	25	14
Paint	2	Included in other non-polymeric
Grouting agents	1	<1.1
Other non-polymer applications	1	3
Total	100	100

Data on use of DBP in Sweden, as registered in the Swedish product register, is shown in Table 2-3. During the period from 1999 to 2006 the main registered application was in adhesives with a fairly constant consumption in the range of 77-115 tonnes. However, data from the Danish product register (Annex 2) indicate paint, lacquers and varnishes as the main use category, with about 60 tonnes/y used for this application in recent years. The data in the Danish product register may, however, not be up-to-date as the register is not updated regularly. The data may reflect specific industrial uses of DBP containing adhesives and paint and Sweden and Denmark, respectively, and not reflect the EU average use pattern. Paint and varnish is, however, also registered in the Swedish product register with 4 tonnes in 2006 and in the Norwegian product register with 1.3 tonnes. The "acrylic emulsions" indicated by manufacturers may in fact be used for this application.

Table 2-3 Use of DBP in Sweden registered in the Swedish product register 1999-2006

Use category	Registered tonnage, t/year							
	2006	2005	2004	2003	2002	2001	2000	1999
Adhesives	83	100	99	115	0	77	82	77
Raw materials for production of plastics	5	4	2	10	5	10	0	
Paint and varnish	4	3	2	1	5	7	7	
Printing inks						1.0	4.0	4.0
Other products						6	14	2.0
Total	92	107	103	126	10	100	103	77

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 DBP for formulation and processing is shown in Table 2-4 and Table 2-5. The processes are further described below the tables.

The RAR does not include information on the number of users of DBP. Based on information obtained from the major supplier of DBP in Europe it is estimated that in total 50-100 major primary users of DBP exist. Furthermore, some minor users, supplied with DBP from 10-20 suppliers of the substance, may exist, but it has not been possible to estimate the number of these minor users.

Table 2-4 Maximum DBP use for formulation in 2007 and 1998

Process	Amount used (t/y), 2007	% of total, 2007	Amount used (t/y), 1998 *1
Formulation of paint	160	7	1,250
Formulation of adhesives	1,890	79	2,500
Formulation of grouting agents	80	3	200
Formulation of other non-polymeric	250	11	550
Total formulation (rounded)	2,380	100	4,500

*1 Source: RAR 2004.

n.d. No data

Table 2-5 Maximum DBP use for processing in 2007 and 1998

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

*1 Source: RAR 2004.
n.d. = No data

Polymer uses of DBP

Formulation and processing of polymers (mainly PVC) - As described elsewhere in this report, the available data does not provide for an allocation of the DBP consumption for this category on specific processes, and this study has not revealed new quantitative data on this aspect. Based on available indications, this DBP may however be used in extrusion and plastisol conversion processes.

Extrusion - During extrusion, the melted PVC compound is pressed through a die with subsequent cooling.

Plastisol applications -"Plastisol" is a pasty liquid obtained by blending (formulating) PVC resin with plasticiser and other ingredients at room temperature. Spread coating with plastisol: 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. By slush/rotational moulding with plastisol a spherical mould of the required geometry is filled with the proper amount of paste. Upon rotation, due to centrifugal force, the paste will be homogeneously spread over the inner walls of the mould. Gelation is accomplished by hot air and, for large shapes, by direct flame heating.

Formulation of adhesives, sealants and paint - Formulation of these chemical products basically consists of mixing of ingredients in batch or continuous processes.

Processing (application) of sealants - DBP is used in polyurethane foam sealants - so-called grouting agents - for sealing of holes in concrete tunnels or sewers, and are thus used in a non-industrial setting.

Processing (application) of paint - A small amount of DBP is still used in paint/lacquer, specifically nitrocellulose lacquers are mentioned. The application is not specified, but nitrocellulose lacquers are mainly applied by professionals.

Processing (application) of adhesives - A significant amount of DBP may still be used in adhesives, where is serves with other plasticisers in the production of dispersion adhesives used in paper and packaging, wood works, building industry and automobile industry (DBP RAR). These are partly industrial settings, and partly more open, non-industrial settings.

Production of glass fibres - According to the RAR, DBP may also be used as solvent (probably in epoxy resin) in fibre glass production.

2.2.2 End-product uses

The "best estimate scenario" for DBP use in end-products, by product type, is shown in Table 2-6. 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 2-5). No data has been available on import and export of DBP with 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.

The end-product uses of DBP containing polymers are not well known. The RAR assumes in a worst case scenario that all the polymers are used outdoors. The available information of the uses, however, indicates that indoor applications like flooring may account for a significant tonnage. In the absence of more specific data, a 50/50 % split between indoor and outdoor applications is considered more likely and is used here.

Table 2-6 "Best estimated scenario" for DBP tonnage in end-products marketed in the EU27 based on EU manufacture data 2007

End-product use area	Tonnage, t/y				% of total use
	EU Manufacture	Import	Export	End-product use	
Polymers (incl. fiber glass), interior use	2,930	n.d.	n.d.	2,930	36
Polymers (incl. fiber glass), exterior use	2,930	n.d.	n.d.	2,930	36
Non polymer applications:					
Paint	160	n.d.	n.d.	160	2
Adhesives	1,900	n.d.	n.d.	1,900	23
Grouting agents	80	n.d.	n.d.	80	1
Other non-polymeric	250	n.d.	n.d.	250	3
Total end-product use (round)	8,250	n.d.	n.d.	8,250	100

n.d. No data

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 off 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 the 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 not specifically mentioned in the ESD but is here considered 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.

The estimated releases of DBP from formulation and processing in EU27 are shown in Table 2-7 and Table 2-8 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 2-4 and Table 2-5.

Table 2-7 Estimated DBP releases from formulation

Process	Releases to working environment (t/y)	Releases to the environment (t/y)			
		Air	Soil	Waste water	Waste
Formulation of paint	n.d.	0.4	0.0	0.5	n.d.
Formulation of adhesives	n.d.	4.7	0.2	5.7	n.d.
Formulation of grouting agents	n.d.	0.0	0.0	0.0	n.d.
Formulation of other non-polymeric	n.d.	n.d.	n.d.	n.d.	n.d.
Total formulation (rounded)	n.d.	5.2	0.2	6.2	n.d.

n.d. No data

Table 2-8 Estimated DBP 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
Polymers formulation and processing	n.d.	6.3	0.0	6.3	n.d.
Formulation and processing of fiber glass	n.d.	0.1	0.0	0.5	n.d.
Non-polymeric, processing:					
Processing of paint	n.d.	0.0	0.8	0.2	n.d.
Processing of adhesives	n.d.	0.2	9.5	1.9	n.d.
Processing of grouting agents	n.d.	0.1	0.0	0.1	n.d.
Processing of other non-polymeric	n.d.	n.d.	n.d.	n.d.	n.d.

n.d. No data

Formulation (pre-processing) for polymer uses

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.

Banbury mixing - Banbury mixers are lidded vessels with a small open vent to the air. The mixing process is a batch process, starting with the raw materials at ambient temperatures and going up to maximum temperatures of 120-140°C. Emissions are comparable to those in dry blending.

