DATA ON MANUFACTURE, IMPORT, EXPORT, USES AND RELEASES OF BIS(2-ETHYLHEXYL)PHTHALATE (DEHP) AS WELL AS INFORMATION ON POTENTIAL ALTERNATIVES TO ITS USE

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

Revised version of 29 January 2009

PREFACE

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

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 manufacture, import, export, uses and releases of DEHP as well as information on the properties and risks of alternative substances and techniques.

The information provided will support ECHA in:

- setting priority of substances on the candidate list for inclusion in Annex XIV;

- defining the conditions related to the entries on Annex XIV such as described in article 58 of the Regulation.

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

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

TABLE OF CONTENT

Executive summary

Di(2-ethylhexyl) phthalate (hereafter referred to as DEHP) is widely used as a plasticiser in polymer products, mainly PVC. DEHP is one of a number of substances used as plasticiser in PVC and other polymer materials. The content of DEHP in flexible polymer materials varies, but is often around 30% (w/w).

DEHP is a cost-effective, general purpose plasticiser used in an range of products including flooring, roofing, cables, profiles and medical products such as blood bags and dialysis equipment.

Figure 0-1 illustrates the fate of the DEHP 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 DEHP accumulated in society and would probably be higher, as the amount of DEHP sent into circulation has been decreasing in recent years.

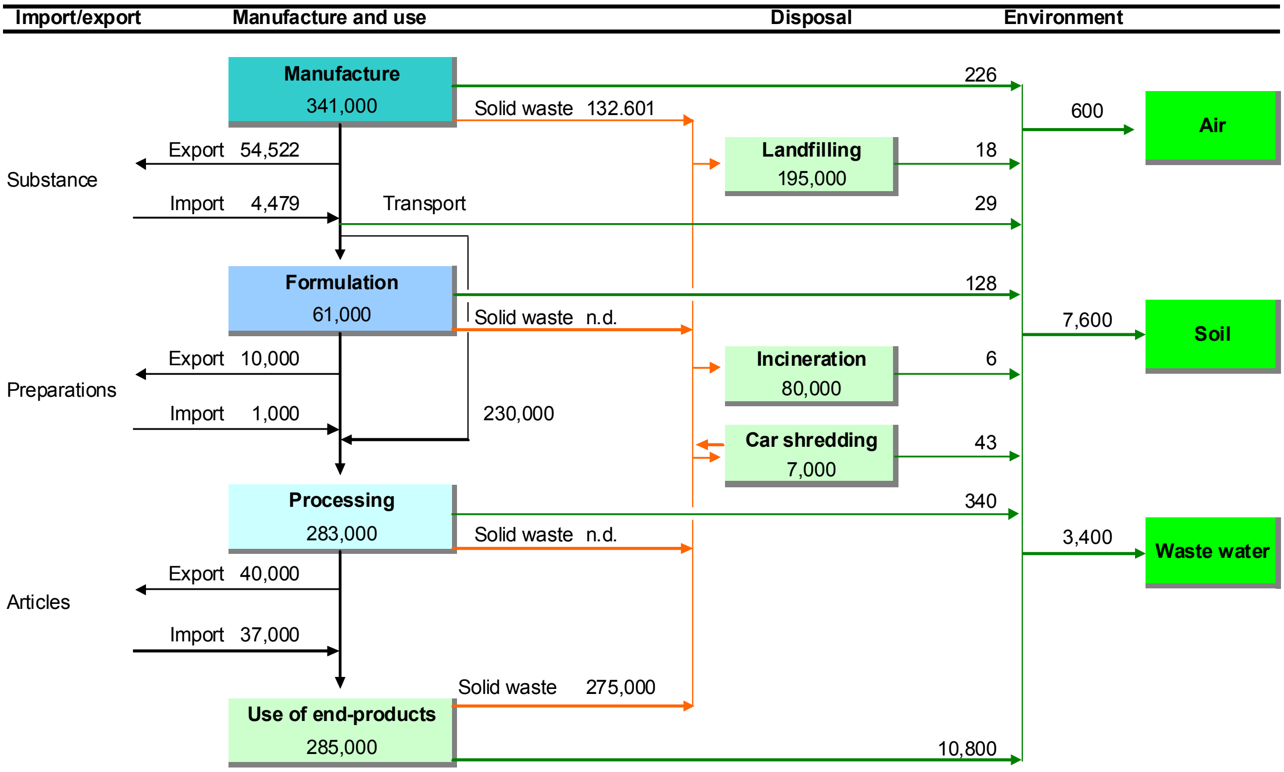

Figure 0-1 Overall flow of DEHP sent into circulation in EU society in 2007. Tonnes DEHP/year

According to information retrieved from all the seven manufacturers of DEHP in the EU, the total manufactured volume in 2007 was 341,000 tonnes; of this 187,000 tonnes was manufactured in Western Europe. The market for DEHP has been decreasing over the last decade. In 1997, the total Western European manufacture of DEHP was 595,000 tonnes, and the total manufacture in the countries included in the present

EU27 was probably significantly higher. Three of the seven present manufacturers of DEHP in the EU are situated in Member States that joined the EU in the past decade.

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

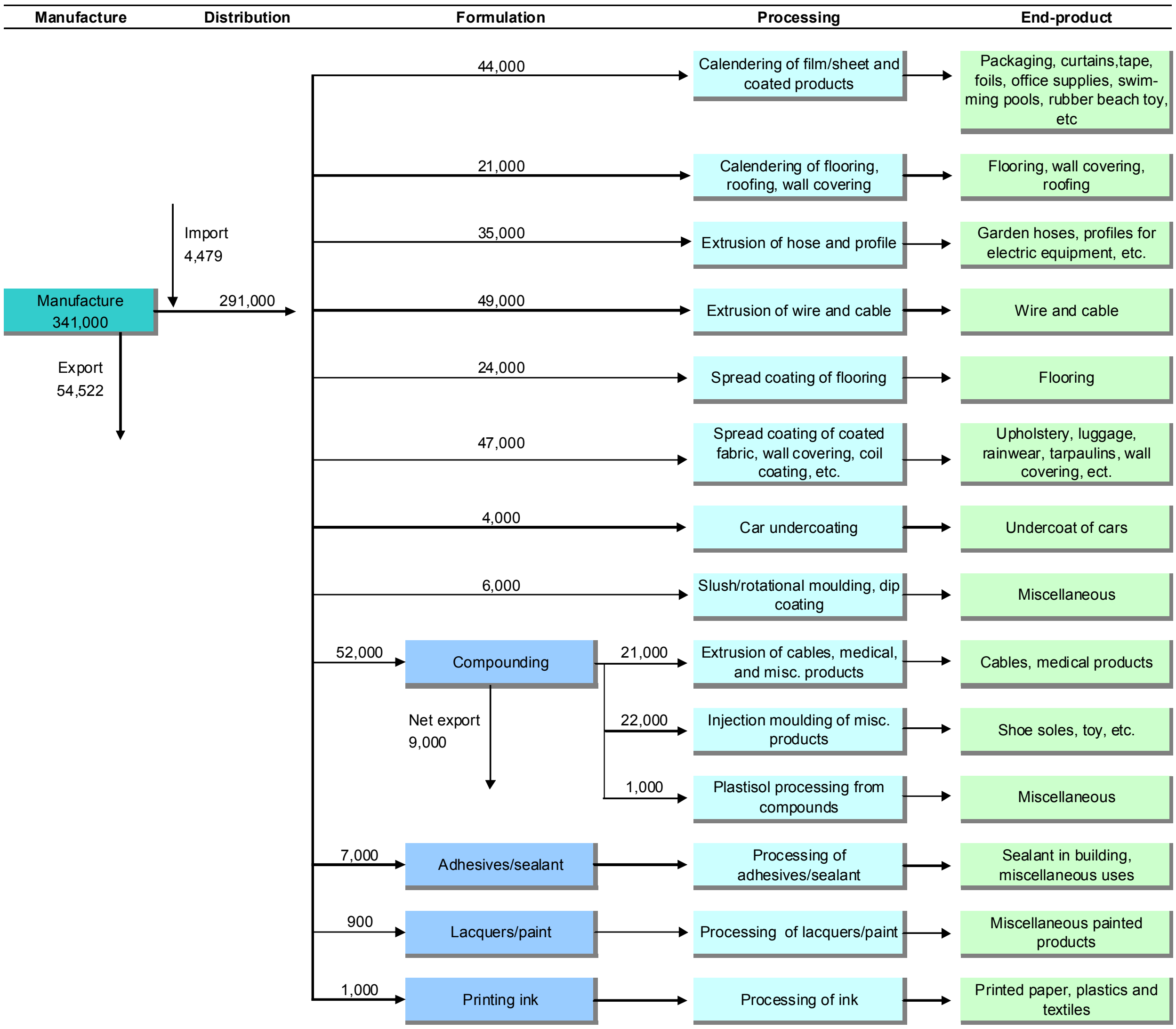

Figure 0-2 Overall flow of DEHP through manufacturing processes. Tonnes DEHP/year

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 DEHP published in 2008. The main releases are to soil and waste water. The use of end-products gives rise to the largest releases to the environment with washing of flooring, releases from underground cables and abrasive releases and pieces lost in the environment as the largest single sources. The releases from landfill may in fact be higher than indicated if total releases until the DEHP is ultimately degraded is considered, but no data on the long term fate of DEHP in landfills have been made available.

Table 0-1 Tonnage handled and releases of DEHP from manufacturing, formulation, processing, end-products use and disposal in the EU in 2007

Activity	Tonnage handled	Emission to (t/y):		
	t/y	Air	Soil	Waste water
EU manufacture of DEHP	341,000	1	4	220
Transportation of substance from manufacturing *1	345,479	0	0	29
Formulation	61,000	30	1	97
Processing	283,000	174	41	125
End-product uses, indoor	223,000	380	0	1,240
End-product uses, outdoor, non-abrasive leakages	33,000	30	3,980	500
End-product uses, outdoor, abrasive leakages	33,000	5	3,500	1,200
Disposal and recycling operations	275,133	9	48	10
Total releases (round)		600	7,600	3,400

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

The decrease in production volumes in recent years reflects the fact that DEHP for many applications has been replaced by other substances, primarily di-isononyl phthalate (DINP). A number of previous assessments of, in total, 18 potential alternative substances have been reviewed and, on this basis, five alternatives were selected for further assessment in this study. The rejection of some of the other alternatives for further assessment does not imply that they would not be feasible and acceptable alternatives, but it has only been possible to assess a limited number of alternatives within the time and resources available for this study.

Non-phthalate alternatives have mainly been applied for applications where there has been a concern as to human exposure to the substance: toys, medical products, packaging for food and water beds are examples. The alternatives are in general more expensive than DEHP with DINP being the least expensive alternatives at an incremental cost of about 10%. Applications for which the selected alternatives are specifically mentioned by suppliers of the alternatives are shown in Table 0-2, but the substances may probably be used for other applications as well.

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

	DINP	DEHT	BTHC	DINCH	ASE
Flooring and wall covering	x	x			
Film/sheet and coated products	x	x		x	x
Medical products			x	x	
Wire and cable	x				
Coated fabric and footwear		x		x	x
Toys		x			x
Automotive	x				
Non polymer applications:					
Adhesives				x	x
Printing inks				x	x
Sealants (glass insulation, construction)	x				x

In order to assess the toxicity of the selected alternatives, information on the intrinsic properties, including their human health hazard profile has been collected. On this basis tentative Derived No Effect Levels (DNELs) for critical endpoints have been established 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 DEHP.

Table 0-3 Tentative 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}
DINP	28553-12-0	Developmental	44	4	22	1
DEHT	6422-86-2	Liver toxicity	409	0.08	204	0.02
BTHC	82469-79-2	Possible liver toxicity	58	6	29	1
DINCH	166412-78-8	Kidney toxicity	75	38	8	2
ASE	91082-17-6	Liver toxicity (increased liver weight)	8	0.8	4	0.2
DINP	28553-12-0	Developmental	44	4	22	1

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

It is evident from the data reviewed that there is a wide variability in the level of information available (and validity of data sources) amongst the potential alternatives and, as such, drawing definitive conclusions on whether any additional risks for the environment would be introduced if these were to be substituted for DEHP is not straightforward for all substances. However, based on the information presented, the following conclusions can be drawn for two of the substances:

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

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

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

Besides the replacement of DEHP with other plasticisers, the soft PVC itself may be replaced with other materials. A range of alternative materials have been investigated in detail in previous studies. The available studies demonstrate that, for many applications of DEHP/PVC, alternative materials exist at similar prices. These other studies suggest that many of the materials seem to have equal or better environmental, health and safety, performance and cost profiles, but clear conclusions are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments.

Abbreviations and acronyms

AGD	Anogenital distance
AGI	Anogenital index
ASE	Alkylsulphonic phenyl ester
ATBC	Acetyl tri-n-butyl citrate
BBP	Benzylbutylphthalate
BCF	Bioconcentration factor
BHT	Butylated hydroxytoluene
BTHC	Butyryl trihexyl citrate
CEPE	European Council of producers and importers of paints, printing inks and artists' colours
CMR	Carcinogenic, mutagenic, reprotoxic
COMGHA	Acetylated monoglycerides of fully hydrogenated castor oil
DBP	Dibutylphthalate
DBS	Dibutyl sebacate
DEHA	Diethylhexyl adipate
DEHP	bis(2-ethylhexyl) phthalate
DEHPA	Tris(2-ethylhexyl) phosphate
DEHT	Di(2-ethylhexyl) terephthalate (identical to DOTP)
DGD	Dipropylene glycol dibenzoate
DIDP	Di-isodecyl phthalate
DINCH	Di-(isononyl)-cyclohexan-1,2-dicarboxylate
DINP	Di-isononyl phthalate
DNEL	Derived No Effect Level
DOP	Di-octyl phthalate (same as DEHP)
DOTP	Di(2-ethylhexyl) terephthalate (same as DEHT)
ECHA	European Chemicals Agency
ECPI	European Council for Plasticisers and Intermediates
ELE	Epoxidised linseed oil
ESBO	Epoxidised soybean oil
ESD	Emission Scenario Document (if nothing else is mentioned, the ESD for plastics manufacturing)
ESIS	European Chemical Substances Information System
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
IUCLID	International Uniform Chemical Information Database
LDPE	Low density polyethylene
LLDPE	Linear low density polyethylene
LOAEL	Lowest observed adverse effects level
LOEL	Lowest observed effects level
NACE	Nomenclature Statistique des Activites Economiques
NOAEL	No Observable Adverse Effect Level
NOEL	No observed effects level
PBT	Persistent, Bioaccumulative and Toxic

PND	Post natal day
PNEC	Predicted No Effect Concentrations
PVC	Polyvinyl chloride
QSAR	Quantitative Structure-activity Relationship
RAR	Risk Assessment Report (if nothing else mentioned, the RAR for DEHP)
SCENIHR	EU Scientific Committee on Emerging and Newly Identified Health Risks
SVHC	Substances of very high concern
TC NES	EU Technical Committee of New and Existing Chemical
TGD	Technical Guidance Document
TOTM	Tris-2-ethyhexyl trimellitate
UCD	Use Scenario Document (if nothing else is mentioned, the USD for plastics manufacturing)
UK	United Kingdom

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

1.1 *Manufacturing sites and manufacturing processes*

The substance di(2-ethylhexyl) phthalate (hereafter referred to as DEHP) is widely used as a plasticiser in polymer products, mainly PVC. DEHP has the CAS N^{o} 117-81-7 and is also known as di-octyl phthalate (DOP).

Manufacturing sites - Seven manufacturers of DEHP in the EU have been identified (Table 1-1). The manufacturers were identified through information from the European Council for Plasticisers and Intermediates (ECPI). Four of the manufacturers are members of the ECPI.

Three of the manufacturers are located in new Member States in Central Europe and have not been covered by the inventories in the EU Risk Assessment Report for DEHP from 2008 (hereafter referred to as the RAR), ESIS (European chemical Substances Information System), the IUCLID data sheet or other previous inventories. It cannot be excluded that one further small manufacturer, not specifically identified in this study, exists in one of the new Member States. ESIS lists 32 manufacturers/importers of DEHP, all in Western Europe [1] (http://ecb.jrc.ec.europa.eu/esis/). The list has apparently not been updated since the 1990's and none of the manufacturers in Table 1-1 are included in the list with their present company name.