Formulation of the PVC material processed to end products takes place on-site in most cases. Off-site formulation does however take place in the form of compound (mixed ingredients processed to solid intermediate) produced by extrusion, or as plastisol. Both process types are described below.

PVC/polymer processing

The DBP RAR (2004) reports that according to industry information there were approximately 50 soft PVC converting plants in the EU of the types relevant here. Judging from the decline in DBP production, this number has likely decreased since the beginning of this decade.

The DBP RAR does not detail the consumption of DBP among different PVC products, but uses a scenario for general distribution among open, partially open and closed processes for PVC production.

Though the available information on DBP use does not allow a quantitative allocation of the consumption among PVC products, this information indicates, as mentioned above, that DBP may be used in:

- Flooring; the main process for production of PVC flooring is plastisol spread coating.
- PVC garden hoses; these are produced by extrusion.
- Automotive industry (industry information to this study); there are no specifics on exact applications, but this could for example be PVC bumpers or cabinet parts which are produced from plastisol with slush/rotation moulding (according to DEHP RAR, 2008).

Table 2-9 below gives an overview of the standard emission rates used in the DBP RAR (based on UCD, 1998) for general PVC conversion, and the emission rates for the three PVC conversion processes mentioned above (based on ESD, 2004, a revision of UCD, 1998). As the general usage of plasticisers in PVC conversion has changed quite markedly, an alternative PVC conversion scenario is used here assuming an equal distribution of the DBP consumption between plastisol coating (as for flooring), extrusion (as for hose), and plastisol slush/rotational moulding (as for some car PVC parts). Utilization of air cleaning equipment is assumed (as for most flooring production (BBP release report, 2009) and for some automotive uses (ESD, 2004). The calculated conglomerate overall emission rate is 0.22%, equalling 0.11% to air and 0.11% to waste water. This is slightly below the weighted mean rate used in the DBP RAR, which may be reasonable considering the general trend in Europe towards higher frequency of air cleaning systems. As for DEHP (DEHP RAR 2008), there is a theoretical spill risk to industrial soils, but it is considered marginal.

Table 2-9 Standard emission rates for PVC conversion used in the DBP RAR (based on UCD, 1998) and emission rates for the three specific PVC conversion processes (ESD, 2004).

Total release rates, % *4	Raw materials handling	Compounding	Conversion
RAR "open" scenario	0.01	0.05	0.25
RAR "partially open" scenario	0.01	0.05	0.15
RAR "closed" scenario	0.01	0.5 *1	0.5 *1
Plastisol coating (ESD, 2004)	0.01	0	0.25 *2
PVC extrusion	0.01	0.05 *3	0.05/0.5 *5
Plastisol slush/rotational moulding	0.01	0	0.05 *3

Notes:

*1: RAR note: "Tonnage of PVC is below suggested (UCD) threshold for presence of fume elimination equipment, so emission factors are increased by 10x" (Ed: According to UCD/ESD procedures).

*2: As air cleaning is generally applied according to the ESD and industry sources (2004).

*3: Assumed large facilities with air cleaning.

*4: Sum of air and water releases; 50/50 contributions in all cases according to ESD.

*5: Assuming and equal distribution between facilities with air cleaning and facilities without air cleaning.

Working environment - The DBP RAR discusses occupational exposure in some detail, and a few examples of workplace air concentrations of DBP for PVC conversion/formulation processes are given. Generally, the main routes of occupational exposure are anticipated to be inhalation of DBP-gas and liquid aerosol, and by dermal uptake of liquid DBP, especially in cases of manual loading of DBP into process equipment. Much of the gas emitted in cases of hot processes with DBP will 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 DBP concentrations generated in the working environment air (exposure via inhalation), on the direct skin contact with surfaces with DBP present (dermal exposure), and in both cases the time span of the exposures. Besides examples of measured workplace air concentrations, the RAR presents model predictions of both inhalation and dermal exposure. These data will not be discussed quantitatively here. The data provided does not enable quantitative assessment of the amounts of DBP released in the working environment.

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 product amounts 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).

Non-PVC formulation and processing

Losses with waste from processing (application) of non-polymer products - The amount of these products ending up in waste from the application is not quantified in the DBP 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 quantity 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).

Adhesives and paint - For the formulation (production) and processing (application) of adhesives, the DBP RAR uses relevant TGD standard emission factors for air and water, depending on the process in question. No data have been available for this study to qualify or adjust these emission factors. For soil, the DBP RAR does not give emission rates, and therefore BBP rates from the same processes (BBP RAR 2007) are used here, as these are considered similar: Formulation: 0.01%; processing: 0.5%. The RAR does not estimate emissions from formulation and processing of paint and the same factors as used for adhesives are applied for paint in this study.

Grouting agent (PUR foam sealant) - For formulation (production) of this grouting agent, no emission rates are mentioned in the DBP RAR. Emission rates used in the BBP RAR (2007) for formulation of sealants, which are considered relevant here, were applied in this study: Air: 0.05% (TGD derived); water: 0.001%; soil: 0.01% (TGD derived).

For processing (application) of the relevant polyurethane foam, the DBP RAR cites an emission rate to water derived from an actual use scenario in tunnel construction: 0.16%. The same rate is used here. No rates to air and soil were mentioned in the DBP RAR, and therefore rates used in the BBP RAR (2007) for processing of sealants (including PUR foam sealants) were applied in this study: Air: 0.1%; soil: 0.

Processing (production) of fibre glass - The DBP RAR uses emission rates for air and water releases derived from a combination of one-site specific data set and TGD standard rates: Air: 0.07%; water: 0.33%. These rates were also used here, as no new data were available for this study.

Other non-polymeric - In the absence of detailed information on non-polymeric applications no releases from these applications have been estimated.

2.3.2 End-product uses

Releases from the entire service life of end-products are summarised in Table 2-10.

The releases are life-time emission indicating the ultimate fate of the substance in the end-products i.e. the total of the releases correspond to the total tonnage of DBP in marketed end-product in 2007 as shown in Table 2 4. 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 DBP from end-products in service in 2007 is probably significantly higher reflecting the higher DBP consumption in previous years resulting in large quantities of DBP accumulated in end-products in society.

The releases from uses can only be estimated at high uncertainty as the actual end-product uses of the DBP are not known as discussed in previous sections.

Table 2-10 DBP releases from end-products during their lifetime

End-product use area	Releases to the environment, t/y			
	Air	Soil	Waste water	Solid waste
Polymers (incl. fiber glass), interior use	3	0	91	2,836
Polymers (incl. fiber glass), exterior use	3	70	70	2,786
Non polymer applications:				
Paint	24	0	8	128
Adhesives	95	38	95	1,672
Grouting agents	4	2	4	70
Other non-polymeric	13	5	13	220
Total	141	115	281	7,710

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

- Emission to air by evaporation for both indoor and outdoor applications;
- Leaching and abrasion; for indoor applications the substance is released to waste water by washing operations.
- Leaching, abrasion and weathering; for outdoor applications the substance is released to waste water, surface water and soil by rainwater or as small pieces of the materials from abrasion.