Table 1-1 Manufacturers of DEHP in the EU

Company	Town of manufacturing site	Country
Arkema	Colombes	France
Deza A.S.	Valašské Meziříčí	Czech Republic
Oltchim S.A.	Valcea	Romania
OXEA GmbH	Oberhausen	Germany
Perstorp AB	Perstorp	Sweden
Polynt Spa	San Giovanni Valdarno	Italy
Zak (Zakłady Azotowe Kędzierzyn SA)	Kędzierzyn-Koźle	Poland

Manufacturing process - All manufacturers of phthalate esters use similar processes (ECPI 2008). DEHP is produced by the esterfication of phthalic anhydride with 2-ethyl-hexanol. This reaction occurs in two successive steps. Elevated temperatures and a catalyst accelerate the reaction rate. Depending on the catalyst used, the temperature in the second step varies from 140°C to 165°C with acid catalysts and from 200°C to 250°C with amphoteric catalysts. Excess alcohol is recovered and recycled and DEHP is purified by vacuum distillation and/or activated charcoal. The reaction sequence is performed in a closed system. This process can be run continuously or

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

batchwise. Production of a particular phthalic ester may in some cases be conducted on a campaign basis, which has also been indicated by manufacturers for this study.

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 each manufacturer. All seven manufacturers have responded with information on manufactured tonnage, whereas only some of the manufactures have provided information on releases and distribution of end-uses.

The total manufactured tonnage in 2005, 2006 and 2007 is shown in Table 1-2. The tonnage has been fairly stable during the period from 2005 to 2007 and the average for the period is approximately 340,000 tonnes per year. As shown in Table 1-3 around 16% of the manufactured tonnage is exported to countries outside the EU. According to ECPI (2008), in Western Europe about one million tonnes of phthalates are produced each year, of which approximately 900,000 tonnes are used to plasticise PVC (polyvinyl chloride). According to ECPI (2008), DEHP accounts for around 18% of all plasticiser usage in Western Europe. The total amount of phthalates produced in the entire EU is not known, but the present data indicates that for the entire EU, DEHP may represent a higher percentage of the production and consumption of phthalates.

The market for DEHP has been decreasing over the last ten years. In 1997, the total Western European production of DEHP was 595,000 t/y and in the early 1990s, DEHP represented about 51% of the total phthalate plasticiser market in the EU (RAR). Of the 341,000 tonnes produced in 2007, 187,000 tonnes were produced in Western Europe corresponding to 31% of the 1997 level.

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

Table 1-2 Manufactured tonnage by manufacturing site (note that the order of sites is different from the order in Table 1-1)

Manufacturer	Tonnage manufactured, t/y		
	2005	2006	2007
Site 1	59,000	50,000	54,000
Site 2	27,638	39,441	47,687
Site 3	41,539	44,190	39,024
Site 4	56,400	54,700	57,300
Site 5	50,000	50,000	50,000
Site 6	67,380	62,920	67,100
Site 7	42,600	34,000	26,000
Total (round)	345,000	335,000	341,000

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

The substance on its own - Data on extra-EU27 import and export of DEHP on its own retrieved from Eurostat are shown in Table 1-3. The dioctyl orthophthlates include DEHP and DIOP (diisooctyl phthalate), but DEHP is assumed to account for the main part of the quantities quoted. In the absence of more specific information on the trade of the two phthalates, the data are taken as representing DEHP import and export.

As can be seen from these data, the EU27is a net exporter of DEHP.

As the data on import/export are considered to be the most comprehensive/authoritative source available, no attempt has been made to identify importers of the substance.

Table 1-3 Extra-EU27 import and export of DEHP 2005-2007 (t/y)

CN8 code	Name	2005		2006		2007	
		Import	Export	Import	Export	Import	Export
29173200	Dioctyl orthophthalates	3,932	61,805	4,402	56,497	4,479	54,522

Preparations - Data on extra-EU27 import and export of "plasticised poly vinyl chloride, in primary forms, mixed with other substances" retrieved from Eurostat are shown in Table 1-4. The content of DEHP is not known, but a rough estimate can be obtained assuming a phthalate content of the polymer of 30% and that DEHP accounts for 18% of the phthalates (EU manufacturing average). On this basis, the extra-EU27 import and export in 2007 can be estimated at approximately 700 and 7,000 tonnes, respectively.

Two other commodity codes may also include polymers containing phthalates: "Vinyl chloride-vinyl acetate copolymers, in primary forms" (3904.30.00) and "Vinyl chloride copolymers, in primary forms (excl. Vinyl chloride-vinyl acetate copolymers" (3904 40.00). No data are available for estimating the DEHP content of these polymer groups, but it is assumed that the total DEHP trade with these product groups is small compared to the plasticised PVC.

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

On this basis, the DEHP content of extra-EU27 import and export of preparations in 2007 can be estimated at approximately 1,000 and 10,000 tonnes, respectively.

Table 1-4 EU27-extra import and export of vinyl chloride containing polymers and copolymers in primary form that may contain DEHP (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*

DEHP may be imported and exported in a large number of articles (reference is made to the description of end-product uses in section 2.1.2).

Data on export and import of relevant product groups were retrieved for the period 2005 to 2007 from Eurostat. The basic data for each commodity group is shown in Annex 2, which also include a further description of the data processing.

The product groups were selected on the basis of the study by Skårup & Skytte (2003) undertaken for the Danish Environmental Protection Agency. The study estimated the total phthalates content of products produced, imported to and exported from Denmark, and compared the estimated phthalates content with import data obtained from the taxation authorities on the basis of the yield of the Danish tax on PVC and phthalates (note that production statistics in Denmark applies the same combined nomenclature as the import/export statistics). For products with tax (representing approximately 50% of the phthalate consumption) the total phthalate consumption estimated on the basis of the import/export statistics, was about 30% higher than the phthalate consumption based on the yield of the tax. The latter is considered the most reliable data.

The estimated amount of plasticised PVC in each commodity group and the phthalate content of the PVC part of the product is shown in the table in Annex 2. For some of the product groups such as floor coverings coated with poly vinyl chloride or electric conductors the estimated phthalates content is considered to be relatively certain, whereas for more heterogeneous product groups the estimated content of plasticised PVC is considered to be very uncertain.

The products are grouped in Table 1-5 into the product groups used for this assessment. The total phthalate content of exported product is, based on the assumptions outlined in the Annex, estimated at about 180,000 tonnes which seems to be quite realistic considering that the total tonnage for manufacturing of products in the EU is 900,000 tonnes. Assuming DEHP accounts for 20% of the total phthalates, the import and export is estimated at 40,000 tonnes and 37,000 tonnes respectively, and the export corresponds to about 20% of the total use for manufacturing of products in the

EU. For the imported products, the percentage of DEHP may well be higher, but no information indicating the DEHP content of imported products was available.

It should be noted that some import/export may take place with articles not covered by the assessment e.g. vehicles, but the total tonnage within these articles are considered not to add significantly to the totals as the major application areas are covered by the statistics.

Whilst there are several uncertainties, the data suggest that the quantities of phthalates in imported articles more or less balance the quantities in exported articles, but due to limited information on the DEHP content in imported articles it is more uncertain whether the same is true for DEHP.

Table 1-5 Estimated DEHP content of EU-extra traded articles based on the assumptions in Annex 2. Average of the years 2005-2007

Product group	Tonnage products t/y		Tonnage phthalates t/y		Tonnage DEHP t/y	
	Import	Export	Import	Export	Import	Export
Hoses and profiles	49,335	80,319	8,000	15,000	1,600	3,000
Flooring and wall covering	78,677	244,355	13,000	32,000	2,600	6,400
Film/sheets and coated products	917,478	852,398	68,000	82,000	13,600	16,400
Coated fabric and other products from plastisol	407,365	739,136	11,000	7,000	2,200	1,400
Wires and cables	483,976	454,392	31,000	28,000	6,200	5,600
Moulded products and other	604,415	529,002	68,000	19,000	13,600	3,800
Total			199,000	183,000	40,000	37,000

1.4 *Releases from manufacture*

The total estimated releases from the manufacturing of DEHP in 2007 are shown in the table below. Only three of the manufacturers (indicated with grey cells in the table) have provided actual data on releases. The releases from the other sites are estimated on the basis on the manufactured tonnage and average emission factors from the RAR. The emission factors for releases from the manufacturing sites reporting for the RAR varied among the sites by a factor of more than a hundred, indicating that it is highly uncertain just to take average factors for each site, but the method is used in the absence of more specific updated information from the manufacturers. The applied average emission factors for air, soil and waste water (before sewage treatment plant) are 0.00034%, 0.0012% and 0.11% of the manufactured tonnage, respectively.

Table 1-6 Manufactured tonnage and estimated releases from manufacture in 2007 by manufacturing site

Manufacturer	Tonnage, 2007	Releases to working environment	Releases to the environment, t/y			
	t/y	t/y	Air	Soil	Waste water	Waste
Site 1	54,000	n.d.	0.2	0.7	62	n.d.
Site 2	47,687	n.d.	0.2	0.6	55	n.d.
Site 3	39,024	n.d.	0.1	0.5	0.00	0
Site 4	57,300	n.d.	0.2	0.7	0.06	0.001
Site 5	50,000	n.d.	0.7	0.6	0.003	131
Site 6	67,100	n.d.	0.03	0.8	76.9	1.6
Site 7	26,000	n.d.	0.1	0.3	29.8	n.d.
Total (round)	341,000		1.4	4.2	220	133

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

Working environment - The RAR discusses occupational exposure in detail, and examples of workplace air concentrations are given. The production of DEHP takes place in closed systems. However, both inhalation and dermal exposure may occur during the production of DEHP. Such exposures may occur during system leaks, drumming and filling of road and rail tankers, cleaning of tanks used for production, storage or transport, during service and maintenance, transfer, and process sampling. The main occupational exposure routes are inhalation of gaseous DEHP and liquid aerosols, and dermal uptake of liquid DEHP, vapour and aerosols. It was concluded in the RAR that a worst case for exposure via inhalation is estimated at 5 mg/m^3 (aerosol) based on measurements, and for dermal exposure to be at 650 mg/day on a skin area of 1,300 cm^2 based on the EASE model.

None of the manufacturers have answered the part of the questionnaire that concerns releases to the working environment and the RAR does not provide data to allow total emissions to the working environment to be estimated.

Transport of DEHP on its own
The release during distribution of pure DEHP is addressed to the cleaning of transport vessels. It is assumed that this release is located at the waste water system outside the production site. Based on data from ECPI (1996a), the RAR estimates an emission factor for transportation of 0.0084% of the transported volume. This emission factor is applied here as well and multiplied with the manufactured (of which some is exported) and imported volume.

2 Information on uses and releases from uses

2.1 *Identification of uses*

DEHP is widely used as a plasticiser in polymer products, mainly PVC. Plasticisers have the function of improving the polymer material's flexibility and workability. DEHP is one of a number of substances used as plasticiser in PVC and other polymer materials. The content of DEHP in flexible polymer materials varies but is often around 30% (w/w).

DEHP is a plasticiser which offers a good all-round performance and is therefore used for a many general purpose products including building material such as flooring, cables, profiles and roofs, as well as medical products such as blood bags and dialysis equipment (ECPI 2008).

The following flow diagram illustrates the relationship between the different processes and the end-product uses described further in this chapter. The background for the tonnages is further described in the following sections.

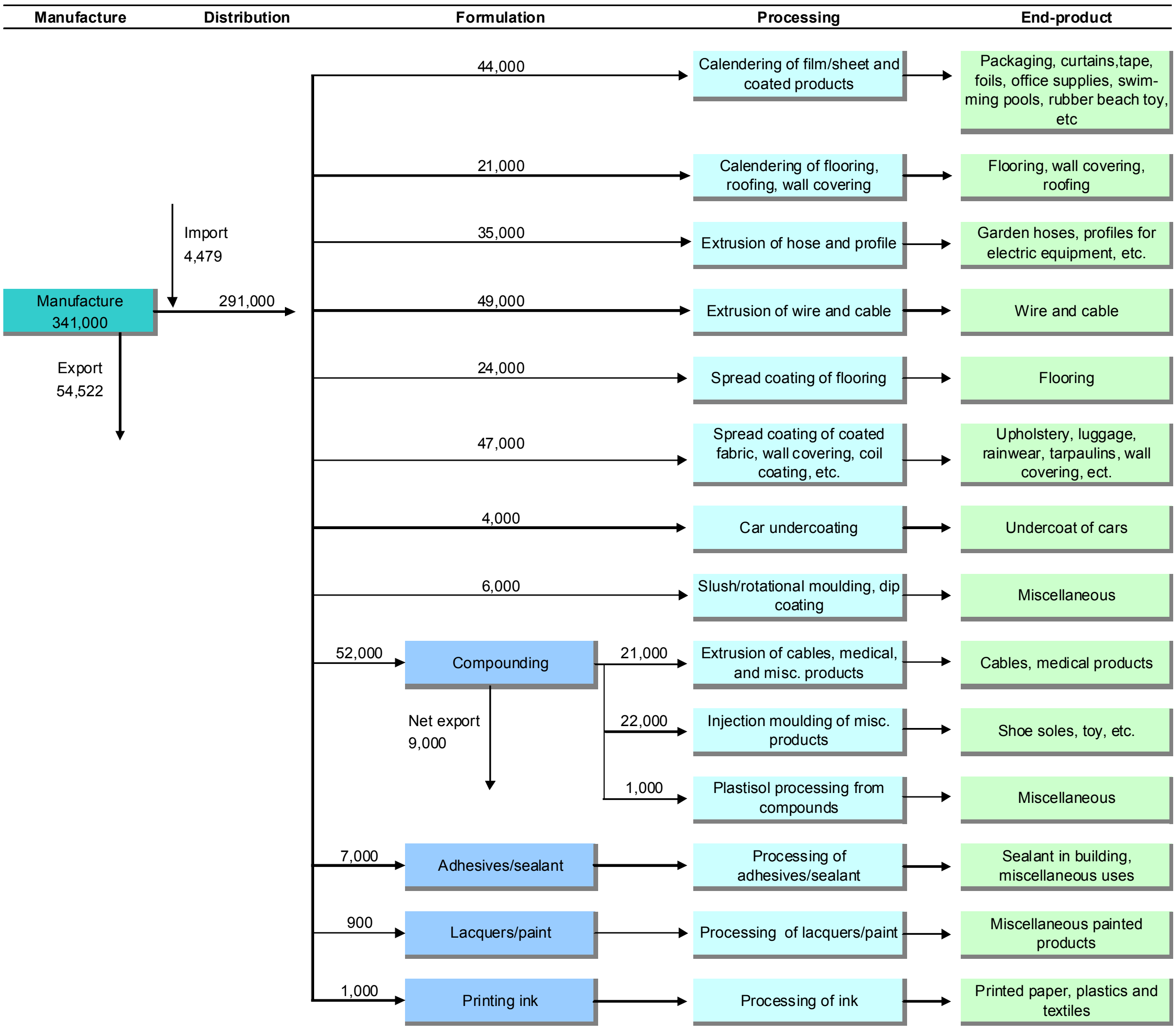

Figure 2-1 Overall flow of DEHP through manufacturing processes in 2007. Tonnes DEHP/year (see next section for further description of tonnages)

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

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
Extrusion of polymer	PROC14	Production of preparations or articles by tabletting, compression, extrusion, pelettisation. Industrial setting;	SU12	Manufacture of plastic products, including compounding and conversion	C22.2.1	Manufacture of plastic plates, sheets, tubes and profiles
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.
Car undercoating (plastisol)	PROC7	Spraying in industrial settings and applications. Industrial setting;	SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment.	C29.2.0	Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers
Slush/rotational moulding, dip coating (plastisol)	PROC3, 13	Use in closed batch process (synthesis or formulation) Industrial setting; Treatment of articles by dipping and pouring. Industrial or non industrial setting;	SU12	Manufacture of plastic products, including compounding and conversion	C22.2.9	Manufacture of other plastic products
Injection moulding of polymer	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;	SU12	Manufacture of plastic products, including compounding and conversion	C27.3.2, C22.2.9	Manufacture of other electronic and electric wires and cables Manufacture of other plastic products
Application of adhesives/sealant	PROC7, 10, 19	Spraying in industrial settings and applications. Industrial setting; Roller application or brushing of adhesive and other coating. Industrial or non-industrial setting; Hand-mixing with intimate contact and only PPE available. Non-industrial setting.	SU6, 19	Manufacture of pulp, paper and paper products Building and construction work	C17.2.9	Manufacture of other articles of paper and paperboard

Process	Process descriptor *1		Descriptor for sector of use *1		NACE codes *2	
Painting (application of lacquers and paint)	PROC7, 11	Spraying in industrial settings and applications. Industrial setting; Spraying outside industrial settings and/or applications	SU18, 19, 21	Manufacture of furniture Building and construction work Private households (= general public = consumers)	C43.3.4, C31	Painting and glazing Manufacture of furniture
Printing (application of printing ink)	PROC10	Roller application or brushing of adhesive and other coating. Industrial or non-industrial setting;	SU6	Manufacture of pulp, paper and paper products	C22.2.9, C17.2	Manufacture of other plastic products Manufacture of articles of paper and paperboard
Production of ceramics	PROC21, 22	Potentially closed processing operations at elevated temperature Open processing and transfer operations at elevated temperature	SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C23.4.9	Manufacture of other ceramic products

*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

As mentioned above, DEHP is a general purpose plasticiser for PVC and is used for production of a wide range of end-products.

The main end-product uses of DEHP are as follows (ECPI 2008, Hoffmann 1995, RAR 2008):

- Flooring:
  - PVC flooring (with PVC surface);
  - Carpets with PVC back-coating;
  - Cork with PVC top-coating or back-coating ;

- Wall covering;

- Roofing;

- Film/sheet and coated products:
  - Curtains, blinds, table linen, etc.;
  - Packaging;
  - Tape and self-adhesive foils;
  - Office supplies (ring binders, files, slip cases, etc.);
  - Toys (swimming pools, rubber beach toy, beach balls, etc.).
  - Medical bag/sheet devices;
  - Bottom sheets for hospitals.

- Wires and cables;

- Hoses and profiles;
  - Garden hoses and tubes;
  - Hoses and tubes in industry;
  - Profiles of windows and electrical products;
  - Medical tubing.

- Coated fabric;
  - Upholstery and car seats (synthetic leather);
  - Luggage;
  - Rainwear;
  - Tarpaulins;
  - Water beds.

- Moulded product;
  - Footwear;
  - Adult toys; (DEHP is not permitted in toys for children)

- Car undercoating;

Non-polymer applications:

- Adhesives;

- Lacquers and paints;
- Printing inks (see comment below);
- Sealants (glass insulation, construction);
- Ceramics.

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

2.2 *Quantification of uses*

The distribution of the DEHP supply to the various formulation and processing activities in 1997 were estimated in the RAR based on a market analysis undertaken by the industry (ECPI). Since 1997, many ECPI members have stopped producing DEHP, and today only four of the manufacturers covered by the RAR are members of ECPI. Three DEHP producers have provided indications of their sales distribution by process type in their questionnaire replies. These data and the distribution percentages from the RAR are presented in Table 2-2 below.

The data confirms the continued usage of DEHP in most of the processes and end-uses mentioned in the RAR. The data set does not explicitly confirm the continued use of DEHP for "calendering of film sheet and coated products", "spread coating of flooring", "car undercoating, and "production of ceramics". The first two applications have been large and there are no other indications of their cessation. The applications for cars and ceramics have constituted smaller consumption, and no other information has indicated either their cessation, or their continuation. This is however a very small sample and it does not rule out the continued use of DEHP for these applications. The producer data are not sufficiently representative to conclude that the usage pattern has changed significantly since the RAR inventory, and does not significantly contradict the usage pattern indicated in the RAR. Therefore, the distribution percentages presented in the RAR have also been used for the calculation of consumption by category in this study, whereas the total is updated on the basis of the information received from manufacturers.

Table 2-2 Available data on distribution of EU sales on process types

Process	Application	Sales distribution estimates, %			
		Producer A	Producer B	Producer C	RAR, 1999 data
Unspecified	Unspecified consumption, plasticiser		65		
Calendering	Calendering of film sheet and coated products			3	13
	Calendering of flooring, roofing, wall covering		15	3	6
	Total calendering	35		6	19
Extrusion	Extrusion of hose and profile		3	20	10
	Extrusion of wire and cable		7	45	14
	Compounding for extrusion of miscellaneous products			20	15
	Total extrusion	26		85	39
Injection moulding	Injection moulding of footwear and miscellaneous	26		7	15
Spread coating	Spread coating of flooring				7
	Spread coating of coated fabric, wall covering, coil coating, etc.		4		14
	Total coating	0.5			21
Other plastisols	Car undercoating				1
	Slush/rational moulding, dip coating (plastisol)	10		2	2
	Total other plastisols	10		2	3
Non-polymer applications	Adhesives/sealant,	1	3		2
	Lacquers and paint	1	3		0.30
	Printing ink	0.5			0.30
	Production of ceramics	0			0.01
	Total	100	100	100	100

According to CEPE (European Council of producers and importers of paints, printing inks and artists' colours), DEHP, DBP and BBP are no longer used in printing inks by CEPE/EuPIA (European Printing Ink Association) members following its classification as reprotoxic category 2 (CEPE 2007). CEPE brings approximately 85% of this industry together in its membership together whereas EuPIA represents close to 90% of the printing ink manufacturers selling in Europe (EuPIA web site). Since 2004, no use of DEHP in printing inks has been registered in the product registers of the Nordic Countries (see Annex 3).

The substances may, however, be used by some manufactures e.g. in new Member States, and one manufacturer of DEHP reports that 2% of the tonnage from the manufacture is used for inks (Table 2-2), which justifies the continued inclusion of printing inks as a use category.

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 in this study is, for most 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 DEHP for formulation and processing in shown in Table 2-3 and Table 2-4. The processes are further described below the tables.

Table 2-3 Estimated DEHP use for formulation in 2007 and 1999

Process	Amount used (t/y), 2007	% of total, 2007	Amount used (t/y), 1999 *1	Number of sites of use, 1999
Compounding by extrusion	52,000	84	85,680	83
Non-polymeric, formulation:				
Formulation of adhesives/sealant, rubber	7,000	11	11,142	n.d.
Formulation of lacquers and paint	900	1	1,448	n.d.
Formulation of printing ink	1,000	2	1,661	n.d.
Formulation of ceramics	20	0	29	n.d.
Total formulation (rounded)	61,000	99	99,960	

*1 Source: RAR 2008.

Table 2-4 DEHP use for processing in 2007 and 1999

Process	Tonnage (t/y), 2007	% of total, 2007	Tonnage (t/y), 1999 *1	Number of sites of use (1999)
Formulation and processing (at same site):				
Calendering of film/sheet and coated products	44,000	16	71,400	74
Calendering of flooring, roofing, wall covering	21,000	7	34,748	20
Extrusion of hose and profile	35,000	12	57,120	82
Extrusion of wire and cable	49,000	17	80,920	62
Spread coating of flooring	24,000	8	39,032	21
Spread coating of coated fabric, wall covering, coil coating, etc.	47,000	17	76,160	115
Car undercoating	4,000	1	7,140	n.d.
Slush/rotational moulding, dip coating	6,000	2	9,520	n.d.
Processing from compound:		0		
Extrusion of cables, medical, and misc. products	21,000	7	41,126	n.d.
Injection moulding of misc. products	22,000	8	42,840	n.d.
Plastisol processing from compounds	900	0	1,714	n.d.
Non-polymeric, processing:		0		
Adhesives/sealant	7,000	2	11,142	n.d.
Lacquers and paint	900	0	1,448	n.d.
Printing ink	1,000	0	1,661	n.d.
Production of ceramics	20	0	29	n.d.
Total processing (rounded)	283,000	97	476,000	

*1 Source: RAR 2008.
n.d. No data

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

Calendering - In the calendering of flexible PVC, the polymer mass runs through the gaps between the hot rolls of the calender. The average DEHP concentration is reported to be about 25% (RAR, 2008).

Extrusion - During extrusion, the melted PVC compound is pressed through a die with subsequent cooling. The major different product types of plasticised PVC extrusion are "profiles" such as wire, cable and hose, and blow moulded film.

Plastisol applications -"Plastisol" is a pasty liquid obtained by blending (formulating) PVC resin with plasticiser and other ingredients at room temperature. The plastisol is applied by spreading it on a substrate (e.g. paper, fabric, or car metal plate), or dipping items into it, and thereafter heating it (to be "gelled" or "fused") to typically above 160°C.

Major application modes for plastisols are:

- Spreading (spread coating). Paste is homogenised 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 at about 180°C. The energy is supplied by an infrared heating source (IR) and/or hot air.

- Spraying or injection of pseudoplastic onto car bodies as an anti-corrosive coating, or into crowns or capsules for beverage bottles. In car undercoating the sprayed coating is “dried” in long air-heated tunnel ovens at relatively low temperatures (130-160°C). The ovens in this industry invariably have integrated air incinerators and insignificant amounts of DEHP are emitted (ECPI, 1996b, as cited in RAR).

- Dipping of moulds into plastisol. This is applied to the production of gloves.

- Slush and rotational moulding (car fenders/bumpers, car door arm rests, balls, dolls, boots, hollow articles). 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.

Injection moulding - In injection moulding, melted compound is pressed into a “negative”, cooled mould (boots or shoe soles). As the hot material is not exposed to air, because the process is closed, very little plasticiser is expected to be released.

Processing (application) of adhesives, sealants, paints, lacquers and printing inks - According to the Swedish product register non-polymer products contain between 0.2 and 50% DEHP. Paints contain a maximum of 40% DEHP. In printing inks, DEHP is used as solvent especially for inks used in the textile industry and inks used on plastics and paper (RAR, 2008).

Production of ceramics - Plasticisers can be used as additives for ceramics to improve their processability. They work in combination with binders to give formed, unfired parts the flexibility or deformability required for subsequent handling and processing. They may also be added to spray dried or granulated powders so that the granules crush easily during pressing. Common constituents in such form liquid are polyethylene glycol, polypropylene glycol, propylene glycol and several phthalates (SRI, 1993).

The volume used for this application is low and is mainly restricted to a limited number of workplaces (RAR, 2008).

2.2.2 End-product uses

The estimated use of DEHP in end-products, by product type, is shown in Table 2-5 divided into indoor and outdoor applications. The allocation of the EU manufactured quantities to different product types has been done on the basis of information on the tonnage used for different processes (Table 2-4). For some processes such as "extrusion of wire and cable", "spread coating of flooring" and "extrusion of hose and profile” the quantities for end-product groups (e.g. wire and cable) can directly be derived from the information on processed quantities (e.g. for extrusion of wire and cable), but some of the tonnage processed from compounds may also end up in these product groups. The percentages of the total used for the different outdoor applications are based on the distribution between outdoor applications in the RAR. No data have been available at this detailed level to make any update of the estimated distribution between use areas. For the indoor applications, however, the RAR does not provide a full distribution. The distribution of some of the processing groups such as "calendering of flooring, roofing, wall covering" is roughly distributed herein based on the authors' best estimate.

The split between the different product groups is consequently quite uncertain and the actual tonnage for each product group may well be 50% lower or higher than estimated, but the total DEHP use in end-products is considered to be quite certain as it is based on information direct from industry.

For practical reasons, the import/export of DEHP within articles has been allocated to the indoor uses only. For most products, the import more or less balances the export and has limited influence on the total tonnages for end-product use.

Table 2-5 Estimated DEHP tonnage in end-products marketed in the EU based on EU manufacture, import, export data

End-product use area	Tonnage, t/y				% of total use
	EU Manu-facture	Import	Export	End-product use	
Indoor uses:					
Flooring	33,000	2,000	4,800	30,200	10.6
Wall covering	11,000	700	1,600	10,100	3.5
Film/sheet and coated products made by calendering	44,000	13,600	16,400	41,200	14.5
Wires and cables	52,000	6,200	5,600	52,600	18.5
Hoses and profiles	31,000	1,600	3,000	29,600	10.4
Coated fabric and other products from plastisol	31,000	2,200	1,400	31,800	11.2
Moulded products	3,000	2,700	700	5,000	1.8
Other polymer applications	12,300	10,900	3,100	20,100	7.1
Non polymer applications:					
Adhesives and sealant	4,000	n.d.	n.d.	4,000	1.4
Lacquers and paints	500	n.d.	n.d.	500	0.2
Printing ink	1,000	n.d.	n.d.	1,000	0.4
Other non-polymeric	20	n.d.	n.d.	20	0.0
Outdoor uses:					
Calendered roofing material	600	n.d.	n.d.	600	0.2
Coil coated roofing material	3,000	n.d.	n.d.	3,000	1.1
Wire and cables - air	2,400	n.d.	n.d.	2,400	0.8
Wire and cables - soil	9,700	n.d.	n.d.	9,700	3.4
Coated fabric	12,800	n.d.	n.d.	12,800	4.5
Car undercoating	4,000	n.d.	n.d.	4,000	1.4
Hoses and profiles	3,700	n.d.	n.d.	3,700	1.3
Shoe soles	19,400	n.d.	n.d.	19,400	6.8
Non polymer applications:					
Lacquers and paints	400	n.d.	n.d.	400	0.1
Adhesives and sealant	3,300	n.d.	n.d.	3,300	1.2
Total end-product use (round)	282,000	40,000	37,000	285,000	100

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 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, exhaust gas burners 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 DEHP from formulation and processing are shown in Table 2-6 and Table 2-7 below. The further description of background for the estimates for each process is provided below the tables.

Table 2-6 Estimated EU 27 DEHP releases from formulation

Process	Releases to working environment (t/y)	Releases to the environment (t/y)			
		Air	Soil	Waste water	Waste
Compounding by extrusion	n.d.	7.8	0.0	7.8	n.d.
Non-polymeric, formulation:					
Formulation of adhesives/sealant, rubber	n.d.	17.5	0.7	70.0	n.d.
Formulation of lacquers and paint	n.d.	2.3	0.1	9.0	n.d.
Formulation of printing ink	n.d.	2.5	0.1	10.0	n.d.
Formulation of ceramics	n.d.	0.1	0.0	0.4	n.d.
Total formulation (rounded)	n.d.	30	1	97	n.d.

n.d. No data

Table 2-7 Estimated EU 27 DEHP releases from processing (including releases from formulation where formulation and processing takes place at the same site)

Process	Releases to working environment (t/y)	Releases to the environment (t/y)			
		Air	Soil	Waste water	Waste
Formulation and processing (at same site):					
Calendering of film/sheet and coated products	n.d.	15.4	0.0	15.4	n.d.
Calendering of flooring, roofing, wall covering	n.d.	7.4	0.0	7.4	n.d.
Extrusion of hose and profile	n.d.	5.3	0.0	5.3	n.d.
Extrusion of wire and cable	n.d.	7.4	0.0	7.4	n.d.
Spread coating of flooring	n.d.	20.7	0.0	20.7	n.d.
Spread coating of coated fabric, wall covering, coil coating, etc.	n.d.	40.6	0.0	40.6	n.d.
Car undercoating	n.d.	7.3	0.0	7.3	n.d.
Slush/rotational moulding, dip coating	n.d.	15.0	0.0	15.0	n.d.
Processing from compound:					
Extrusion of cables, medical, and misc. products	n.d.	1.1	0.0	1.1	n.d.
Injection moulding of misc. products	n.d.	1.1	0.0	1.1	n.d.
Plastisol processing from compounds	n.d.	2.3	0.0	2.3	n.d.
Non-polymeric, processing:					
Adhesives/sealant	n.d.	0.7	35.0	0.0	n.d.
Lacquers and paint	n.d.	0.0	4.5	0.9	n.d.
Printing ink	n.d.	50.0	1.5	0.5	n.d.
Production of ceramics	n.d.	0.0	0.0	0.0	n.d.
Total processing (rounded)	n.d.	174	41	125	n.d.

n.d. No data

Formulation (pre-processing)

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

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

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

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

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 conversion processes in general
The RAR reports that there were approximately 800 soft PVC converting plants in EU15 of the types relevant here. The total number of such PVC conversion plants in EU27 has not been available for this study.

Working environment - The RAR discusses occupational exposure in some detail, and examples of workplace air concentrations for various PVC conversion/formulation processes are given. Generally, the main routes of occupational exposure are anticipated to be by inhalation of DEHP-gas and liquid aerosol, and by dermal uptake of liquid DEHP, vapour and aerosol. In the polymer industry, exposed workers may be working close to processes emitting DEHP, drumming the substance, handling products containing the substance or transferring the substance or the products to other systems. Much of the gas emitted from the hot processes with DEHP will rapidly condense to form an aerosol with the consequence that workers will be exposed to both gas and aerosol. Most of the total releases mentioned below under "Air/waste water" are released in the actual working environment. The exposure of workers in the further depends on the DEHP concentrations generated in the working environment air (exposure via inhalation), on the direct skin contact with surfaces with DEHP 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. According to data from industry in the RAR, DEHP was formulated in about 560 sites in EU. The number of sites processing materials containing DEHP was assumed to be more than 1,000.