DBP, which is 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.

Indoor applications of polymers - The RAR does not estimate any emissions to air from indoor uses as all end-product uses are assumed to be outdoor uses. As mentioned above it will here roughly be assumed that half of the use is for indoor applications. Specifically flooring is mentioned by a major supplier and in ECPI comments to the Annex XV dossier. The releases will therefore be estimated assuming all the DBP is used for flooring. The releases from flooring will partly be due to leaching of the DBP from the flooring, partly abrasive releases from walking on the floor. For DEHP the Risk Assessment Report (DEHP RAR 2008) applies a life-time emission factor for leaching of 0.04% and applies for abrasive releases a factor of 0.15% per year giving a total life-time emission factor of 3% over 20 years. For DBP the emission by leaching may be higher due to the higher solubility of DBP, but as the emission factor for abrasive releases must be expected to be the same, the total life-time emission factor for releases to wastewater from the products are estimated at 3.5%.

A life-time emission factor for emissions to air from flooring can on the basis of information in the RARs be estimated at 0.04% for DEHP (based on DEHP RAR 2008) and 0.03% for BBP (based on BBP RAR 2007). DBP emission is assumed to be higher than the emission of BBP and DEHP, due to the higher volatility, and a factor of 0.1% will be applied.

Outdoor applications of polymers - The RAR applies a figure for DBP releases to water from plasticised PVC used outdoors of 5% of the annual consumption based on an assumed product life of 7.5 years. The only indication of out-door uses is that the DBP may be used in some garden hoses (RAR), but no actual usage for this application has been confirmed. It must be assumed that a part of the releases from outdoor uses ends up in the soil (e.g. from garden hoses). In the absence of specific information on the uses, the life-time emission factors are here assumed to be 2.5% to waste water and soil, respectively. The emission factor for releases to the air is estimated to be similar to the emission factor used for in-door applications of 0.3%.

Paints and adhesives - It is assumed that air is the main release compartment for these use categories. The specific end-uses for the products are not known, but it is assumed that the major part is used for indoor applications. For paints the RAR applies a lifetime emission factor of 15% mentioning that the reference for the emission factor (ECETOC 1985) does not provide any further rationale for this estimate. For use in paint, based on the RARs for DEHP, the life time emission factors for DEHP can be estimated at 4% and considering the higher volatility of DBP, an emission factor of 15% seems to be realistic and will be applied here. The same factor is applied in the RAR for adhesives, but considering that one of the main application of the adhesives seems to be paper and packaging, the average life-time of the products are considered to be significantly shorter than for paint, and an emission factor of 5% for adhesives seems more adequate. The RAR does not estimate any releases to water for paint and adhesives. For painted surfaces there will be a release to waste water by washing of the painted surfaces for indoor applications or releases to soil and water for outdoor applications. In the absence of more specific information the releases will be assumed to be at 5% for releases to water and 2% for releases to soil. The releases to water and soil from the end-product use of adhesives are considered small and not further estimated.

Other non-polymer products - The releases from the use phase of grouting agents and other non-polymer products are not estimated in the RAR. In the absence of more detailed information the same emission factors as for paints are applied.

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, approx. 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 seems fair to accept that in reality all phthalates presented 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 DBP were measured (Kjølholt *et al.* 1994):

Flue gas: 0.54 - 9.2 µg/m^3
Clinker: 0.05 - 1.2 mg/kg
Fly ash: <0.05 - 1.0 mg/kg
Flue gas cleaning residue: 0.28 - 5 mg/kg
Waste water:<1.0 µg/l

The emission data were used for estimating the total releases of DBP from Danish incinerators in a Danish substance flow analysis for phthalates (Hoffmann 1996) and these data are used in the RAR 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 here 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 have 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 EU27 emission is on this basis estimated at 0.9 t/y (Table 2-12).

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

Table 2-11 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 not estimated as the analysis was below the detection limit and releases to waste water from incinerators are considered insignificant and not further discussed.

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

Landfilling

Municipal landfills are considered to release DBP mainly through leachate water (RAR). The amount of DBP discharged with leachate was estimated as 18 tonnes/year in the RAR based on a leachate rate of 0.25% of the total consumption. Based on measured leachate rates from Danish landfills, Hoffmann (1996) estimated the total DBP content of leachate from Danish landfills at 1.9 kg/year. Extrapolated to the EU27 on a per capita basis would give a total leachate of 0.18 t/year, a factor of 100 less than the estimates from the RAR. It illustrates well the uncertainty on these estimates.

The low leachate rate of DBP 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 DBP directed to landfill will be released from the landfill before it is ultimately degraded. In the absence of such data, the release rate from the RAR will be used, recalculated to reflect the decreased use of DBP 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 - 0.7 mg DBP/kg has been registered corresponding to a total quantity of 2.1 kg DBP 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 DBP directed to soil with compost may be roughly estimated as 2.1 kg * 488.5/5.3 corresponding to 0.2 tonnes DBP/year.

Waste water and sewage sludge

Reported measurements indicate that about 90% of DBP present in waste water will be removed by waste water treatment processes, mainly by degradation processes (Miljøstyrelsen 2004; Hoffmann 1996). However, some differences between treatment plants can be observed. Three series of measurements undertaken in Denmark covering waste water from a large mixed urban area, an industrial area and a mostly residential areal revealed reductions from approx. 67% to 98% with a calculated average of 84% (Hoffmann 1996).

Effluent concentrations <2 µg/l have been reported (Hoffmann 1996). Probably the concentrations differ between countries. Recent investigations from Denmark covering 213 measurements divided across 38 treatment plants from the years 2000-2003 indicates typical concentrations of 0.0 - 0.4 µg/l and an average of 0.1 µg/l (Miljøstyrelsen 2004).

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

In Denmark the amount of water emitted from municipal waste water treatment plant is registered 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 waste water treatment. The figure seems to correspond reasonably well with figures from other EU countries reported in (Eurostat 2001).

Assuming an average effluent concentration of 0.1 µg/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 the EU27 would give a total emission of DBP from waste water treatment plants to the aquatic environment of 6 tonnes/year. Compared to the quantities estimated to be directed to waste water from different processes of 317 tonnes the data is in agreement with the observations that the main part of the phthalates are removed by the treatment process.

Measurements from Denmark reported by Hoffmann (1996) indicate that 0.4-8.2% (average 3.4%) of the amount of DBP directed to waste water treatment will end up in sewage sludge.

Sludge concentrations between 0.03 and 1.2 mg DBP/kg DS have been reported (Hoffmann 1996). Based on the data reported the mean values would likely be in the range of 0.5-1.0 mg DBP/kg DS.

If it is assumed that some 3% of the DBP in the waste water ends up in sludge, the total amount in sludge would be around 10 tonnes per year.

About 32-35% of sewage sludge produced in 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 2-12 below. Compared to the releases during the use of the end-product the releases from waste disposal are small.

Table 2-12 Releases of DBP from main solid waste operations

	Tonnage (t/y)	Releases to the environment, t/y		
		Air	Soil	Waste water
Incineration	2,200	0.9	0.0	0
Landfilling	5,500	0.0	0.2	14
Total		0.9	0.2	14

3 Information on alternatives

3.1 *Identification of alternative substances and techniques*

3.1.1 Identification of alternative substances

Following the classification of DBP as toxic to reproduction (Repr. Cat. 2), DBP has been replaced by alternative substances for many applications, which is reflected in the steep decline in the total consumption of the substance as described in the previous chapter.

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

DBP is a specialist plasticiser often used in combination with other high molecular weight phthalates. In polymer applications it is a fast fusing plasticiser used as a gelling aid in combination with other plasticiser.

Alternatives may be considered at three levels:

- Alternative substances that have similar processing properties and provide similar end-product properties, i.e. fast fusing plasticisers that can be used in the same processes as DBP in combination with other plasticisers;

- Alternative plasticiser/polymer systems that can be used for production of end-products with the 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 DBP in different applications

When considering suitable alternatives, which 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.

Plasticisers are essentially selected to meet product end-use specifications (e.g. heat ageing properties of a flexible electrical cable) but also to meet industrial requirements.

As mentioned above, DBP is used for many different application areas, but it has been very difficult to obtain information on the specific applications. It has not been possible to identify alternatives that are specifically marketed as alternatives to DBP. The Annex XV dossier mentions a number of alternatives, but the alternatives mentioned generally have other properties than DBP and would not be suitable for directly substituting for DBP in specific processes.

Alternatives that can directly substitute for DBP have been searched for by request to major suppliers of plasticisers and Internet searches, but only limited information has been obtained.

DIBP- According to ECPI (2008b), Di-isobutyl phthalate (DIBP, CAS No 84-69-5) has application properties very similar to the properties of DBP and may therefore be used to substitute for DBP in most, if not all, of its applications. The application of DIBP ranges from the plasticisation of PVC to the production of paints, printing inks and adhesives. DIBP is, like DBP, a fast fusing plasticiser which by itself it is too volatile for PVC applications (BASF 2008b). It is frequently used as a gelling aid in combination with other plasticisers. It is used as plasticiser for nitrocellulose, cellulose ether, and polyacrylate and polyacetate dispersions. It is soluble in the usual organic solvents and is miscible and compatible with all of the monomeric plasticisers commonly used in PVC. DIBP is therefore selected for further assessment.

Glyceryl triacetate (GTA) - Glyceryl triacetate (CAS No 102-76-1) has been specifically suggested by Lanxess for this study as an alternative for DBP for various coatings and adhesives applications. Glyceryl triacetate is marketed for the solidification of acetyl cellulose fibres in the manufacture of cigarette filters, support for flavourings and essences in the food industry, as a plasticiser for chewing gum, a core sand binder in the metal foundry sector, inks and, plasticiser for cellulose-based plastics. (Lanxess 2008). Glyceryl triacetate (same as 1,2,3-propantriyl triacetate) was also specifically mentioned as an alternative to DBP in adhesives and sealants in a Danish assessment of alternatives to phthalates in non-PVC products (COWI 2000). The summary results of the assessment are shown in Table 3-1 below. No previous assessments of health and environmental properties of GTA used as DBP alternative have been identified.

Dibenzoates - According to ECPI's comments on the Annex XV dossier for DBP, benzoates can in combination with DINP substitute for DBP in certain applications such as PVC flooring. Many dibenzoate plasticisers are marketed as substance blends.

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

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

Applications	Genovique Product 1	Genovique Product 2	Bulk Pricing compared to DBP
Floor covering (vinyl flooring)	Benzoflex 2088	Benzoflex 9-88	Slightly higher
Gelling additive	Benzoflex 2088	Benzoflex 9-88	Slightly higher
Adhesives	Benzoflex LA-705	Benzoflex 2088	Slightly higher
Dispersions	Benzoflex 2088	Benzoflex 9-88	Slightly higher
Nitrocellulose	Benzoflex 2088	Benzoflex 9-88	Slightly higher

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

Dibenzoates were specifically mentioned as alternatives to DBP in adhesives and 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 below.

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.

An environmental and health assessment of DGD was conducted 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 an alternative 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.

DINCH - Di-(isononyl)-cyclohexan-1,2-dicarboxylate (DINCH) has been designed as an alternative to phthalate plasticisers. DINCH has a wide range of applications. Of relevance as a DBP alternative, DINCH can be applied in thermoplastics and polar rubbers, coatings and printing inks, dispersions and adhesives (BASF 2008c). The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has assessed DINCH among a number of alternatives to DEHP for use in medical devices and among these (SCENIHR 2008). DINCH has been selected for further assessment here.

Other alternatives - For non-PVC applications COWI (2000) identified 21 alternatives to phthalates (not only DBP) and set up a substitution matrix indicating which substances may be suitable for substituting for phthalates in different applications (Table 3-2). New substances may have been marketed since then, but most substances on the list are still marketed as plasticisers. For adhesives, the study specifically mention that DBT was the main phthalate used and the study concerned alternatives to the use of DBT in the adhesives. For adhesives, besides the dibenzoates and GTA (1,2,3-propantriyl triacetate in the table), the study identified 2,2,4-trimethyl 1,3-pentandiol di-isobutyrate, diphenyl-2-ethylheyl phosphate, Di-isononyl adipate and di-(2-ethylhexyl) adipates. For other applications, where DBP may be used as well as other phthalates, the study identified a number of other alternatives. It has been beyond the limits of the present study to assess all possible alternatives to DBP, and some selected alternatives for major application areas proposed by market actors are included in the assessment.

One non-polymer application of DBP for which substitution is particularly difficult is included in the confidential part of this report.

Table 3-2 Indentified 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
Tricresylphosphate (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 DBP with another plasticiser, end-products may be produced using other plasticiser/polymer systems. PVC flooring and garden hoses, for example, are mainly produced without using DBP, although the process conditions may be different. For the individual manufacturer using DBP it may imply major changes in processing conditions and tools and be very expensive to replace DBP. But end-products produced using other plasticisers are widely marketed and may not necessarily be much more expensive. It has not been possible to identify any use of DBP in polymers, where the final product has properties that cannot be met by similar products containing other plasticisers. As it has not been possible to identify all specific applications of DBP, it cannot be excluded that some very special applications exist for which the technical properties of the end-product with other plasticisers cannot match the properties of products containing DBP.

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 products, medical devices, food packaging and water mattresses. Alternatives marketed specifically for these products groups includes among others adipates, citrates, carboxylates, alkylsulphonic acid ester and castor oil derivatives. The alternatives are mainly used as alternatives to DEHP, and an assessment of selected alternatives is included in the sister report on DEHP (ECHA 2008c). For some specific applications of DBP in polymer end-products, the alternatives to DEHP may also be considered alternatives to end-products containing DBP, although the introduction of the alternative may imply process changes.