Air, waste water - The RAR presents and uses emission factors for various PVC conversion processes from the Use Category Document on plastic additives (draft, UCD, 1998), later revised and published as Emission Scenario Document on Plastic Additives (ESD 2004). The RAR also reports "90 percentile" consumption and release values derived from industry reporting (EuPC, 2005) in a manner that does not enable derivation of production-related emission factors.

The total release factor is (in the cited UCD/ESD) composed of separate contributions from raw materials handling, formulation (whether on-site or off-site), and a contribution from the conversion process itself (e.g. calendaring).

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

Soil - For all PVC conversion processes, the RAR mentions a theoretical spill risk, but the amounts are deemed insignificant and are not quantified.

Solid waste – This is not reported in the RAR for conversion processes.

Specifics for calendering

Air, waste water - The total release factor used in the RAR is (in the cited UCD/ESD) composed of a contribution from raw materials handling (0.01%), a contribution from formulation (0.01%), and a contribution from the conversion process, calendering, itself. The 2004 ESD proposed a release factor of 0.05% for facilities with air cleaning, and 0.2% for facilities with no such system. The RAR, however, uses a value designated as "average air cleaning" of 0.05%.

Specifics for extrusion

During extrusion, releases/exposure does not occur in the extruder itself, but occur temporarily when the hot material leaves the dye. In addition, the surface to volume factor is much lower than in calendaring of sheet/film.

Air, waste water - The total release factor is (in the cited UCD/ESD) composed of a contribution from raw materials handling (0.01%), a contribution from formulation (0.01%), and a contribution from the conversion process, extrusion, itself (0.01%).

Specifics for plastisol coating

Working environment - The RAR provides examples of workplace air concentrations for car undercoating only, among plastisol application processes. The main routes of occupational exposure are the same as for other PVC conversion processes.

Air, waste water - The total release factor used in the RAR is (in the cited UCD/ESD) composed of a contribution from raw materials handling (0.01%) and a contribution from the conversion process, plastisol application, itself of 0.05% for facilities with air cleaning and 0.5% without such cleaning.

The RAR reports that, for plastisol spread coating, 75% of the DEHP consumption is processed with air cleaning, the rest without, and a resulting calculated release factor of 0.1625 is thus derived. For "other plastisol" processes the RAR reports that 18% of the facilities have air cleaning and 38% have not, and on this basis an "average" release factor of 0.2% is derived. This seems however to be a miscalculation. If the 18% and 38% are meant to be representative of all involved facilities, a correctly calculated average emission factor would be 0.356%, which is used in this study. This group is heterogeneous as it includes car under-coating, reported to be with virtually no releases except in the raw material handling, but also rotational coating, dip coating and slush moulding, for which release factors of 0.05/0.5% with/without air cleaning (respectively) are given in the UCD (1998, as cited in the RAR).

Specifics for injection moulding

Air, waste water - The release factor used in the RAR for the conversion process, injection moulding, itself is 0.01%, bearing in mind that this conversion process is based on extruded compound (with separate releases for raw materials handling, formulation and extrusion; see extrusion emission factors above).

Non-PVC uses

For non-PVC uses, the RAR uses different TGD standard emission factors, depending on the process in question.

Sealants, adhesives, paints, inks

Formulation of paints: Based on TGD standard scenarios it was estimated in the RAR that 1% is released to waste water during the formulation of paints.

Formulation of sealants, adhesives, etc: The same emission factor for emissions to waste water of 1% as for paint can be used for this product group, as the processes are similar (RAR, 2008).

Processing (application) of sealants, adhesives, etc.: The processing will be mostly at construction sites and therefore the releases would be mainly to solid waste. The release to waste water is probably negligible (RAR, 2008). The amounts of these products ending up in application waste are not quantified in the RAR. An actual quantification of these losses, e.g. on construction sites, has not been included in this study either. A rough estimate would be that on average up to 5% of the total amount of paint, sealant and adhesives used in non-industrial settings may be lost as waste during the application steps. The 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. The lack of quantitative inclusion of such losses to waste in this study may result in a slight over-estimation of the product amounts actually applied, and thereby of the releases during the use phase. Ultimately, the full amount of the article will be allocated to waste (in the disposal phase).

Formulation of printing inks: The RAR states that, according to the TGD, a default for formulation of 2% is assumed to be released to waste water. However, for the formulation of these compounds, the same emission factor for release to waste water of 1% as for paint could be used for inks, as the processes are similar.

Processing of printing inks: As no details on the nature of DEHP-containing inks and their use in paper are reported, emission factors from the TGD were proposed in the RAR.

Losses with waste from downstream article production
Losses with waste from downstream article production, such as for example PVC film waste from the production of ring binders, or PVC membrane waste from construction of house roofs, 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).

2.3.2 End-product uses

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

The releases are life-time 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 DEHP 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 DEHP from end-products in service in 2007 is probably higher reflecting the higher DEHP consumption in previous years resulting in large quantities of DEHP accumulated in end-products in society.

Many of the product groups contribute to emissions to air. For indoor applications, film/sheet and coated products and wires and cables are estimated to be the main sources. Flooring and wall covering contribute less to the total, but it should be noted that the highest concentrations in the indoor environment are expected in rooms with DEHP-plasticised flooring and wall covering, because of the large surfaces from where the substance can be released.

The overall main sources of releases to the environment are abrasive releases from outdoor applications. The abrasive releases are particles/fragments abraded from end-use products during their service life and during disposal. The RAR for DEHP introduces a waste pathway designated "waste remaining in the environment", from which the DEHP is ultimately released to the environment. The RAR assumes a distribution with 75% to soil, 25% to waste water/surface water and 0.1 % to the air. The uncertainties on these releases are quite high, but the approach is used in the absence of more certain release factors based on actual measurements. It is the ultimate fate of this waste in the environment which is indicated for the abrasive releases in Table 2-8. The large emission to soil for wire and cables are releases from cables in the ground. The DEHP is released below 5 cm of the soil but the present assessment does not distinguish between releases to topsoil (upper 5 cm) and to soil <5 cm.

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

End-product use area	Releases to the environment, t/y			
	Air	Soil	Waste water	Solid waste
Indoor uses:				
Flooring	12	0	942	29,000
Wall covering	3	0	2.0	10,000
Film/sheet and coated products made by calen-dering	132	0	0.0	41,000
Wires and cables	79	0	0.0	53,000
Hoses and profiles	3	0	0.0	30,000
Coated fabric and other products from plastisol	16	0	0.0	32,000
Moulded products	0	0	0.0	5,000
Other polymer applications	4	0	76	20,000
Non polymer applications:				0
Adhesives and sealant	4.0	0	77	4,000
Lacquers and paints	18	0	141	0
Printing ink	106	0	0.0	1,000
Other non-polymeric	0.0	0	0.0	0
Outdoor uses:				
Calendered roofing material	0.2	15	15	1,000
Coil coated roofing material	3.6	157	157	1,000
Wire and cables - air	3.6	38	38	2,000
Wire and cables - soil *1	0.0	3,505	0	6,000
Coated fabric	6	134	134	12,000
Car undercoating	0.8	13	40	4,000
Hoses and profiles		10	10	4,000
Shoe soles	0.0	18	18	17,000
Non polymer applications:				
Lacquers and paints	14.8	33	33	0
Adhesives and sealant	3.3	61	61	3,000
Total non-abrasive releases (round)	400	4,000	1,700	275,000
Outdoor uses, abrasive releases:				
Calendered roofing material	0.03	21	7	
Coil coated roofing material	1.3	1,006	335	
Wire and cables - air	0.0	35	12	
Wire and cables - soil *1	0.1	93	31	
Coated fabric	0.5	376	125	
Car undercoating	0.4	296	99	
Hoses and profiles	0.1	55	18	
Shoe soles	1.9	1,452	484	
Non polymer applications:				
Lacquers and paints	0.0	12	4	
Adhesives and sealant	0.2	119	40	
Total abrasive releases (round)	5	3,500	1,200	
Total releases (round)	400	7,500	2,900	275,000

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

- Emission to air by evaporation (both indoor and outdoor uses);
- Leaching and abrasion released to waste water by washing operations for indoor uses;
- Leaching and abrasion released to soil, surface water and wastewater by exposure to rainwater for outdoor uses;
- Degradation of parts of products released to or disposed of in the environment.

DEHP, 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.

Regarding emission factors, it has not been possible to identify new information that could form a basis for updating the emission factors presented in the RAR and, in general, the emission factors used in the RAR will also be used in this study. A wealth of newer studies on the effect of DEHP and other phthalates in the indoor environment are available; for example the recent international conference Indoor Air 2008 had a special session on phthalates in the indoor environment, but the identified studies do not provide information justifying any changes in the emission factors. (Examples are Afshari *et al.* 2004; Clausen *et al.* 2004; Xu *et al.* 2008; Little *et al*. 2008).

The basic emission factors are summarised in Table 2-9.

Table 2-9 Emission factors applied (except for abrasive releases from outdoors uses shown in Table 2-11)

Product	Use	Recipient	Emission factor	Comment
Indoor uses:				
Polymer	All uses	Air	9.5 mg/m^2/year	Recommended in RAR
Polymer	All uses	Air	0.05%, lifetime	Applied in RAR
Polymer	PVC printing on clothes	Waste water	280 g/person/year	
Polymer	Flooring/washing, leaching	Waste water	26 mg/m^2/year	One cleaning per week is assumed
Polymer	Wall covering and other uses/washing, leaching	Waste water	6 mg/m^2/year	One cleaning per month is assumed 1)
Polymer	Flooring /Abrasion removed by washing	Waste water	0.15%/year	The emission relates to offices and institutions with extensive traffic.
Polymer	Flooring /Abrasion removed as dust	Solid waste (as dust)	0.15%/year	The emission relates to offices and institutions with extensive traffic.
Non-polymer - indoor	Sealants-adhesives	Waste water	2 g/m^2/year	The emission factor is indicated in the RAR but in fact not used for the estimation
Non-polymer - indoor	Lacquers and paint	Waste water	2 g/m^2/year	- " _
Outdoor uses:				
Non-polymer	All uses	Air	9.5 mg/m^2/year	Recommended in RAR
Non-polymer	All uses	Air	0.05%	
Polymer - outdoor	All uses exposed to open air	Water	1 g/m^2/year	
Polymer - outdoor	Gravelled surface	Water	2.3 g/m^2/year	
Polymer - outdoor	Cables and wires buried underground	Soil	1.2%/year	
Non-polymer - outdoor	Sealants-adhesives	Waste water	1 g/m^2/year	
Non-polymer - outdoor	Sealants-adhesives	Soil	1 g/m^2/year	
Non-polymer - outdoor	Lacquers and paint	Waste water	1 g/m^2/year	
Non-polymer - outdoor	Lacquers and paint	Soil	1 g/m^2/year	

Emissions from washing of wall coverings and other indoor uses are not included in RAR but included in this study. The same emission factor per m^2 as for flooring (non-abrasive releases) is adopted. The frequency of washing is, however, reduced to once per month.

Emissions to the air and waste water during the use of end-products will be determined by calculating the amount of surface corresponding to the volume in question. Basic assumptions and estimated life-time emission factors are presented in Table 2-10. Some product groups include several different products, and characteristics for product types that have been used to estimate the average figures are shown in the table.

Life-time emission factors, EF_{life} are calculated on the basis of the expression:

$$EF_{life} = \frac{life * EF_{sqr}}{100 * content * weight\_per\_sqr} \qquad \text{(eq. 1)}$$

Where EF_{life} is the percentage of the substance in the new product that is released during the entire service life, "life" is the lifespan in years, EF_{sqr} is the area specific emission factor in mg/(m^2*year), "content" is the concentration of the substance in the material in percent, and "weight_per_sqr" is the weight of the material in kg/m^2.

For abrasive releases the lifetime emission factor is calculated from the expression:

$$EF_{life} = life * EF_{sqr,ab} \qquad \text{(eq. 2)}$$

where $EF_{sqr,ab}$ is the percentage of the content of DEHP in the material that is released annually by abrasion.

The lifetime emission is then calculated on the basis of the expression:

$$Emission = \frac{EF_{life} * C}{100} \qquad \text{(eq. 3)}$$

where "Emission" is the total emission in tonnes calculated by multiplying the lifetime emission factor, EF_{life} (in %) with the consumption the year concerned, C (in tonnes). 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, with inherent uncertainties in this approach as discussed above.

Emission to air- For emission to the air a general emission factor of 9.5 mg/(m^2 * year) has been used. The factor is recommended in the RAR, although the RAR ends up using a general lifetime emission factor of 0.05% for all indoor uses. As the products have very variable thickness, and consequently variable surface to volume ratio, and variable in-service life, it has been attempted to estimate the emission factors for each product group (see Table 2-10). As shown in the table the emission factor from flooring is consequently lower than the 0.05% used in the RAR while the emission factor for films is nearly ten times higher. The total estimated emission from indoor uses is significantly higher using the emission factors in Table 2-10 than using the general factor of 0.05%.

Table 2-10 Life-time emission factors for emission to air and basic assumptions for estimating the emission factors

Product	Typical content of phthalates % (average)	Typical thickness mm	Typical weight per unit area kg/m^2	In-service life years	Life-time emission factor % of content of new products
Flooring (with/without lining)	10-20 (15)	1-4	2.9	20	0.04
Wall covering	30	1-2	2	20	0.03
Roofing, calendered	30	1.5	2	20	0.03
Roofing, coil coated	30	0.2	0.26	10	0.12
Film/sheets, average	30		0.1	10	0.32
Vapour barrier	*30*	*0.05*	*0.07*	*30*	
Equipment for bathing and swimming	*30*	*0.05-0.1*	*0.07-0.13*	*1-5*	
Film (packaging)	*30*	*0.05*	*0.07*	*< 1*	
Curtains	*30*	*0.05-6*	*0.07-8*	*5*	
Medical equipment	*30-40*	*0.1-0.5*	*0.13-0.7*	*<1*	
Office equipment (Ring binder, boxes etc.)	*30*	*0.1*	*0.13*	*10*	
Cables and wires, average	22.5		0.7	25	0.15
Electrical cable - outdoor	*20 - 25*			*30*	
Telephone wire	*20 - 25*	*0,5 (wire 2)*	*0.3*	*20*	
Electrical wire	*20 - 25*	*1 (wire 3)*	*0.5*	*10*	
Electrical cable	*20 - 25*	*1 (wire 10)*	*1.2*	*30*	
Hoses and profiles	30	3 (hose 20)	3.3	10	0.01
Coated fabric, average	30		0.6	10	0.05
Table cloth (with lining)	*30*	*0.5 (of PVC)*	*0.7*	*10*	
Gloves (working purpose - with lining)	*30*	*0.5 (of PVC)*	*0.7*	*1*	
Imitated leather (with lining)	*30*	*0.3-0.5 (of PVC)*	*0.4-0.7*	*10*	
Tarpaulins	*30*	*0.3-0.5 (of PVC)*	*0.4-0.7*	*10*	
Car undercoating	30	1.5	2	12	0.02
Moulded products - assumed average				5	0.001
Dolls and figures	*30*	*1-?*		*5*	
Sex toys	*30-50*	*100-300*		*5*	
Shoe soles	*30*	*10*		*5*	
Other polymeric appl.	30		2	10	0.02
Adhesives and sealants	10	1.5	2	20	0.1
Sealants	*10 (5-30)*	*1.5*	*2*	*20*	
Adhesives	*4 (0.5-30)*			*20*	
Lacquers, paint	1-5	0.04	0.04-0.08	7	3.7
Printing ink	1-5	0.0015	0.003	<1	10.6

Sources: DEHP RAR (2008); Christensen et al 2008; Hoffmann 1996; Skårup and Skytte 2002; product data available on the Internet and author's own assessments.

Emission to waste water and soil - The emission to waste water from flooring and wall covering are calculated by adding the releases by leaching to the releases by abrasion. The life time emission factors for DEHP leaching from the products are calculated using eq. 1 and the area specific emission factors shown in Table 2-9, whereas the lifetime emission factors for abrasion are calculated using eq.1 and the emission factors for abrasion in Table 2-9.

Besides the releases from flooring and wall covering the only significant source of DEHP releases to waste water from indoor polymer uses is the washing of t-shirts with PVC print. The PVC print is assumed to be included in "other polymer application". The RAR applies an emission factor of 280 g/person/year and estimates the total releases to water from washing at 108 t/y (range: 18-180 t/y). No data are available for reconsidering this emission factor, but it is roughly assumed that the consumption of DEHP for this application (and the resulting releases) has followed the general decreasing trend in overall consumption.