Substances selected for further assessment
The available assessments show that a number of potential alternatives to DBP exist for application in different application areas. None of the alternatives have undergone a comprehensive environmental and health assessment combined with an assessment of the economic and technical feasibility of substitution.

It has not been possible to make a comprehensive assessment of all substances within this study and, for this reason, a limited number of substances has been selected, representing some of the most used alternatives. The rejection of some substances for the further assessment does not indicate that these substances would not be suitable and acceptable alternatives to DEHP.

The following substances are selected for the more detailed assessment:

- Di-isobutyl phthalate (DIBP); CAS N^o 84-69-5;
- Di-isononyl phthalate (DINP); CAS N^o 28553-12-0;
- Di-(iso-nonyl)-cyclohexan-1,2-dicarboxylate (DINCH); CAS N^o 166412-78-8;
- Glyceryl triacetate (GTA); CAS N^o 102-76-1;
- Dipropylene glycol dibenzoate (DGD); CAS N^o 27138-31-4.

3.1.2 Identification of alternative techniques

For some polymer applications, the polymer with DBP may be replaced by a totally different material. Of the described applications of DBP this may in particularly be relevant for flooring.

In a recent American study, the Toxics Use Reduction Institute (TURI 2006) investigated alternative materials to DEHP/PVC flooring and the conclusions may also be relevant for material alternatives to DBP-containing flooring. The Institute identified and assessed in detail three material alternatives to DEHP/PVC in resilient flooring based on an initial screening of five materials. 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 evaluation of alternatives materials is further described in the sister report on DEHP (ECHA 2008c).

For the non-polymer uses, alternative techniques are in general not considered relevant. Nitrocellulose lacquers with DBP may e.g. be replaced by a lacquer based on another resin and plasticiser, but this will not be considered an alternative technique and would be included in the previous section.

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 have 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 Di-isobutyl phthalate (DIBP)

NICNAS (2007) have recently reviewed the toxicity of DIBP and the following review is based on their report.

DIBP appears to be readily absorbed via the dermal route. It undergoes primary metabolism into the hydrolytic monoester, MIBP, before excretion. Urine was the major route of excretion with minor biliary excretion being observed. There was little accumulation in the rat tissues.

Acute toxicity - DIBP has a low order of acute toxicity by the oral, intraperitoneal and dermal route.

Skin irritation - DIBP is reported to cause minimal skin irritation in guinea pigs. No eye irritation or skin sensitisation has been observed in animals but the available information is limited.

A 4-month repeated dose toxicity study reported low body and testes weights and increased liver weights in rats with a 5% diet (doses in mg/kg bw not provided in source study). The NOAEL was 1% in diet. DIBP was not mutagenic in bacterial mutation assays but there is evidence that it induced DNA damage in human cells *in vitro*. No *in vitro* chromosomal aberrations, mammalian mutation and *in vivo* genotoxicity studies are available. Overall, the genotoxic potential of DIBP cannot be determined.

No carcinogenicity data are available for DIBP. Due to insufficient testing on other phthalates, it is not possible to extrapolate carcinogenic potential for DIBP.

Reproductive toxicity - With respect to reproductive toxicity, DIBP induced decreased body weight after 1 week oral dosing in rats and mice as well as effects on testis weight and testosterone content (Oishi & Hiraga, 1980 b; c – cited by NICNAS). Relative testes weight was increased in mice and decreased in rats while testicular testosterone content was decreased in both species. Similar results were obtained when rats and mice were fed diets containing MIBP (Oishi & Hiraga, 1980 a; d cited by NICNAS). A NOAEL was not established in any of the animal studies.

Development toxicity - Limited developmental toxicity studies are available. Oral exposure to DIBP during gestation was associated with complete loss of litters at maternally toxic doses. At lower doses, DIBP induced decreased foetal weight and increased incidence of undescended testes (Saillenfait et al., 2006) and in male foetuses at term decreased testicular testosterone production *ex vivo* and testosterone levels in testes and plasma, decreased AGD, and induced pathological changes in the testes including clustering of small Leydig cells and vacuolisation of Sertoli cells (Borch et al., 2005 - cited by NICNAS). The NOAEL was 250 mg/kg bw/day based on decreased pup weight and increased incidence of undescended testes (Saillenfait et al., 2006 cited by NICNAS).

A recent human study (Swan et al. 2005 - cited by SCENIHR) showed urinary DIBP concentration was inversely related to anogenital index (AGI) (i.e. anogenital distance normalized for body weight) in male children. However, multiple exposures to different phthalates may have contributed to this effect. In addition, the reliability of endpoint measured, anogenital index, has not been verified in humans. Although data for DIBP are limited, the fertility and developmental effects observed are similar to those phthalates with side chain backbone of carbon side chains of 4-6 carbon atoms in length (C4-6) (NICNAS, 2007). These C4-6 phthalates previously referred to as ‘transitional’ phthalates (Phthalate Esters Panel HPV Testing Group, 2001 - cited by NICNAS) have also been associated with male reproductive (decreased in testicular testosterone production) and developmental (decreased anogenital distance and pathological changes in the testes) effects. Therefore, it could be argued that DIBP has a similar reproductive toxicity profile to ‘transitional’ (C4-6) phthalates for which reproductive and developmental effects are recognised.

Table 3-3 Human health effects of Di-isobutyl phthalate

Name of substance	Di-isobutyl phthalate	
Abbreviation	DIBP	
CAS No.	84-69-5	
Endpoint	Value	Reference
LD_{50}	16000-60320 mg/kg	NICNAS 2007
NOAEL mg/kg bw		
Reproductive toxicity Effects on male fertility	1000 mg/kg/day	NICNAS 2007
Repeated dose Toxicity, NOAEL	1% in diet	NICNAS 2007
Developmental Toxicity NOAEL	250 mg/kg/day (rat)	Saillenfait 2006
Genotoxicity	Insufficient data	NICNAS 2007
Carcinogenicity	Insufficient data	NICNAS 2007
Maternal toxicity	NOAEL 250 (rat)	NICNAS 2007
Critical endpoint	Developmental toxicity	Dose: 250 mg/kg/day - rat
Preliminary DNELs	DNEL for critical endpoint, mg/kg/day	Remarks
Workers, oral	350 mg/day	Default assessment factors
General population, oral	175 mg/day	
Workers, inhalation	35 mgm^{-3}	
General population, inhalation	8.75 mgm^{-3}	

3.2.2 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 the dog 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 cited in DINP RAR)) 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 applied 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 3-4 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}	

3.2.3 Di-(isononyl)-cyclohexan-1,2-dicarboxylate (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 day 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 3-5 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}	

3.2.4 Glyceryl triacetate (GTA, triacetin)

The toxicity information in this section is primarily derived from the OECD SIDS (UNEP 2002) and the IUCLID data sheet (IUCLID 2000). As the SIDS document contains more details in the dossier section and especially in the section with robust study summaries this information is used as the primary source for studies referred to in both documents. Other supporting information largely refers to the same studies as reported in IUCLID and OECD SIDS.

Acute toxicity - Triacetin has low acute toxicity. A limit dose study in male and female rats according to OECD TG 401 and GLP demonstrated that the oral LD50 was > 2000 mg/kg bw (UNEP 2002), Triacetin). No signs of toxicity were observed during the observation period. Other studies that are less well documented show higher LD_{50} values but no studies at dose levels producing adverse effects have been identified. Dermal LD_{50} in rabbits and guinea pigs were determined to be > 2000 mg/kg bw. No information is available on the test protocols used. Acute inhalation toxicity (LC_{50}) in male and female rats was determined to be 1,721 mg/m^3 in a study according to OECD TG 403. No clinical symptoms were observed.

Irritation - Triacetin was not irritating to rabbit skin in a test performed according to OECD TG 404 and GLP and was also not irritating to eyes in a study performed according to OECD TG 405 and GLP. Only very mild skin reactions were observed in 20 human volunteers exposed (24 hours occl. skin contact) to a 50% solution of triacetin (IUCLID 2000; Triacetin). Another group of 33 volunteers exposed during a maximisation test to a 20% solution of triacetin showed no skin reactions (UNEP 2002).

Sensitising properties - Triacetin did not induce skin sensitisation in a maximisation test exposing 33 human volunteers to a 20% solution of triacetin in petrolatum (UNEP 2002). One case report of contact eczema in a female patient based on sensitisation towards triacetin in a cigarette factory is reported (UNEP 2002).

Repeated dose toxicity - In a combined repeat dose and reproductive/developmental toxicity screening test (OECD TG 422 and GLP) groups of rats received doses of 0, 40, 200, and 1,000 mg/kg bw/day by oral gavage for 44 days starting 2 weeks prior to mating for males and 41-48 days starting 14 days prior to mating to day 3 postpartum for females. Based on the study it was concluded that triacetin had no effects on clinical signs, body weight, food consumption, and organ weight or necropsy findings. Triacetin did not induce histopathological changes in either sex or effects on haematological or blood chemical parameters in males. A NOAEL was established at 1,000 mg/kg bw/day for both sexes (UNEP 2002).

In a 90 days feeding study male rats tolerated up to 20 % triacetin in the diet corresponding to 10 g/kg bw/day. The NOAEL for the feeding study was considered to be 10 g/kg bw/day for male rats.

In a 90 days vapour inhalation toxicity study (from 1955, non GLP), rats were exposed to an average dose of 249 ppm (2,220 mg/m^3) for six hours every working day. It is not quite clear whether the test was conducted in both male and female rats or in males only. In the dossier information in UNEP SIDS (UNEP, 2002) it is indicated that the test is conducted in males only but the robust study summary indicates that no information is available regarding sex of the test animals. Exposure produced no treatment-related clinical signs or effects on body weight, haematology, urine parameters, organ weight, or histopathology. A NOAEL was established at 249 ppm (2,220 mg/m^3) for (male) rats.

Other studies are available but are not considered relevant as they are not conforming to GLP and currently approved test methods.

Mutagenicity - Triacetin did not induce gene mutations at concentrations up to 5,000 µg/plate in an in vitro bacterial reverse mutation assay (OECD TG 471 and 472 and GLP) in *S. typhimurium* and *E. coli* with and without metabolic activation. Several other in vitro bacterial (and yeast) reverse mutation assays show negative results (UNEP 2002).

An in vitro mammalian chromosome aberration test (OECD TG 473 and GLP) in Chinese hamster lung cells was conducted with and without metabolic activation at concentrations of 0, 0.55, 1.1 and 2.2 mg/mL (UNEP 2002). Chromosomal aberration was observed at 2.2 mg/mL (10 mM) with metabolic activation but not considered biological relevant due to the lowered pH of the medium caused by triacetin. It is reported that increased frequency of chromosomal aberrations is a recognised artifact induced by changes in pH. Triacetin did not induce polyploidy and was not considered genotoxic.

Carcinogenicity - No carcinogenicity studies have been identified.

Reproductive toxicity - In the combined repeat dose and reproductive/developmental toxicity screening test (OECD TG 422 and GLP) in rats dosed at 0, 40, 200, and 1,000 mg/kg bw/day by oral gavage, no maternal or foetal toxicity or adverse effects on reproductive parameters were observed. Reproductive parameters included mating index, fertility index, gestation length, numbers of corpora lutea and implantations, implantation index, gestation index, delivery index, parturition and maternal behaviour at delivery and lactation. The NOAEL for fertility and maternal toxicity is considered to be 1,000 mg/kg bw/day (UNEP 2002).

Examination of neonates showed no significant differences in number of offspring or live offspring, the sex ratio, the live birth index the viability index, or body weight compared to the control group. No developmental toxicity, clinical signs of toxicity or abnormal necropsy findings were found in the offspring. The NOAEL for developmental toxicity is considered to be 1,000 mg/kg bw/day (UNEP 2002).

Table 3-6 Human health effects of glyceryl triacetate

Name of substance	Glyceryl triacetate, triacetin	
Abbreviation	GTA	
CAS No.	102-76-1	
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	> 2000 mg/kg (limit dose, gavage)	IUCLID (2000)
LD_{50} (dermal, rabbit)	> 2000 mg/kg (from MSDS)	UNEP (2002)
LC_{50} (inhal, rat)	> 1721 mg/L	UNEP (2002)
Endpoint	NOAEL mg/kg bw	Reference
Reproductive toxicity	1000 mg/kg bw/day	UNEP (2002)
Developmental toxicity	1000 mg/kg bw/day	UNEP (2002)
Maternal toxicity	1000 mg/kg bw/day	UNEP (2002)
Repeated dose toxicity,		
NOAEL oral gavage	1000 mg/kg bw/day	UNEP (2002)
NOAEL inhalation	2,220 mg/m3	UNEP (2002)
Genotoxicity	Considered negative	UNEP (2002)
Carcinogenicity	No data	-
Critical endpoint		
Preliminary DNELs	DNEL for critical endpoint, mg/kg/day	Remarks
Workers, oral	1,400 mg/day	Default assessment factors
General population, oral	700 mg/day	
Workers, inhalation	141.05 mg/m^3	
General population, inhalation	34.78 mg/m^3	

3.2.5 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 3-7 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	

3.2.6 Summary for health effects

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

Table 3-8 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}
DIBP	84-69-5	Developmental	350	35	175	9
DINP	28553-12-0	Developmental	44	4	22	1
DINCH	166412-78-8	Kidney toxicity	75	8	38	2
GTA	102-76-1	Reproductive toxicity	1,400	141	700	35
DGD	27138-31-4	Developmental	700	71	350	17

3.3 *Environmental effects*

This section provides a review of the environmental hazards and risks associated with the selected alternative substances. 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 Di-isobutyl phthalate (DIBP)

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

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[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 3-9 Hazard properties for DIBP

Name of substance	Di-isobutyl phthalate	
Abbreviation	DIBP	
CAS No.	84-69-5	
Classification	Not included in Annex I of Directive 67/548/EEC Included on working database (agreed in 2006): ▪ Classification = Repr. Cat. 2; R61 Repr. Cat. 3; R62 ▪ R61 = May cause harm to the unborn child ▪ R62 = Possible risk of impaired fertility	
Compartment	Hazard / risk conclusions	Reference
Water	96h LC50 = 2500 – 3600 µg/l (crustacea) 730 – 1100 µg/l (fish)	Ecotox (2008), DOSE (2005)
Sediment	Unknown	
Soil	Unknown	
Atmosphere	Unknown	
STP	Unknown	
Secondary poisoning	Unknown	
Bioaccumulation	Estimated BCF = 800	HSDB (2008)
Persistence	"Phthalate esters undergo ≧ 50% ultimate degradation within 28 days in standardised aerobic biodegradation tests with sewage sludge inocula. Biodegradation is expected to be the dominant loss mechanism in surface water, soils and sediments"	DOSE (2005)
Risk assessment conclusions	None identified	

3.3.2 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 3-10 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)

3.3.3 Di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH)

The table below describes the environmental hazard properties of DINCH.