Life-time emission factors for releases to waste water from indoor uses of sealants/adhesives and lacquers/paint from the RAR of 1.9% and 28%, respectively are applied. Likewise are lifetime emission factors for releases to soil and water for outdoor emission applied. All emissions to surface water and waste water, respectively, are here allocated to waste water.

Abrasive releases from outdoor uses - The RAR for DEHP introduces a waste pathway designated "waste remaining in the environment". This is expected to be particles/fragments abraded from end-use products during their service life and during disposal. Examples are particles abraded from car undercoating, coil coating, shoe soles and fragments of plastic bags. These particles are primarily released to the urban/industrial soil compartment. However a fraction may ultimately be distributed to the air or surface water compartments. The ultimate fate of the DEHP in the waste remaining in the environment is (in the RAR) estimated to be 0.1% to air, 25% to water (waste water and surface water) and 75% to soil. These emission factors will be used as best estimates, and for the present assessment the abrasive releases will be estimated as direct emissions to the three compartments, not introducing the life cycle step of "waste remaining in the environment". The emissions to waste water and surface water are combined and indicated as emission to waste water only. Emission factors and basic assumptions for the abrasive releases used for the assessment are shown below.

Table 2-11 Emission factors and basic assumptions for the abrasive releases from outdoor uses (from RAR)

Product group	Percentage released over entire service life	Emission factors (% of quantity remaining in products) *1		
		Air	Soil	Waste water
Calendered roofing material	5	0.005	3.8	1.3
Coil coated roofing material	50	0.050	37.5	12.5
Wire and cables - air	2	0.002	1.5	0.5
Wire and cables - soil *1	2	0.002	1.5	0.5
Coated fabric	4	0.004	3.0	1.0
Car undercoating	10	0.010	7.5	2.5
Hoses and profiles	2	0.002	1.5	0.5
Shoe soles	10	0.010	7.5	2.5
Non polymer applications:				
Lacquers and paints	5	0.005	3.8	1.3
Adhesives and sealants	5	0.005	3.8	1.3

*1 The emission factor is multiplied by the tonnage used less the amount released from the products released by other processes.

2.4 *Quantification of releases from waste disposal*

The total quantity of municipal solid waste generated in the EU27 around 2005 was by the European Topic Centre on Resource and Waste Management estimated 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 present in end-products will ultimately be directed to either landfills or incineration. Thus, the figures presented above are here adjusted to 71% to landfills, 29% to incineration and 0% to recycling. Phthalates may be involved in some recycling operations as described below for car shredders, but the phthalates containing materials are generally not recycled from the operations.

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 DEHP were measured (Kjølholt *et al.* 1994):

Flue gas: 5.7 - 17 µg/m^2
Clinker: 0.86 - 4.0 mg/kg
Fly ash: <0.4 - 2.8 mg/kg
Flue gas cleaning residue: 1 - 5 mg/kg

Waste water: <0.5 - 1.0 µg/l

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

With improved flue gas treatment on incinerators in recent years the actual emission factors are probably lower today, but the estimated emission factors are applied as a worst case in the absence of more recent information.

Table 2-12 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 DEHP to waste water from the Danish incinerators was estimated at less than 1 kg and releases to waste water from incinerators are considered insignificant and not further discussed.

The total amount of DEHP in residues was 1.5 tonnes indicating that about 0.1% of the DEHP was not destroyed by the incineration.

Landfilling

Municipal landfills are considered to release DEHP mainly through leachate water (RAR). The amount of DEHP discharged with leachate was estimated as 15 tonnes/year in the RAR based on data from the UK (RAR). The low leachate rate of DEHP 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 DEHP directed to landfill will be released from the landfill before it is ultimately degraded. In the absence of data, the release rate from the RAR will be used corrected for the decreased amount of DEHP brought into circulation in society.

Car shredding
Shredding of disposed vehicles is a potential source for release of DEHP (from car-undercoating and cables). Shredding is carried out to separate the non-ferrous from the ferrous metals for recycling purpose. The RAR estimates the total DEHP content of shredded cars at some 11,000 tonnes. Releases to air takes place either as emission due to elevated temperatures by the shredding and as particle emission. The RAR estimates the total DEHP releases to air at 5.5 t/y and to soil at 67 t/y. The same emission rates will be used in this study corrected for the decreased use of DEHP for car undercoating.

Paper recycling
The RAR assesses the releases of DEHP from the deinking of recycled paper. Considering the uncertainty on whether DEHP is used in such inks today and the relatively small release from the process, this process will not be further investigated.

Biological treatment/compost
Phthalates may be present in materials directed to biological waste treatment. In compost produced in Denmark, DEHP has been measured at a concentration of 8 - 23 mg DEHP/kg corresponding to a total quantity of 118 kg for all compost produced in Denmark (Hoffmann 1996). This quantity will be directed to soil.

Assuming a similar situation in other European countries, the total amount of DEHP directed to soil with compost may be roughly estimated at 118 kg * 488.5/5.3 corresponding to 11 tonnes DEHP/year using a per capita approach. Considering the decreased use of DEHP compared with the 1990s when the measurements were taken, only a few tonnes of the DEHP brought into circulation in 2007 will end up in compost and this disposal route is not further investigated.

Waste water and sewage sludge
Reported measurements indicate that about 90% of DEHP present in waste water will be removed by waste water treatment processes (Miljøstyrelsen 2004; Hoffmann 1996; Thornton et al 2001). However, significant 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 area revealed reductions of approximately 43% to 99% with a calculated average of 76% (Hoffmann 1996).

Recent investigations from Denmark covering 213 measurements divided on 38 treatment plants from the years 2000-2003 indicates typical concentrations of 0.3 - 6.1 µg/l and an average of 1.8 µg/l (Miljøstyrelsen 2004).

Assuming an average effluent concentration of 1.8 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 DEHP from waste water treatment plants of 100 tonnes/year. If the effluent represents 10% of the influent, the total amount directed to waste water treatment plants would be around 1,000 tonnes, which is in the same order of magnitude as the 2,400 tonnes estimate to be directed to waste water in this study.

Summary
The releases from the main waste operations are shown in Table 2-13 below. Note that the amount directed to car shredding will ultimately be disposed of to either incineration or landfilling and included these as well. Compared to the releases during the use of the end-product the releases from waste disposal are small.

Table 2-13 Releases of DEHP from main waste operations

Waste operation	Tonnage DEHP (t/y)	Releases to the environment, t/y		
		Air	Soil	Waste water
Incineration	80,000	5.6	0	0
Landfilling	195,000	0.0	9	10
Car shredding	7,000	3.5	39	0
Total		9.1	48	10

3 Information on alternatives

3.1 *Identification of alternative substances and techniques*

3.1.1 Identification of alternative substances

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

Further, for some applications the plasticised PVC has been replaced with other materials.

The main alternatives to DEHP have been the two phthalates di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP). As illustrated in Figure 3-1 in Sweden the shift from DEHP to first of all DINP took mainly place in the period 1999 to 2002.

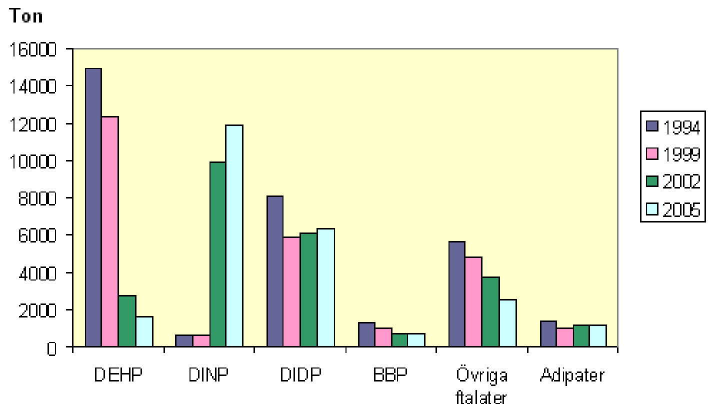

Figure 3-1 **Use of plasticisers for PVC in Sweden. KemI (2008) quoting the Swedish Productregister as source. 2005 figures are indicated as "preliminary". "Övrige ftaalter" = "Other phthalates", "Adipater" = "Adipates".**

Alternatives to DEHP applied in Sweden by product type are shown in Table 3-1. According to a recent Danish investigation, DINP and DIDP after 2000 have been totally dominating in marketed PVC flooring, wall coating and carpets with PVC backcoating. In synthetic (PVC) leather for upholstery, in toys and products for babies and in soft PVC for medical applications, DEHP has to a large extent been replaced by DINP or DIDP (Chistensen *et al.* 2008).

Table 3-1 **Alternatives to DEHP applied in Sweden by product type (Based on Annex XI dossier)**

Application area	Alternative plasticisers
Coil coated roofing	DIDP, polyurethane, polyester
Fabric coating	DIDP, DINP
Floor and wall coating	DINP, polyolefins
Cable	DIDP or other phthalates
Foil	DIDP
Profiles	DINP

A large number of substances are used as plasticisers in PVC, in other polymers and in non-polymer applications. Plasticisers applied in soft PVC and non-polymer applications are listed in Table 3-2. Some of the most common application areas are described at the web site of the Plasticiser Information Centre (http://www.plasticisers.org/), an initiative of the European Council for Plasticisers and Intermediates (ECPI). For some of the plasticisers the description refers to websites of the manufacturers or to previous assessments.

The plasticisers have different technical properties and may not necessarily be useful alternatives to DEHP for the different application areas. 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 children care, medical devices, food packaging and water mattresses. Alternatives marketed specifically for these product groups includes among others adipates, citrates, carboxylates, alkylsulphonic acid ester and castor oil derivatives.

For non-PVC applications, COWI (2000) identified 21 substances and set up a substitution matrix indicating which substances may be suitable for substituting for phthalates in different applications (Table 3-3). New substances may have been marketed since then, but most substances on the list are still marketed as plasticisers.

A number of alternatives to DEHP (and other phthalates) in PVC applications have been evaluated in previous studies as summarised in Table 3-4. In the table it is indicated whether the assessments include a health assessment (H), an environmental assessment (E) and/or a technical/economic assessment (T). Three of the studies included all three aspects. None of the substances are included in the List of Dangerous Substances (Directive 67/548/EEC).

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

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

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

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

Table 3-2 Plasticisers applied in soft PVC and non-polymer applications

Chemical group	Application areas
Terephthalates	Bottle caps and closures, coatings for cloth, electric connectors, flexible film, sheet vinyl flooring, toys, vinyl gloves and others (Eastman website)
Adipates	Broad application in PVC and non-PVC *2 Additive to other plasticisers in: profiles, wires and cables, films and sheets (BASF website)
Citrates	Applications of citrates includes medical equipment and packaging films (ECPI *1)
Phosphate esters	Widespread use in flexible PVC applications (ECPI *1)
Trimellitate esters	Large volumes of trimellitate esters are used in high specification electrical cable insulation and sheathing. (ECPI *1)
Polymeric	Polymeric plasticiser for PVC and paints (BASF website)
Alkylsulphonic acid esters	Is suitable for a large number of applications which include toys, gloves, film for water beds, sealants and casting compounds for the construction sector, as well as swimming floats and rubber boots. (Lanxess website)
Butane esters	Printing ink, paint, glue, adhesive and concrete products *2
Polyesters	Cables, toys, cling film, conveyer belts, furniture surface, gloves,
Epoxy esters and epoxidized oils	Other materials which are often referred to as secondary plasticisers include materials such as epoxidised soybean oil (ESBO) and epoxidised linseed oil (ELO) and similar materials. These can act as lubricants but also act as secondary stabilisers to PVC due to their epoxy content which can remove HCl from the degrading polymer (ECPI *1)
Benzoates	Glue, adhesive *2
Carboxylates	Can be used in applications that are particularly sensitive from the toxicological point of view. Application fields: Toys, medical articles, shoes, food (PVC-Sealants, Cling-film) (BASF website)
Castor oil derivatives	Medical equipment (Danisco website)
Sebacates	* Usage is generally limited to extremely demanding low temperature flexibility specifications (e.g. underground cable sheathing in arctic environments). (ECPI *1)

*1 Information from Plasticiser Information Centre, an initiative of the European Council for Plasticisers and Intermediates (ECPI)

*2 Mentioned in Stuer-Lauridsen *et al.* 2001

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

Chemical name	Printing inks	Paint and lac-quer	Adhe-sives	Sealants	Rubber	Mould-ing 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.

Table 3-4 Alternatives to DEHP assessed in the studies cited

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

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

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

To compare the toxicity, a short summary of the potential genotoxicity, the carcinogenicity, repeated dose toxicity and reproductive toxicity were summarised (Table 3-5). In this table (as well as in Table 3-6) the NOAEL is shown as the lowest effects in male or female rat. Available information on the leaching behaviour of alternative plasticisers was sparse, but in general appears to be of the same order of magnitude as that of DEHP The margin of exposure for DEHP in neonates seems to be very low. For blood transfusion peak values up to 22 mg/kg bw/day have been estimated showing a dose 4 times higher than the NOAEL of DEHP.

Table 3-5 NOAEL of DEHP compared with some alternative plasticisers. The critical endpoint is shown to indicate that for some of the chemicals it is different from reproductive effects (SCENIHR 2008)

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

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

According to the SCENIHR, considering similar leaching rates, the margin of safety of other plasticisers will be at least 20 times higher for most alternatives. The toxicological profile of DEHP and the alternative plasticisers with respect to repeated dose toxicity, genotoxicity, carcinogenicity and maternal toxicity in Table 3-6.

Table 3-6 Comparison of the toxicological profiles of DEHP and potential alternatives to its use (SCENIHR 2008)

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

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

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

Alkylsulphonic phenyl ester in water mattresses

The SCENIHR evaluation did not include alkylsulphonic phenyl ester, which is widely applied as an alternative to DEHP in toys, gloves, water beds, etc. A Danish study (Nilsson *et al.* 2002) demonstrated the feasibility of the substance as alternative in waterbeds where it is used today. A health and environmental assessment identified as critical parameters that it was not demonstrated (at the time of the study) whether the alternative had endocrine disrupting properties and that the substance was not easily degradable in the aquatic environment. The latter is an advantage when used in water mattresses but the study concludes that it may be critical for other applications e.g. articles with short lifetime, e.g. packaging.

The main constituents have recently been assessed and are not considered as PBT by the TC NES Subgroup on Identification of PBT and vPvB Substances (ECB 2008). The constituents do not meet the P/vP criteria based on screening data, but they meet the screening B (bioaccumulative) criteria. This substance contains other substances as impurities, which may meet the P/vP and B/vB criteria based on screening data; however, these impurities are present in such low concentrations that they are not considered to be of concern at present due to a very limited potential for environmental release from the current production and use within the EU.

Substitutes to phthalates in soft PVC for toys and childcare
The availability of substitutes for soft PVC containing phthalates in certain toys and childcare articles was evaluated for the European Commission by Postle *et al.* (2000). At the time of the study, the only substitute plasticiser which had been confirmed as definitely being used was o-acetyltributyl citrate (ATBC). Products using PVC formulations containing ATBC could reportedly match all of the technical requirements which are met when phthalates are used. Other plasticisers that were assessed as technically suitable were adipates (DEHA), benzoates, alkylsulphonic phenyl esters, trimellitates and polymerics. The citrates, benzoates and alkylsulphonic phenyl esters were assessed as technically suitable for products intended to be placed in the mouth whereas all substances were technically suitable for other plasticised PVC toys and childcare articles. The use of DEHP, DDP and DBP in toys and childcare products is today prohibited in the EU.

Technical evaluation of alternatives for medical products
Karbæk (2003) evaluated the technical properties of seven marketed plasticisers for use in medical products. PVC compounds plasticised with these selected substances were prepared and tested for a number of properties. None of the substances was rejected, but the author concluded that much more data was needed before DEHP could be seriously substituted in medical devices. During the five years since the study was concluded, however, DEHP seems to have been replaced in a number of medical applications.

Health, environmental and technical/economic assessment of DEHP alternatives for three application areas
The Toxics Use Reduction Institute (TURI 2006) at the University of Massachusetts Lowell investigated a number of alternatives to DEHP for three application areas: Resilient flooring, wall coverings and medical devices for neonatal care.