Table 3-11 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	

3.3.4 Glyceryl triacetate (GTA)

The table below describes the environmental hazard properties of GTA. No EU or similar comprehensive environmental risk assessment report exists, but SIDS documents do.

The OECD SIDS (OECD 2008) is updated regularly and was found to contain at least the same data as the ECB IUCLID document and the UNEP SIDS (all accessed via the OECD eChemPortal), and therefore the OECD document is used as general data reference.

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

Table 3-12 Hazard properties for GTA (triacetin)

Name of substance	Glyceryl triacetate (triacetin)	
Abbreviation	GTA	
CAS No.	102-76-1	
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; *O. latipes*) >100 mg/l LC50, 96 h (fish; *P. promelas*) = 165 mg/l LC50, 14 d (fish; *O. latipes*) >100 mg/l Other test results on fish support the above but are slightly less sensitive. EC50, 48 h (*D. magna*) = 380 mg/l NOEC, 21 d (*D. magna*) = 100 mg/l EC50, 72 h (*P. subcapitata*) >1000 mg/l NOEC, 72 h (*P. subcapitata*) = 556 mg/l	OECD (2008) OECD (2008) OECD (2008) OECD (2008) OECD (2008) OECD (2008)
Sediment	Unknown	
Soil	Unknown	
Atmosphere	50% photodegradation in 2 days Fugacity level III model calculations show that only 0.9% of GTA emitted to air will remain in the atmosphere.	OECD (2008) OECD (2008)
STP	NOEC, 16 h (*Pseudomonas putida*) = 3000 mg/l NOEC, 18 h (*P. putida*) >541.6 mg/l	OECD (2008)
Secondary poisoning	Based on the low BCF and that GTA is readily biodegradable, it is assessed that the risk of secondary poisoning is negligible.	
Bioaccumulation	Log Pow = 0.21 BCF = 2.1 (calculated)	OECD (2008)
Persistence	97 % degradation in 28 days measured as TOC, i.e. the substance is readily biodegradable. Biodegradation = 77% after 14 d based on BOD; 93% after 28 days based on $ThCO_2$ and 79% after 30 days based on BOD, i.e. ready biodegradability. Hydrolysis 25 deg. C); Half life at pH 7 = 60.4 days and half life at pH 9 = 16.5 hours.	NITE (2009) OECD (2008) OECD (2008)
Risk assessment conclusions	None identified. "The chemical is currently of low priority for further work because of its low hazard potential."	UNEP (2002)

3.3.5 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 would 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.

Table 3-13 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_r50 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	Half life 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 half life 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.

3.3.6 Summary for environmental effects

With regard to potential environmental hazards and risks of the investigated alternatives to DBP, 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 of the data) 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:

- 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).

- 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.

- GTA is easily biodegradable and does not have bioaccumulative properties. The toxicity to aquatic organisms is considered to be low. In conclusion, from an environmental point of view, GTA may be an acceptable alternative based on the available data.

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 DBP for different applications depends on a range of performance criteria, including inter alia material compatibility, temperature performance, volatility, migration and permanence of the alternative 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.

DBP seems for polymer applications mainly to serve as processing aid.

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

DBP has in recent years been extensively replaced by other plasticisers for a number of applications, and a range of alternatives are available from suppliers of plasticisers.

The five selected alternatives used for the present environmental, health and technical assessment are all today marketed for a number of applications shown in Table 3-14. Note that DINP may not substitute for DBP in itself but together with a dibenzoate plasticiser. Some of the applications mentioned may not be relevant in a DBP context, as DBP has not typically been used for the applications e.g. toys and medical devices. 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.

Table 3-14 Applications specifically mentioned by suppliers of selected alternatives relevant in DBP context

	DIBP	DINP	DINCH	GTA *1	DGD
Floor covering	x	x			x
Gelling additive	x				x
Non polymer applications:					
Adhesives	x		x		x
Dispersions	Nitrocellulose, cellulose ether, and polyacrylate and polyacetate dispersions		Dispersions		x
Nitrocellulose					x

Information sources:

DIBP	PALATINOL® IC from BASF http://www.plasticizers.basf.com/icms/basf_1/en/dt.jsp?setCursor=1_214171
DINP	Jayflex ® from ExxonMobil Chemical http://www.exxonmobilchemical.com/Public_Files/Oxo/Plasticisers/Worldwide/jayflex_broch_EN.pdf
DINCH	HEXAMOLL® DINCH from BASF. http://www.hexamoll.com/icms/basf_6/en/dt.jsp
DGD	Covered by different BENZOFLEX types. Contain also other dibenzoates http://www.genovique.com/cms.aspx?TabID=29
GTA *1	Not specifically indicated on website but indicated by Lanxess for this study as alternative to DBP in adhesives and dispersions.

Noting that the price of a possible alternative may be one of the main determining factors for substituting DBP in all major applications, the assessment will focus on the costs of substitution.

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

The price of DIBP is indicated by BASF to be similar to the price of DBP. The price of dibenzoate plasticiser (containing DGD) is indicated by Genovique to be slightly higher than DBP.

Price estimates for the other alternatives have not been obtained.

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Annex 1: Applied emission factors

Table A-1 Applied emission factors for DBP releases from manufacturing

Emissions based on actual reporting from manufacturers

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

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Formulation of paint	n.d.	0.25	0.01	0.3	n.d.
Formulation of adhesives	n.d.	0.25	0.01	0.3	n.d.
Formulation of grouting agents	n.d.	0.05	0.01	0.001	n.d.
Formulation of other non-polymeric	n.d.	n.d.	n.d.	n.d.	n.d.

n.d. no data

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

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Polymers formulation and processing	n.d.	0.110	0	0.110	n.d.
Formulation and processing of fiber glass	n.d.	0.07	0	0.33	n.d.
Non-polymeric, processing:					
Processing of paint	n.d.	0.01	0.5	0.1	n.d.
Processing of adhesives	n.d.	0.01	0.5	0.1	n.d.
Processing of grouting agents	n.d.	0.1	0	0.16	n.d.
Processing of other non-polymeric	n.d.	n.d.	n.d.	n.d.	n.d.

n.d. no data

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

Application	Emission factor, %			
	Air	Soil	Waste water	Waste
Polymers (incl. fiber glass), interior use	0.1	0	3.1	97
Polymers (incl. fiber glass), exterior use	0.1	2.4	2.4	95
Non polymer applications:				
Paint	15	0	5	80
Adhesives	5	2	5	88
Grouting agents	5	2	5	88
Other non-polymeric	5	2	5	88

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 di-butyl phthalate (DBP) 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**
Filling materials (see also Fillers; Insulation materials)	0.2	0.2	0.2	2.7	1.3	1.3	50.2
Other filling materials					47.8	47.8	
Hardeners					1.7	1.7	28.6
Hardeners for filling materials					1.5	1.6	
Hardeners for Paint- and lacquers					0.5	0.5	
Adhesive hardeners					0.7	1.1	
Plastic hardeners					5.4	5.4	
Flooring materials (joint-less floors)		0.1	0.1	18.3	18.9	19.0	19.0
Binding agents - for binding together the individual constituents in the product	9.1	1.4	0.8	21.1			
Binding agents (see also Adhesives)					9.7	9.7	21.7
Binding agents for paints, adhesives etc.					3.6		
Other binding agents						8.1	
Binding agents for paints, adhesives etc.						3.6	
Construction materials (building materials)	0.0			8.5			8.3
Casting materials	0.5	0.1	0.1	3.3	4.2	4.3	6.1
Surface treatment for non-metals	0.0	0.1	0.1	1.7	1.7	1.7	1.7
Polishing agents	0.2	0.2	0.2	0.6			1.2
Cleaning/washing agents	0.0			0.2			0.4
Other cleaning/washing agents						0.1	
Electric and electromechanical components				0.0			0.0
Paint, lacquers and varnishes	64.7	69.4	67.0	29.0	4.2	4.3	63.4

DENMARK Product group (continued)	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Other paint, lacquers and varnishes					23.6	23.6	
Wax and other polishing preparations for floors					0.4	0.6	
Printing inks	0.7	0.9	0.1	0.7	0.3	0.3	102.0
Aniline printing inks					2.0	4.8	
Serigraphy inks					0.2	0.2	
Adhesives	0.0	0.0	0.0	4.4	0.2	0.2	16.8
Other adhesives					11.4	11.8	
Dispersion adhesives					1.0	1.0	
Additives for printing inks					0.1	0.1	
Protection lacquers					0.1	0.1	
Padding materials					0.1	0.1	
Corrosion inhibitors (anti-corrosion materials)	3.9	0.1	0.1	0.2	0.1	0.1	0.7
Anticorrosive paints					0.0		
Resins for 1- and 2-comp. hardening adhesives					3.3	3.3	
Underseal materials, incl. cavity seals					0.2	0.2	
Stopping material					0.1	0.1	
Primer					3.7	3.7	
Curing agents	1.7	2.0	2.0	5.9			

Table A2-2 Use of di-butyl phthalate (DBP) 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
Adhesives Water based Industrial use	83	99		111				
Adhesives Based on organic thinners Industrial use				3				
Adhesives Water based Consumer use		1		1				
Adhesives No thinner Industrial use				0				
Adhesives (solvent-based)						0		
Adhesives, glues						1	1	1
Raw materials for production of plastics	4	3	2	4	2			
Curing agents for plastic	1	1	0	6	3			
Paint and varnish Hardeners to paint and varnish Decorative/protection Industrial use	2	1	1					
Paint and varnish Volatile organic thinner Decorative/protection Industrial use	1	1	1	1				
Paint and varnish Volatile organic thinner Decorative/protection Interior					3			
Paint and varnish Volatile organic thinner Decorative/protection Other (including ship-, road-, art-,furniture-, autopaint)					2			
Paint and varnish Volatile organic thinner Active corrosion inhibitor Industrial use	0	0	0	0				
Paint and varnish Volatile organic thinner Active corrosion inhibitor Other (including ship-, road-, art-,furniture-, autopaint)					0			
Moulding compounds	0	0	0	0	0			
Wax and other polishing preparations for floors			0	0	0			
Other polishing agents				0	0			
None indicated *(code L10110)			99					

SWEDEN Product group (continued)	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y	1999 t/y
Stopping material				0	0			
Tightening materials (putty)				0	1			0
Dispersion adhesives						76	81	76
Hardeners for plastics						8	7	9
Paints, varnishes						3	4	3
Printing inks						1	4	4
Other paints and varnishes, solvent-based						4	3	9
Binders (for other products)						2	2	2
Intermediates (plastics manufacture)						2	2	3
Polishing agents						1	1	1
Sealing compounds						1	3	2
Dyestuffs, pigments						2	2	2
Fillers (plastics, paint etc)						0	0	0
Cast compounds						0	0	2
Other paints, aqueous						0	1	1
Hardeners (1- and 2-component adhesives)						0	1	1
Hardeners for paints						0	0	0
Anti-corrosive paints						0	0	0
Intermediates, raw material						0	0	0
Metal surface treatment agents						0	0	
Floor covering materials							0	0
Cleaning agents							0	0

Table A2-3 Use of di-butyl phthalate (DBP) 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**
Printing inks				0.6	0.9	19.1	17.8
Paint, lacquers and varnishes				2.2	4.5	6.7	5.5
Paint and varnish Volatile organic thinner Decorative/protection Other (including ship-, road-, art-,furniture-, autopaint)		0.0	0.0				
Paint and varnish Volatile organic thinner Decorative/protection Industrial use	1.3	1.5	1.7				
Filling agents & materials (see also Fillers; Insulation materials)				2.9	3.7	5.0	5.4
Adhesives (see also Binding agents)				3.6	3.2	2.6	4.6
Binding agents - for binding together the individual constituents in the produc (incl. for paints, adhesives etc.) see also adhesives	0.7		0.1	3.1		4.3	4.0
Hardeners						2.1	3.0
Curing agents				1.0	1.2		
Cement/concrete/mortar		0.0	0.1				
Flooring materials (joint-less floors)		1.0	1.2	1.3	1.2		
Construction materials (building materials)				0.1	0.1		
Anti-corrosion materials				0.0	0.0	0.1	

Table A2-4 **Use of di-butyl phthalate (DBP) 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**
Plastic additives and auxiliaries							n.a.
Activators							
Corrosion inhibitors						n.a.	n.a.
Pharmaceuticals						n.a.	
Protective chemicals							n.a.
Laboratory chemicals							n.a.
Lubricants						n.a.	
Vulcanizers							n.a.
Catalysts							n.a.
Cleaning and washing agents						n.a.	n.a.
Dyeing auxiliaries						n.a.	
Dyestuff, pigments						n.a.	n.a.
Building materials and additives							n.a.
Leather impregnating agents							n.a.
Adhesive and binding materials							n.a.

ANNEX 3: CONFIDENTIAL INFORMATION

[Not included in published report]