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

The assessment of alternatives for sheet devices for medical applications (storage of blood products, nutritional solutions and intravenous solutions and drugs) concluded that no single alternative can be promoted for all potential uses. For red blood cell storage, DEHP/PVC continues – according to the study – to be the material of choice and there is a continuing need for research to identify other plasticiser and material alternatives for this use. TOTM, DEHA, BTHC and DINCH all appeared to be potentially appropriate alternatives to DEHP for other medical solution storage options, though DINCH has not yet received FDA (U.S. Food and Drug Administration) approval for use in medical products in the U.S. According to the study, more research is required to determine the migration potential of these plasticisers into various solutions, and to assess the potential toxicology associated with exposure to these plasticisers and their metabolites in neonates. Modifications in processing requirements are likely to be associated with a switch to any of these alternative plasticisers. In addition, the costs of TOTM, BTHC and DINCH were relatively higher than of DEHP. For tubing devices, DINP and DEHA were assessed as alternative plasticisers. Both were reported to be comparable in cost, with some processing and environmental, health and safety issues that require further study before determining a preferred alternative to DEHP.

The Institute assessed two plasticiser alternatives to DEHP in wall covering: DEHA and DINP. Both DEHA and DINP appeared to be technically feasible alternatives to DEHP in wall covering applications, exhibiting comparable environmental, health and safety, performance and cost profiles.

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

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

The evaluation of risks to humans or the environment (see Table 3-8) indicated that none of the five assessed substances (diethylhexyl adipate, o-acetyl tributyl citrate, di(2-ethylhexyl) phosphate, tri(2-ethylhexyl) phosphate, and tri-2-ethylhexyl trimellitate) reached concentrations in the aquatic environment which exceeded the predicted no-effect level for the aquatic environment in general. For the adipate, the study concluded that there may be a risk for the sediment compartment due to the sorptive properties of the substance combined with low degradability. The risk to the aquatic environment from o-toluene sulfonamide, epoxidised soybean oil, diisobutyrate and dioctyl sebacate could not be calculated due to lack of data.

Table 3-7 Human health and environmental properties of the investigated substances and materials (Stuer-Lauridsen *et al.* 2001)

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

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

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

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

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

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

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

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

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

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

Table 3-8 Evaluated risks to humans or the environment. The estimated exposure of humans is compared to the Acceptable Daily Intake (ADI). (Stuer-Lauridsen *et al.* 2001)

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

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

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

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

Substances selected for further assessment
The available assessments show that a number of potential alternatives to DEHP exist, which may be suitable to replace DEHP in different application areas. Only a few of the alternatives have undergone a comprehensive environmental and health assessment combined with an assessment of the economic and technical feasibility of substitution. For some critical applications, non-phthalate alternatives are widely used, demonstrating the feasibility of substitution for at least these applications, but for many of the large volume applications like flooring or cable/wires, phthalates (mainly DINP) are still the plasticiser of choice.

Some of the alternatives have also been shown to also cause reproductive toxicity and will not be evaluated further. Others seem not to have widespread use today indicating that they are not considered feasible alternatives.

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

The following substances are selected for the more detailed assessment:

- Di-isononyl phthalate (DINP), CAS N^{o} 68515-48-0, 28553-12-0;
- Di(2-ethylhexyl) terephthalate (DEHT); CAS N^{o} 6422-86-2;
- n-Butyryl-tri-n-hexyl citrate (BTHC); CAS N^{o} 82469-79-2
- Di-(isononyl)-cyclohexan-1,2-dicarboxylate (DINCH); CAS N^{o} 166412-78-8
- Alkylsulphonic phenyl ester (ASE); CAS N^{o} 91082-17-6.

3.1.2 Identification of alternative techniques

Besides the replacement of DEHP with other plasticisers, the soft PVC may be replaced with other materials. Alternative materials proposed or assessed in selected previous studies are listed in Table 3-9.

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

Application	Proposed by TNO 2002 as cited in Annex XV dossiers	Assessed in TURI 2006	Assessed in Postle *et al.* 2000	Proposed in Stuer-Lauridsen *et al.* 2001
Flooring	Linoleum, rubber, polyolefins, wood and textile (sometimes different functionalities)	Natural Linoleum, cork, polyolefin, polyethylene/limestone blend, rubber	n.a.	
Wall coverings		Glass woven textiles, wood fiber/polyester, polyethylene, cellulose/polyester, polyester, biofibers, polyolefins, recycled paper, wool/Ramie	n.a.	
Cables	Polyethylene	n.a.	n.a.	
Roofing	Tar/bitumen, chlorinated polyethylene and ethylene propylene rubber	n.a.	n.a.	
Building plate	Polyester	n.a.	n.a.	
Garden hoses	n.a.	n.a.	n.a.	Low density polyethylene (LDPE)
Car undercoating	Bitumen/rubber mix and polyurethane	n.a.	n.a.	
Tarpaulins	Polyurethane, ethylene propylene rubber, rubber coated cotton, polyethylene and polypropylene	n.a.	n.a.	
Coated fabrics	Polyurethane for artificial leather. Paper for wall paper. Polyethylene for foils and acrylates	n.a.	n.a.	Polyurethane based on diphenylmethane-4,4'-diisocyanate (MDI) monomer
Toys	Polyethylene, polypropylene and rubber	n.a.	Polyethylene and ethylene vinyl acetate, polyethylene, styrenic block copolymer	Low density polyethylene (LDPE)
Medical devices	Some applications: polyethylene, glass and latex (gloves)	n.a.	n.a.	
Medical devices for neonatal applications	n.a.	Ethyl vinyl acetate, polyolefins (polyethylene and polypropylene), thermoplastic Polyurethane, glass, silicone	n.a.	

n.a. Not assessed

Comparison of DEHP/PVC with alternative materials is complicated by the fact that the materials cannot be compared on the basis of the difference in health and environmental profiles only, as for a comprehensive comparison it is necessary to include many other technical aspects and environmental parameters. For a full comparison of the materials it is thus necessary to compare the materials in a life cycle perspective taking also into account e.g. the life-span of the materials, the energy consumption by manufacturing and the maintenance of materials.

In the following the results of previous studies are shortly reviewed in order to obtain a first estimate of the feasibility of the alternative materials.

Alternative materials for toys
Postle *et al.* (2000) note that a number of companies have undertaken DEHP substitution by shifting to entirely different plastic materials rather than by simply replacing the plasticiser for PVC. For those products which are specifically intended to be placed in the mouth, the substitute plastics, which appeared to be most widely used, were polyethylene (PE) and ethylene vinyl acetate (EVA). These materials can reportedly be used as adequate alternatives in the products in question. However, the technical performance of the final product has been indicated to be often slightly inferior to that obtained with PVC. For example, products produced from these materials may sometimes have lower resistance to biting and tearing than plasticised PVC. The products may also have reduced longevity. In terms of the wider range of toys and childcare articles, plastics which are reported to be used as substitutes for plasticised PVC include various forms of polyethylene (LDPE, and LLDPE) styrenic block copolymers and again EVA.

In terms of substitute plastics, very little information was available on the migration of organic additives from toys and childcare articles. One additive, butylated hydroxytoluene (BHT), was taken as an illustrative substance since this was known to be used in some teething products made from substitute plastics. The consideration of BHT for the purposes of the study served only to highlight that there existed a potential risk associated with other organic additives used in the products in question. BHT appeared to be more toxic than any of the plasticisers which had been considered (phthalates, ATBC, DEHA) and should, according to the authors, thus be considered more hazardous than those substances with respect to its tolerable daily intake. However, BHT was used in much lower quantities than the phthalates, decreasing the likely risk.

Alternative materials for flooring, medical devices and wall covering
The Toxics Use Reduction Institute (TURI 2006) investigated a number of alternatives materials for three application areas: Resilient flooring, wall coverings and medical devices for neonatal care.

Resilient 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 summary for the comparison of flooring materials is shown in Table 3-10 and the results of the assessment of the alternative materials are provided in Table 3-11.

Wall coverings - For wall coverings numerous alternative materials were assessed, including woven glass textiles, a wood fiber/polyester blend, cellulose polyester blends, a wood pulp/recycled paper blend, biofiber products, and polyolefin/synthetic textiles. According to the authors, each appeared to present a feasible alternative to DEHP/PVC for wall covering applications. Further details of the assessment are provided in the study report

Medical applications - For medical applications, several alternative materials were assessed for both sheet (EVA, polyolefins and glass) and tubing (polyolefins, silicone and TPU) applications. Products utilising the alternative materials, either singly or in multi-layer laminates, were commercially available for sheet and tubing device applications with the notable exception of red blood cell storage. Many manufacturers were offering non-DEHP and/or non-PVC alternatives for both sheet and tubing uses. The study does not provide a clear conclusion for medical applications. For the detailed assessment summary reference is made to the study report.

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

Material	Performance			Availability (No. of suppliers/mfgr) *1	Cost (purchase & install.) $/sf *2	Environmental		Comments
	Maintenance / Durability	Lifespan (years)	Colors/ Patterns			Hazards	Benefits	
DEHP/PVC	Clean with water and ammonia when needed. Many require routine stripping and wax re-application.	25+	Many	Many	$3-8	Ref.	Ref.	
Natural Linoleum	Dust mop, vacuum or sweep with a broom to remove grit and dust from the surface	40+	Many patterns and colors	Many	$3-6	Outgases linseed oil VOCs	Rapidly renewable, decomposes in dump, may be compostable	
Cork	Sweep or vacuum floor frequently. Wet maintenance is entirely forbidden. Recoat with polyurethane 4-8 yrs or when floor starts to show wear	80+	Limited solid colors	Many	$6 - $11.50	Some manufacturers use urea formaldehyde binders	Rapidly renewable, biodegradable at end of useful life	
Polyolefin (Stratica)	Sweep or vacuum floor frequently; mop with water when necessary			Many	$6.50/sf	Petrochemical based	Low VOC, solvent free adhesive, limited recycling	
Polyethylene / Limestone (LifeLine)	Moist or wet-cleaning method with mildly alkaline cleaner should be used	30-50		Despite printed literature, does not appear to be available in the US	$5-$6	Installed with a regular acrylic based adhesive	Recycled during production, disposed of by burning and used as an energy waste since contains no PVC	Not currently available in the US
Rubber	Sweep or vacuum to remove loose dirt, spot clean and use damp mop			Many	$3-10	Some outgas of VOCs – varies between differing products	Recyclable but no infrastructure to take back	Limited colors and prints; more of a niche product for high traffic industrial & commercial installations

*1: mfgr = manufacturer. *2: sf: square foot = 0.093 m^3

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

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

Comparison Key: + Better - Worse ? Unknown = equal

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

For applications of soft PVC the study concludes:

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

- For roofing applications the study concludes that higher quality of the systems (thermal conductivity per thickness of roofing sheet layers) as well as the accuracy of the laying and maintenance processes have a large influence on the reduction of environmental impacts. Additionally, the study concludes that 'green roofing' (e.g. planting on the roof) further decreases environmental impacts because of the subsequent longer lifetime of the roofing systems. Three polymer solutions (one PVC system and two competing systems) have the potential to perform better, with similar environmental impacts on global warming, acidification and ozone formation over the life cycle. The study reports that some polymer solutions tend to have lower environmental impacts than competitive systems.

- Few comparative LCA studies pertaining to consumer goods are available. No useful general conclusions on material comparisons could be drawn.

- The only toy applications requiring significant amounts of PVC are applications such as inflatable toys, paddling pools and rubber boats/rafts. The potential risks associated with the misuse of toys (e.g. ingestion, sucking or chewing) are of particular concern. However, a LCA cannot analyse these risks properly; therefore, these concerns should be addressed using other tools, such as risk assessment.

- PVC cable does not seem to have significant competitors in many cable applications; therefore few PVC cable LCA studies exist. Recycling processes have been in place for some time, due to the high economic value of the recovered copper and aluminium. Economically feasible options exist for the recycling of recovered PVC.

- No comparative LCA studies exist for materials used in medical applications, and little environmental optimisation in medical products has taken place thus far.

Conclusion
The available studies demonstrate that for many applications of DEHP/PVC alternative materials exist at similar prices. Many of the materials seems to have equal or better environmental, health and safety, performance and cost profiles, but clear conclusion are complicated by the fact that not all aspects of the materials' lifecycles have been included in the assessments.

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

3.2 *Human health effects*

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

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

3.2.1 Di-isononyl phthalate (DINP)

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

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

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

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

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

After the DINP RAR was finalised, the Chronic Hazard Advisory Panel on DINP of the US Consumer Product Safety Commission reported its risk characterisation using spongiosis hepatis as the critical endpoint [CSTEE/2001/12-Add. 3 - Report to the

U.S. Consumer Product Safety Commission by the Chronic hazard advisory panel on di(isononyl) phthalate (DINP) – June 2001]. The CPSC have calculated the benchmark dose corresponding to a 5% response for this effect to be 12 mg/kg/d based on the Exxon study and 15 mg/kg/d on the Aristech study. The CSTEE considers the approach 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 cited in DINP RAR). 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 3-12 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}	

3.2.2 Di(2-ethylhexyl) terephthalate (DEHT)

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

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

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

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

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

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

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

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

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

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

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

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

Table 3-13 Human health effects of di(2-ethylhexyl) terephthalate

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

3.2.3 n-Butyryl-tri-n-hexyl citrate (BTHC)

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

BTHC is well absorbed after oral administration. It is rapidly metabolised by hydrolysis of the ester bonds to a number of metabolites. The principal metabolite is n-hexanol. Radiolabelled BTHC is cleared rapidly from the body following iv administration through a combination of urinary and biliary excretion and expired air. BTHC related material does not accumulate in any of the body tissues. The clearance is biphasic with half lives of <15 minutes and >24hours. The findings indicate that BTHC is unlikely to accumulate in the body even after a prolonged period of exposure.

Acute toxicity - No mortality was observed by the oral route in rats for BTHC up to 5000 mg/kg kg bw. Acute iv injection studies with doses of up to 462 mg/kg did not produce any significant adverse effects. In dogs at the same iv dose level the only changes of note observed were in serum glutamate pyruvate transaminase and alkaline phosphatase. It was concluded that BTHC has a low acute toxicity.

Irritation and sensitisation - One acute study in rabbits indicates that BTHC is a very mild irritant to the skin. In a second study in rabbits undiluted BTHC (0.1ml) produced a mild and transient reaction when instilled into the eye. Findings from the maximisation test method in guinea pigs using undiluted BTHC show a slight patchy reddening in one male and one female animal only. A further study using the Buehler method did not show any indication of sensitisation. It can be concluded that under the conditions of these experiments BTHC has a low irritation and sensitisation potential.

Repeated dose toxicity - The toxicological properties of BTHC have been investigated by both the oral and iv routes of administration. In an oral dosing study rats were given BTHC by gavage at 0, 250, 500 or 1000 mg/kg kg bw/day for 28 days. No clinical signs of toxicity were observed during the study. Statistically significant increases in the relative liver weight of males were noted at 500 and 1000mg/kg kg bw/ per day but no absolute changes in liver weight were found. Statistically significant changes in urinary pH, aspartate aminotransferase, blood albumin, creatinine and blood calcium were found at the higher dose levels. These findings did not show a clear dose dependency nor were the changes consistent between the sexes. It is difficult to identify a precise NOEL from these findings but a value of 250mg/kg kg bw/ per day is reasonable.

In one study BTHC was administered intravenously to adult rats at dose levels of 5, 50, and 500 mg/kg bw/day for 28 days. At 500 mg/kg bw/day no changes were observed in kg body weight, but there were moderate increases in both liver and spleen weight. These changes were associated with an accumulation of pigment laden macrophages in both organs. This dose group also showed statistically significant changes in some blood parameters. Namely, a decrease in haemoglobin, mean red cell volume and platelet levels and an increase in fibrinogen and reticulocyte levels. No other adverse histopathological changes were observed in any organs. No adverse effects were observed at the two lower dose groups. Thus an NOEL by the iv route of 50mg/kg bw/day can be identified.

In a study in neonatal rats, BTHC was administered daily either iv or ip to male and female neonatal rats at 5, 50, and 500 mg/kg kg bw/ per day for eighteen days. At the top dose of BTHC following ip administration an increase in liver weight was noted but without evidence of adverse histopathological changes. After iv administration some histopathological changes were also observed in the lungs (macro granulomas and foreign body infiltration) at each dose. These effects following iv administration are probably due to the route of administration rather than to BTHC itself. By either administration route some tissue damage was noted around the injection sites. The study supports a NOEL by the iv and ip routes of 50mg/kg bw/day.

A specific study was also conducted to investigate the potential of BTHC to cause peroxisome proliferation. Rats were given 3% BTHC in the diet for six weeks. No increase in hepatic peroxisome proliferation was found.

Mutagenicity and genotoxicity - No mutagenic effects were observed for BTHC in several bacterial tests either with or without the presence of a metabolic activation system. In one study the urine, from mice given oral doses of BTHC of up to 1000 mg/kg bw/day, was assessed in various Ames strains of salmonella. No mutagenic effects were observed. In mouse lymphoma cells BTHC produced different findings in two experiments. In the first there was a slight but statistically significant increase in mutations whereas in a second comparable experiment no significant changes were observed. Using human peripheral lymphocytes no significant alteration in the incidence of either chromosomal breaks or mitotic frequency was found.

One in vivo study was also carried out in a bone marrow cytogenetic assay. Mice were given an oral dose of 1000 mg/kg bw/day either as an acute dose or daily for five days. In neither study was there any indication of BTHC genotoxicity. It can be concluded that BTHC is not genotoxic. This conclusion is supported by the lack of structural alerts for both BTHC and its metabolites.

Carcinogenicity - A lifetime bioassay test has not been conducted. However it is noted that BTHC is neither genotoxic nor is it a peroxisome proliferating agent.

Reproductive studies - A fertility study was carried out in albino rats at dietary levels of 0, 0.6 0r 1.2% BTHC. Males were exposed to BTHC continuously to BTHC for ten weeks prior to mating and during the mating period. Females were exposed for two weeks before mating, during mating, gestation and lactation. No effects on fertility and other reproductive indices, or on litter weights and pup weights were observed. The body weight of the lactating females exposed to the top dose was slightly lower. No increase in abnormalities in the F1 pups was found.

Developmental toxicity was also examined in rats following the iv administration of BTHC (0, 5, 50, 500 mg/kg/day) on days 6-15 of gestation. No deaths or dose dependent changes in kg bw or uterine weight were identified. Nor were any dose related changes observed in resorptions, or embryo or foetal development or foetal toxicity. However in line with the findings from repeat dose studies changes were observed in liver, lung and spleen weight in the mothers. An NOEL for foetal/embryo toxicity of 500 mg/kg kg bw/day can be estimated in this study.

Table 3-14 Human health effects of n-butyryl-tri-n-hexyl citrate

Name of substance	n-Butyryl-tri-n-hexyl citrate	
Abbreviation	BTHC	
CAS No.	82469-79-2	
Endpoint	Value	Reference
LD50	>5000 mg/kg (rat,oral)	SCENIHR 2008
NOAEL mg/kg bw		
Reproductive toxicity	No	- " -
Developmental toxicity	No	
Repeated dose Toxicity, NOAEL	250 mg/kg bw/day (rat, oral)	- " -
Genotoxicity	Negative	- " -
Carcinogenicity	No data	- " -
Critical endpoint	Repeated dose Toxicity – effects on liver weight, enzyme activity	Dose: 250 mg/kg/day: NOEL
Preliminary DNELs	DNEL for critical endpoint	Remarks
Workers, oral	58.3 mg/day	Default assessment factors
General population, oral	29.2 mg/day	
Workers, inhalation	5.8 mgm^{-3}	
General population, inhalation	1.5 mgm^{-3}	

3.2.4 1,2-Cyclohexanedicarboxylic acid, diisononylester (DINCH)

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

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

Repeated dose toxicity - 28 day study. The 28 day toxicity study (dosing 0-600-3000-15,000 ppm in the diet corresponding to 0-64/66-318/342-585/1670 mg/kg bw for males/females, respectively) was followed by a 14 days recovery period. The highest dose induced gamma-glutamyltransferase serum level and degenerated epithelial cells in the urine. The NOAEL was 318 mg/kg bw for males and 342 mg/kg bw for females. The 90 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 3-15 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}	

3.2.5 Alkylsulphonic phenyl ester (ASE)

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

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

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

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

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

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

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

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

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

Table 3-16 Human health effects of alkylsulphonic phenyl ester

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

3.2.6 Summary for health effects

The derived DNELs for critical endpoints are summarised in Table 3-17

Table 3-17 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}
DINP	28553-12-0	Developmental	44	4	22	1
DEHT	6422-86-2	Liver toxicity	409	0.08	204	0.02
BTHC	82469-79-2	Possible liver toxicity	58	6	29	1
DINCH	166412-78-8	Kidney toxicity	75	8	3s8	2
ASE	91082-17-6	Liver toxicity (increased liver weight)	8	0.8	4	0.2

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 is 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-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.

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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 3-18 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 eco-system. No PNEC derived.	ECB (2003)
Sediment	Tentatively concluded that DINP has no adverse effects towards benthic organisms. No PNEC de-rived.	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 de-rived.	ECB (2003)
Secondary poisoning	$PNEC_{oral}$ = 150 mg/kg food	ECB (2003)
Bioaccumulation	BCF = 4,000 for secondary poisoning; 840 for hu-mans 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 compart-ment, the terrestrial compartment, the atmosphere, microorganisms in sewage treatment plant as well as secondary poisoning).	ECB (2003)

3.3.2 Di(2-ethylhexyl) terephthalate (DEHT)

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

Table 3-19 Hazard properties for DEHT

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

3.3.3 N-butryl tri-n-hexyl citrate (BTHC)

The table below describes the environmental hazard properties of BTHC.

Table 3-20 Hazard properties for BTHC

Name of substance	N-butryl tri-n-hexyl citrate	
Abbreviation	BTHC	
CAS No.	82469-79-2	
Classification	Not included in Annex I of Directive 67/548/EEC Not included in working database agreed by TC C&L	
Compartment	Hazard / risk conclusions	Reference
Water	Unknown	
Sediment	Unknown	
Soil	Unknown	
Atmosphere	Unknown	
STP	Unknown	
Secondary poisoning	Unknown	
Bioaccumulation	BCF = 44	TURI (2006)
Persistence	Unknown	
Risk assessment conclusions	None identified	

3.3.4 1,2-Cyclohexanedicarboxylic acid, diisononylester (DINCH)

The table below describes the environmental hazard properties of DINCH.

Table 3-21 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 inverte-brates, 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	

3.3.5 Alkylsulphonic phenyl ester (ASE)

The table below describes the environmental hazard properties of ASE.

Table 3-22 Hazard properties for ASE

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

3.3.6 Summary for environmental effects

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

It is evident from the data above 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 DEHP by one of the alternatives. However, based on the information presented, the following conclusions can be drawn for two of the 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).

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

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

3.4 *Technical and economic feasibility and availability*

The technical feasibility of replacing DEHP 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.

As mentioned above DEHP has in recent years been extensively replaced by other plasticisers for a number of applications, and a range of alternative substances are readily available from suppliers of plasticisers. The main alternative has been DINP which has more or less the same application profile as DEHP, but a number of other alternatives have as well been used as DEHP alternative for certain applications.

In a recent study conducted in the USA (TURI 2006) plasticiser alternatives that were identified by discussion with stakeholders, discussions with industry experts and literature research included: 18 substances for flooring, 8 substances for medical devices and 6 for wall coverings. Based on an initial screening of environmental health and technical properties the number of suitable alternatives that was evaluated in detail were reduced to four for flooring (DEHT, DINP, DGD and DEHA), four for medical devices (TOTM, DEHA, BTHC and DINCH) and two for wall coverings (DEHA and DINP).

The five selected alternative substances discussed in the environmental, health and technical assessment presented in this report are all today marketed for a number of applications shown in Table 3-17. The alternatives may well also be applied for other applications, but it is noted that the plasticisers are considered by the suppliers as particularly suitable for these applications. DINP may e.g. be applied for all applications, but for some of the applications other plasticisers are mentioned as the plasticiser of choice at the consulted web-sites of manufacturers. The balance between price and health properties influences for which applications the alternatives are marketed for use in. For instance, the price of an alternative plasticiser may be of less importance for medical applications than for flooring applications. With regard to the major applications of DEHP, none of the alternative substances is specifically identified as suitable for manufacturing of PVC based roofing material.

Table 3-23 Applications specifically mentioned by suppliers of selected alternatives

	DINP	DEHT	BTHC	DINCH	ASE
Flooring and wall covering	x	x			
Film/sheet and coated products	x	x		x	x
Medical products			x	x	
Wire and cable	x				
Coated fabric and footwear		x		x	x
Toys		x			x
Automotive	x				
Non polymer applications:					
Adhesives				x	x
Printing ink				x	x
Sealants (glass insulation, construction)	x				x

Information sources:

DINP, DIDP Jayflex ® from ExxonMobil Chemical
http://www.exxonmobilchemical.com/Public_Files/Oxo/Plasticisers/Worldwide/jayflex_broch_EN.pdf

DEHT Eastman 168 Plasticiser from Eastman Chemical Company
http://www.eastman.com/products/producthome.asp?product=71045700

BTHC Citroflex® from Morflex, Inc. (owned by Reilly Industries, Inc.) Citric Acid Esters.
http://www.morflex.com/pdf/bul101.pdf

DINCH HEXAMOLL® DINCH from BASF. http://www.hexamoll.com/icms/basf_6/en/dt.jsp

ASE Mesamoll® and Mesamoll II from Lanxess
http://techcenter.lanxess.com/fcc/emea/en/products/datasheet/Mesamoll_e.pdf?docId=78076&gid=2082&pid=780

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

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

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

Table 3-18 presents estimates of plasticiser costs based on data obtained from industry sources in the US, and includes estimated substitution factors, which allow for a normalised comparison of costs based on how they are used to create a comparably flexible product. It is considered that the price of alternatives relative to DEHP would not be significantly different on the EU market whereas the absolute prices vary.

Table 3-24 Costs of selected alternatives normalised to the cost of DEHP

	Costs of substance €/kg *1	Substitution factor *1	Normalised cost in percentage of DEHP
DEHP	1.21	1	100
DINP	1.28	1.06	112
DIDP	1.34	1.1	121
DEHT	1.28	1.03	109
BTHC	2.00	0.975	160
DINCH	1.58	unknown	n.d
ASE	n.d.	n.d	n.d

*1 US market in 2006 (TURI 2006). Recalculated from $/lb using kg:lb = 1 : 2.204; € : $ = 1 : 1.27

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Annex 1: Applied emission factors

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

	Emission factor, %			
	Air	Soil	Waste water	Waste
Manufacturing	0.00034	0.0012	0.11	n.d.

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

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Compounding by extrusion	n.d.	0.015	0	0.015	n.d.
Non-polymeric, formulation:					n.d.
Formulation of adhesives/sealant, rubber	n.d.	0.25	0.01	1	n.d.
Formulation of lacquers and paint	n.d.	0.25	0.01	1	n.d.
Formulation of printing ink	n.d.	0.25	0.01	1	n.d.
Formulation of ceramics	n.d.	0.25	0.01	2	n.d.

n.d. no data

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

Process	Emission factor, %				
	Working env.	Air	Soil	Waste water	Waste
Formulation and processing (at same site):					
Calendering of film/sheet and coated products	n.d.	0.035	0	0.035	n.d.
Calendering of flooring, roofing, wall covering	n.d.	0.035	0	0.035	n.d.
Extrusion of hose and profile	n.d.	0.015	0	0.015	n.d.
Extrusion of wire and cable	n.d.	0.015	0	0.015	n.d.
Spread coating of flooring	n.d.	0.086	0	0.086	n.d.
Spread coating of coated fabric, wall covering, coil coating, etc.	n.d.	0.086	0	0.086	n.d.
Car undercoating	n.d.	0.183	0	0.183	n.d.
Slush/rotational moulding, dip coating	n.d.	0.250	0	0.250	n.d.
Processing from compound:					
Extrusion of cables, medical, and misc. products	n.d.	0.005	0	0.005	n.d.
Injection moulding of misc. products	n.d.	0.005	0	0.005	n.d.
Plastisol processing from compounds	n.d.	0.250	0	0.250	n.d.
Non-polymeric, processing:					
Adhesives/sealant	n.d.	0.01	0.5	0	n.d.
Lacquers and paint	n.d.	0	0.5	0.1	n.d.
Printing ink	n.d.	5	0.15	0.05	n.d.
Production of ceramics	n.d.	0	0	0	n.d.

n.d. no data

Table A-4 Applied life-time emission factors for DEHP releases from end-products

	Emission factor, %			
	Air	Soil	Waste water	Waste
Indoor uses:				
Flooring	0.04	-	3.1	97
Wall covering	0.03	-	0.02	100
Film/sheet and coated products made by calendering	0.32	-	0.02	100
Wires and cables	0.15	-	0.02	100
Hoses and profiles	0.01	-	0.02	100
Coated fabric and other products from plastisol	0.05	-	0.02	100
Moulded products	-	-	0.02	100
Other polymer applications	0.02	-	0.38	100
Non polymer applications:				
Adhesives and sealant	0.10	-	1.9	98
Lacquers and paints	3.69	-	28	68
Printing ink	10.56	-	-	89
Other non-polymeric	-	-	-	100
Outdoor uses:				
Calendered roofing material	0.03	2.45	2.45	90
Coil coated roofing material	0.12	5.24	5.24	39
Wire and cables - air	0.15	1.57	1.57	95
Wire and cables - soil *1	-	36.14	-	62
Coated fabric	0.05	1.05	1.05	94
Car undercoating	0.02	0.33	0.99	89
Hoses and profiles	0.01	0.26	0.26	97
Shoe soles	-	0.09	0.09	90
Non polymer applications:	-			
Lacquers and paints	3.69	8.34	8.34	75
Adhesives and sealant	0.10	1.84	1.84	91
Outdoor uses, abrasive releases:				0
Calendered roofing material	0.005	3.75	1.25	0
Coil coated roofing material	0.05	37.5	12.5	0
Wire and cables - air	0.002	1.5	0.5	0
Wire and cables - soil *1	0.002	1.5	0.5	0
Coated fabric	0.004	3	1	0
Car undercoating	0.01	7.5	2.5	0
Hoses and profiles	0.002	1.5	0.5	0
Shoe soles	0.01	7.5	2.5	0
Non polymer applications:	0	0	0	0
Lacquers and paints	0.005	3.75	1.25	0
Adhesives and sealant	0.005	3.75	1.25	0

ANNEX 2: Statistics on extra-EU import and export

Import/export statistics
Data on export and import of relevant product groups were retrieved for the period 2005 to 2007 from the Easy Comext (or Easy XTnet) interface to the public at Eurostat's External Trade database.

For each country EU27 trade data on import and export (in weight figures) to/from the EU (trade with countries outside EU27) was retrieved and reported in Table A2-1 and Table A2-2.

Extrapolations and Assumptions
The nomenclature follows that of the Combined Nomenclature (CN8) which is used for the trade statistics. The selected product groups in the tables below are chosen on basis of the study of Skårup & Skytte (2003) undertaken for the Danish EPA. The categories used in the study of 2003 are revised for relevance and when found applicable inserted in Table A2-2. Due to the continuous updating of the Combined Nomenclature (CN), several product groups in this study have been replaced by others. The table below illustrates changes made since the 2003 study and the resulting nomenclature. Where not otherwise indicated the category number covers the same product group as in the study from 2003. In one instance a product category number in CN8 was split up (9503.49.30 to 9503.00.41 and 9503.00.49). Other categories have slightly altered wordings but no group was altered to a greater extent, therefore none has been removed as a result.

All empty fields in the table represent "no data". In the study by Skårup & Skytte (2003) assumptions have been made regarding the amount of soft poly vinyl chloride (PVC) and the estimated percentage of phthalates in selected product groups (for each commodity code).

Table A2-1 Changes and extrapolations made to reflect changes in the updated CN8.

Changes and extrapolations	
39 20 43 10	Replaces no. 3920.42.91
39 20 43 90	Replaces no. 3920.42.19
39 20 49 10	Replaces no. 3920.41.91
39 21 90 55	Replaces no. 3920.42.99
39 26 90 92	Replaces no. 3926.90.91
39 26 90 97	Replaces no. 3926.90.99
48 11 51 00	Replaces no. 4811.31.00
48 11 59 00	Replaces no. 4811.39.00
8544.59.20	Different wording (Value set according to 2003-report)
85 44 60 93	New (Value set according to 2003-report)
95 03 00 21	Replaces no. 9502.10.10
95 03 00 41	Divided from 9503.49.30
95 03 00 49	Divided from 9503.49.30

Table A2-2 Estimated tonnages phthalates in articles and materials, EUROSTAT EU27

CN8 code	Product group	Average tonnage, 2005-20007 t/y		Percentage soft PVC of product	Percentage phthalate in PVC products	Tonnages phthalate (import, t/y)	Tonnages phthalate (ex-port, t/y)
		Import, t	Export, t				
3916.20.10	Monofilament with any cross-sectional dimension of > 1 mm, rods, sticks and profile shapes, whether or not surface-worked but not further worked, of poly"vinyl chloride"	23,099	833,889	10	30	693	8,339
3916.20.90	Monofilament with any cross-sectional dimension of > 1 mm, rods, sticks and profile shapes, whether or not surface-worked but not further worked, of polymers of vinyl chloride (excl. Poly"vinylchloride")	6,049	9,623	10	30	181	96
3917.32.35	Flexible tubes, pipes and hoses, of polymers of vinyl chloride, not reinforced or otherwise combined with other materials, seamless and of a length > the maximum cross-sectional dimension, whether or not surface-worked, but not otherwise worked	4,186	52,832	100	30	1,256	5,283
3917.32.99	Flexible tubes, pipes and hoses of plastics, not reinforced or otherwise combined with other materials, without fittings (excl. Seamless and cut to length only and artificial guts)	7,661	24,901	50	30	1,149	1,245
3917.33.10	Flexible tubes, pipes and hoses, of plastics, not reinforced or otherwise combined with other materials, with fittings attached, for the piping of gases or liquids, for civil aircraft	0	0	50	30	0	0
3917.39.90	Flexible tubes, pipes and hoses, of plastics, reinforced or otherwise combined with other materials (excl. Seamless or cut to length only; tubes with a burst pressure of >= 27,6 mpa)	21,406	60,298	50	30	3,211	4,522
3917.39.99	Flexible tubes, pipes and hoses, and fittings therefor, of plastics, reinforced or otherwise combined with other materials (excl. Seamless or cut to length only; tubes with a burst pressure of >= 27,6 mpa; tubes for the piping of gases or liquids, with fittings attached, for civil aircraft)	16,083	24,259	50	30	2,412	3,639
3918.10.10	Floor coverings, whether or not self-adhesive, in rolls or in the form of tiles, and wall or ceiling coverings "in rolls with a width of >= 45 cm, consisting of a layer of plastics fixed permanently on a backing of any material other than paper, the face side of which is grained, embossed, coloured, design-printed or otherwise decorated", on a support impregnated, coated or covered with poly"vinyl chloride"	38,043	432,830	5	30	571	2,164
3918.10.90	Floor coverings of polymers of vinyl chloride, whether or not self-adhesive, in rolls or in the form of tiles (excl. Those on a backing coated, impregnated or covered with poly"vinyl chloride")	40,634	300,236	100	30	12,190	30,024
3919.90.10	Self-adhesive plates, sheets, film, foil, tape, strip and other flat shapes, of plastics, whether or not in rolls > 20 cm wide, further worked than surface-worked or other than merely cut into squares or rectangles (excl. Floor, wall and ceiling coverings of heading 3918)	4,273	42,237	19	19	152	502
3919.90.38	Self-adhesive plates, sheets, film, foil, tape, strip and other flat shapes, of condensation polymerization products and rearrangement polymerization	2,974	10,937	25	19	141	173

CN8 code	Product group	Average tonnage, 2005-20007 t/y		Percentage soft PVC of product	Percentage phthalate in PVC products	Tonnages phthalate (import, t/y)	Tonnages phthalate (export, t/y)
		Import, t	Export, t				
	products, whether or not chemically modified, whether or not in rolls of a width of > 20 cm, not worked, or only surface-worked, or only cut to rectangular, incl. Square, shapes (excl. Of polyesters, and floor, wall and ceiling coverings of heading 3918)						
3919.90.61	Self-adhesive plates, sheets, film, foil, tape, strip and other flat shapes, of plasticised poly"vinyl chloride" or of polyethylene, whether or not in rolls > 20 cm wide, unworked or not further worked than surface-worked or merely cut into squares or rectangles (excl. Floor, wall and ceiling coverings of heading 3918)	10,892	213,730	19	19	388	2,538
3919 90.90	Self-adhesive plates, sheets, film, foil, tape, strip and other flat shapes, of plastics, whether or not in rolls > 20 cm wide, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Those of addition polymerization products, condensation and rearrangement polymerization products, and floor, wall and ceiling coverings of heading 3918)	22,110	109,681	19	19	788	1,302
3920 43.10	Plates, sheets, film, foil and strip, of non-cellular polymers of vinyl chloride, containing by weight >= 6% of plasticisers, of a thickness of <= 1 mm, not reinforced, laminated, supported or similarly combined with other materials, without backing, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Self-adhesive products, and floor, wall and ceiling coverings of heading 3918)	21,238	151,980	100	30	6,371	15,198
3920 43.90	Plates, sheets, film, foil and strip, of non-cellular polymers of vinyl chloride, containing by weight >= 6% of plasticisers, of a thickness of > 1 mm, not reinforced, laminated, supported or similarly combined with other materials, without backing, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Self-adhesive products, and floor, wall and ceiling coverings of heading 3918)	18,254	50,615	0	0	0	5,061
3920 49.10	Plates, sheets, film, foil and strip, of non-cellular polymers of vinyl chloride, containing by weight < 6% of plasticisers, of a thickness of <= 1 mm, not reinforced, laminated, supported or similarly combined with other materials, without backing, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Self-adhesive products, and floor, wall and ceiling coverings of heading 3918)	27,791	269,192	100	30	8,337	26,919
3920 49.90	Plates, sheets, film, foil and strip, of non-cellular polymers of vinyl chloride, containing by weight < 6% of plasticisers, of a thickness of > 1 mm, not reinforced, laminated, supported or similarly combined with other materials, without backing, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Self-adhesive products, and floor, wall and ceiling coverings of heading 3918)	18,777	78,455	100	30	5,633	7,845
3920.99.28	Plates, sheets, film, foil and strip, of non-cellular condensation polymerization products and rearrangement polymerization products, n.e.s., not reinforced, laminated, supported or similarly combined with other materials, not worked or only surface-worked, or only cut to rectangular, incl. Square, shapes (excl.	990	7,958	25	30	74	199

CN8 code	Product group	Average tonnage, 2005-20007 t/y		Percentage soft PVC of product	Percentage phthalate in PVC products	Tonnages phthalate (import, t/y)	Tonnages phthalate (export, t/y)
		Import, t	Export, t				
	Self-adhesive products, floor, wall and ceiling coverings in heading 3918 and polyimide sheet and strip, uncoated, or coated or covered solely with plastic)						
3921.12.00	Plates, sheets, film, foil and strip, of cellular polymers of vinyl chloride, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Self-adhesive products, floor, wall and ceiling coverings of heading 3918)	29,149	109,729	100	30	8,745	10,973
3921.90.55	Plates, sheets, film, foil and strip, of condensation or rearrangement polymerization products, whether or not chemically modified, reinforced, laminated, supported or similarly combined with other materials, unworked or merely surface-worked or merely cut into squares or rectangles (excl. Products of polyesters, phenolic resins and amino-resins; self-adhesive products and floor coverings of heading 3918)	8,597	21,558	100	30	2,579	2,156
3923.29.10	Sacks and bags, incl. Cones, of poly"vinyl chloride"	16,371	17,401	100	30	4,911	1,740
3923.30.10	Carboys, bottles, flasks and similar articles for the conveyance or packaging of goods, of plastics, with a capacity of <= 2 l	82,953	347,856	1	30	311	435
3923.50.90	Stoppers, lids, caps and other closures, of plastics (excl. Caps and capsules for bottles)	43,835	195,666	5	30	658	978
3926.10.00	Office or school supplies, of plastics, n.e.s.	73,800	97,616	5	30	1,107	488
3926.20.00	Articles of apparel and clothing accessories produced by the stitching or sticking together of plastic sheeting, incl. Gloves, mittens and mitts	136,923	26,941	15	42	8,626	566
3926.90.92	Articles made from plastic sheet, n.e.s.	127,869	26,389	50	30	19,180	3,958
3926.90.97	Articles of plastics and articles of other materials of heading 3901 to 3914, n.e.s.	534,393	432,314	3	30	4,008	3,242
4811.51.00	Paper and paperboard, surface-coloured, surface-decorated or printed, coated, impregnated or covered with artificial resins or plastics, in rolls or in square or rectangular sheets, of any size, bleached and weighing > 150 g/m² (excl. Adhesives)	97,300	891,138	2	30	584	1,782
4811.59.00	Paper and paperboard, surface-coloured, surface-decorated or printed, coated, impregnated or covered with artificial resins or plastics, in rolls or in square or rectangular sheets, of any size (excl. Bleached and weighing > 150 g/m², and adhesives)	89,894	1,196,390	2	30	539	2,393
5903.10.10	Textile fabrics impregnated with poly"vinyl chloride" (excl. Wallcoverings of textile materials impregnated with poly"vinyl chloride")	5,170	7,646	20	42	434	214
5903.10.90	Textile fabrics coated, covered or laminated with poly"vinyl chloride" (excl. Wallcoverings of textile materials covered with poly"vinyl chloride"; floor coverings consisting of a textile backing and a top layer or covering of poly"vinyl chloride")	13,743	67,998	20	42	1,154	1,904
6210.40.00	Men''s or boys'' garments of textile fabrics, rubberised or impregnated, coated,	37,742	8,837	0	0	0	0

CN8 code	Product group	Average tonnage, 2005-20007 t/y		Percentage soft PVC of product	Percentage phthalate in PVC products	Tonnages phthalate (import, t/y)	Tonnages phthalate (export, t/y)
		Import, t	Export, t				
	covered or laminated with plastics or other substances (excl. Of the type described in subheading 6201,11 to 6201,19, and babies'' garments and clothing accessories)						
6210.50.00	Women''s or girls'' garments of textile fabrics, rubberised or impregnated, coated, covered or laminated with plastics or other substances (excl. Of the type described in subheading 6202,11 to 6202,19, and babies'' garments and clothing accessories)	26,595	18,459	0	0	0	0
8544.41.10	Electric conductors of a kind used for telecommunications, for a voltage <= 80 v, insulated, with connectors (excl. Coaxial)	26,660	10,617	32	25	2,133	425
8544.41.90	Electric conductors for a voltage <= 80 v, insulated, fitted with connectors, n.e.s.	72,974	37,491	24	25	4,378	1,125
8544.49.20	Conductors, electric, for a voltage <= 80 v, insulated, not fitted with connectors, of a kind used for telecommunications, n.e.s.	51,666	75,474	32	25	4,133	2,013
8544.49.80	Conductors, electric, for a voltage <= 80 v, insulated, not fitted with connectors, n.e.s.	34,187	87,019	24	25	2,051	2,611
85 44.51.10	Electric conductors of a kind used for telecommunications, for a voltage > 80 v but <= 1.000 v, insulated, fitted with connectors, n.e.s.	9,666	3,103	32	2500	773	124
85 44.51.90	Electric conductors, for a voltage > 80 v but <= 1.000 v, insulated, fitted with connectors, n.e.s. (other than of a kind used for telecommunications)	104,263	53,594	24	25	6,256	1,608
8544.59.10	Electric wire and cable, for a voltage > 80 v but <= 1.000 v, insulated, not fitted with connectors, with individual conductor wires of a diameter > 0,51 mm, n.e.s.	34,908	123,997	24	25	2,094	3,720
8544.59.80	Electric conductors for a voltage > 80 v but < 1.000 v, insulated, not fitted with connectors, with individual conductor wires of a diameter <= 0,51 mm, n.e.s.	90,355	240,755	24	25	5,421	7,223
8544.59.99	Electric conductors, for a voltage > 80 v but =< 1 000 v, not fitted with connectors, with individual conductor wires of a diameter =< 0.51 mm, insulated with materials other than plastics or rubber, n.e.s.			24	25	0	0
8544.60.10	Electric conductors for a voltage > 1.000 v, insulated, with copper conductors, n.e.s.	16,876	265,530	24	25	1,013	5,311
8544.60.90	Electric conductors for a voltage > 1.000 v, insulated, not with copper conductors, n.e.s.	29,256	93,056	24	25	1,755	1,861
8544.59.20	Electric conductors for a voltage <= 80 v, insulated, not fitted with connectors, with individual conductor wires of a diameter <= 0,51 mm, n.e.s.	13,165	62,837	24	25	790	1,885
8544.60.93	Electric conductors, for a voltage > 1 000 v, with conductors other than of copper, insulated with plastics other than elastomers, incl. Cross-linked materials, n.e.s.			24	25	0	0
9018.39.00	Needles, catheters, cannulae and the like, used in medical, surgical, dental or veterinary sciences (excl. Syringes, tubular metal needles and needles for	24,734	51,501	80	27	5,343	3,708

CN8 code	Product group	Average tonnage, 2005-20007 t/y		Percentage soft PVC of product	Percentage phthalate in PVC products	Tonnages phthalate (import, t/y)	Tonnages phthalate (ex-port, t/y)
		Import, t	Export, t				
	sutures)						
9503.00 .21	Dolls representing only human beings, whether or not clothed	64,975	2,016	60	30	11,696	363
9503.00 .41	Stuffed toys representing animals or non-human creatures	94,087	2,577	60	30	16,936	464
9503.00.49	Toys representing animals or non-human creatures (excl. Stuffed)	64,980	2,713	60	30	11,696	488
9506.99.90	Articles and equipment for sport and outdoor games n.e.s; swimming and paddling pools	199,702	126,552	30	35	20,969	4,429
SUM						204,124	225,087

ANNEX 3: 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 A3-1, Table A3-2. and Table A3-3 below. The registers in Norway, Denmark and Finland mainly include products containing dangerous substances.

Table A3-1 Use of Bis(2-ethylhexyl)phthalate (DEHP) 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
Softeners (Plastic-, Rubber-, Paint-, Adhesive softeners) (Plasticizing additives)	4.0	150.0	150.0	375.7	1125.2	1971.2	2569.4
Colouring agents (see also Hair-dyes; Printing inks)	2.3			1.9			1.9
Paint, lacquers and varnishes	0.7	0.7	0.7	18.0	0.9	0.9	18.5
Filling materials (see also Fillers; Insulation materials)	0.4	1.2	1.2	10.8	0.2	0.2	8.2
Adhesives	0.0	0.0	0.0	0.1	0.1	0.1	0.2
Binding agents - for binding together the individual constituents in the product				2.1			0.1
Casting materials				0.6	0.7	0.5	0.6
Construction materials (building materials)				0.3			1.3
Printing inks				0.1			0.1
Padding materials					9.5	9.5	
Stopping material					4.9	4.9	
Pigments					1.0	1.0	
Hardeners for filling materials					0.2	0.2	0.2
Tightening materials (putty)					0.2	0.2	
Covering lacquers					0.2	0.4	
Adhesive hardeners					0.1	0.1	
Other printing inks					0.1	0.1	
Resins for 1- and 2-comp. hardening adhesives					0.0		
Other binding agents					0.0	0.0	

Table A3-2 Use of Bis(2-ethylhexyl)phthalate (DEHP) in Products in Sweden

SWEDEN Product group	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y	1999 t/y
Softeners for plastic, rubber, paint and adhesive	1,405	2,427	3,693	9,754	8,225	1,405	2,427	3,693
Raw materials for production of rubber products	55	42		26		55	42	
Intermediates (rubber manufacture)			26	26	9			26
Intermediates (plastics manufacture)			1	1	1			1
Tightening materials (putty)	3	9				3	9	
Binders (for paints, adhesives etc)			22	19	22			22
Other binding agents	0	1	153	108	143	0	1	153
Dyestuffs, pigments	0	1	3	10	10	0	1	3
Paint and varnish Volatile organic thinner Active corrosion inhibitor Industrial use/ Corrosion inhibitor Other (including ship-, road-, art- ,furniture-, autopaint)		0					0	
Paint and varnish Volatile organic thinner Decorative/protection Other (including road-, art-,furniture-, autopaint)	0	8	5		45	0	8	5
Other paints and varnishes, solvent-based	0		7	13	15	0		7
Other colouring agents	0	0				0	0	
Printing inks			6	6	54			6
Flame retardants / Fire prevention additives	0	0	0	0	0	0	0	0
Moulding compounds	5					5		
Padding (filling) materials	0	0				0	0	
Adhesives Water based Industrial use	0					0		
Sealing compounds			11	19	22			11
Pesticides			13					13

Table A3-3 Use of Bis(2-ethylhexyl)phthalate (DEHP) 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
Softeners (Plastic-, Rubber-, Paint-, Adhesive softeners) (Plasticizing additives)							376.9
Paint, lacquers and varnishes				2.5	4.1	8.5	5.3
Filling materials (see also Fillers; Insulation materials)			0	0.1	0.1	0.1	0.2
Colouring agents (see also Hair-dyes; Printing inks)				1.1	1.8	1.7	
Other colouring agents			0.6				
Adhesives (see also Binding agents)						0.1	
Process regulators (synthesis regulators)					1.5		
Paint and varnish Volatile organic thinner Decorative/protection Other (including ship-, road-, art-,furniture-, autopaint)			0				

Very limited data from Finland are available and are therefore not included

ANNEX 4: CONFIDENTIAL INFORMATION

[Not included in published report]