Institute for Health and Consumer Protection
Toxicology and Chemical Substances (TCS)
European Chemicals Bureau
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BENZYL BUTYL PHTHALATE (BBP)

CAS No: 85-68-7

EINECS No: 201-622-7

Summary Risk Assessment Report

2008 **EUR 22773 EN/2**

The mission of the IHCP is to provide scientific support to the development and implementation of EU polices related to health and consumer protection. The IHCP carries out research to improve the understanding of potential health risks posed by chemical, physical and biological agents from various sources to which consumers are exposed.

The Toxicology and Chemical Substances Unit (TCS), commonly known as the European Chemicals Bureau (ECB), provides scientific and technical input and know-how to the conception, development, implementation and monitoring of EU policies on dangerous chemicals including the co-ordination of EU Risk Assessments. The aim of the legislative activity of the ECB is to ensure a high level of protection for workers, consumers and the environment against dangerous chemicals and to ensure the efficient functioning of the internal market on chemicals under the current Community legislation. It plays a major role in the implementation of REACH through development of technical guidance for industry and new chemicals agency and tools for chemical dossier registration (IUCLID5). The TCS Unit ensures the development of methodologies and software tools to support a systematic and harmonised assessment of chemicals addressed in a number of European directives and regulation on chemicals. The research and support activities of the TCS are executed in close co-operation with the relevant authorities of the EU MS, Commission services (such as DG Environment and DG Enterprise), the chemical industry, the OECD and other international organisations.

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2008

Norway

Rapporteur for the risk assessment of benzyl butyl phthalate is the Norwegian Pollution Control Authority in consultation with the Directorate of Labour Inspection, on behalf of the European Union. The scientific work on this report has been prepared by the National Institute of Public Health, the Norwegian Institute of Water Research and the National Institute of Occupational Health.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance benzyl butyl phthalate (BBP) that has been prepared by Norway in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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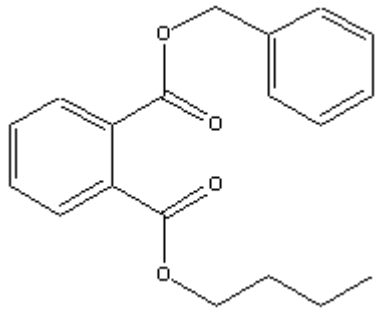
1 GENERAL SUBSTANCE INFORMATION



1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number:	85-68-7
EINECS Number:	201-622-7
IUPAC Name:	benzyl butyl phthalate
Synonyms:	1,2-benzenedicarboxylic acid, butyl phenylmethyl ester; benzyl-n-butyl phthalate; phthalic acid, butyl benzyl ester; Santicizer 160; Sicol 160; Unimoll BB
Molecular weight:	312.35
Molecular formula:	$C_{19}H_{20}O_4$
Structural formula:	

1.2 PURITY/IMPURITIES, ADDITIVES

Purity/impurities

Purity: >98.5% (w/w)

Identity and percentage (w/w) of impurities:

< 1.0% dibenzyl phthalate (CAS No. 523-31-9)
< 0.5% benzyl benzoate (CAS No. 120-51-4)
< 0.5% dibutyl phthalate (CAS No. 84-74-2)
< 2 ppm α-clorotoluen (CAS No. 100-44-7)
< 2 ppm α-α-diclorotoluen (CAS No. 98-87-3)

Additives

< 0.5 ppm pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4-hydoxyphenyl)propionate (CAS No. 6683-19-8).

1.3 PHYSICO-CHEMICAL PROPERTIES

A summary of physico-chemical information of BBP which is used in further calculations is shown in **Table 1.1**.

Table 1.1 Summary of physico-chemical properties of BBP

Property	Value
Physical state	Liquid
Boiling point	370°C at 10.10 hPa
Melting point	<-35°C
Vapour pressure	0.00112 Pa at 20°C
Water solubility (20-25°C)	2.8 mg/L
partitioning coefficient n- octanol/water	log K_{ow} 4.84
Flash point	198°C (390 °F)
Autoignition temperature	425°C
Density (25°C)	1.116 g/cm^3
Henry's Law constant (calculated)	0.176 Pa*m3*mol-1

1.4 CLASSIFICATION

Classification according to Annex I (29th ATP) of Directive 67/548/EEC[2]

Human Health:	Repr. Cat. 2 ; R61	May cause harm to the unborn child
	Repr. Cat 3 ; R62	Possible risk of impaired fertility
	Symbol: T	Toxic
Environment:	R50-53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
	Symbol: N	Dangerous for the environment
Labelling:	T, N R: 61-62-50/53 S: 53-45-60-61	

[2] The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substance (OJ L 216/3, 16.06.2004, p. 123).

2 GENERAL INFORMATION ON EXPOSURE

2.1 PRODUCTION

In the period 1994-1997 there were 3 producers of benzyl butyl phthalate (hereafter referred to as BBP) in the EU. Reported production in this period was 45,000 tonnes/annum, with approximately 9,000 tonnes/annum being exported outside the EU. This leads to a use volume of about 36,000 tonnes/annum in the EU. For the year 2004 industry has estimated a use volume of 19,500 tonnes/annum in the EU. According to industry the considerable decline of BBP consumption over the recent years is due to the classification and labelling according to 29th ATP.

Phthalate plasticisers are produced by esterification of phthalic anhydride in closed systems with a surplus of alcohol at temperatures of about 90^{o}C. After virtually complete esterification the surplus alcohol is evaporated off under vacuum at 160^{o}C. The second step involves the conversion of phthalic acid-monobutylester to BBP via reaction with benzylchloride. The product is then neutralised, washed and finally filtered.

2.2 USE

The information on use patterns is based on data from 1997 and as no further information is available it is assumed to be the same in 2004.

Based on the available information the substance is mainly used (more than 95%) as a plasticizer of PVC or other polymers in the European Community. A softener (plasticizer) is incorporated into plastic in order to increase its process ability, flexibility and extensibility. The largest usage of BBP (about 60%) is as a softener (plasticizer) in PVC products, with flooring as the largest single use category (41% of the total use volume). BBP is further used with other polymers in e.g. sealants, adhesives, paints, coatings and inks. One of the other uses is of confidential nature and submitted information is regarded as confidential.

Consumer products such as sealants, adhesives, car care products, food packaging material and cosmetics may contain BBP. The use of BBP in adhesives, cosmetics and food packaging material has decreased during the recent years. Furthermore BBP has been reported at low concentrations in baby equipment and children toys; however, in these products BBP probably occurs as byproduct/impurity and have not been added intentionally to the products.

2.3 LEGISLATIVE CONTROLS

The marketing and use of BBP and preparations containing BBP intended for consumer use is prohibited through the 29th amendment[3] to the Directive on Restrictions on the Marketing and Use of Certain Substances and Preparations (76/769/EEC).

[3] DIRECTIVE 2005/90/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 January 2006 amending, for the 29th time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (substances classified as carcinogens, mutagens or substances toxic to reproduction — c/m/r)

The marketing and use of BBP and preparations containing BBP in toys and childcare articles is prohibited through the 22nd amendment[4] to the Directive (76/769/EEC). It bans the use of i.e. BBP in toys and childcare articles.

The use of substances classified as carcinogenic, mutagenic or toxic to reproduction of category 1 and 2 according to Directive 67/548/EEC is prohibited in cosmetic products according to Directive 76/768/EEC concerning cosmetic products. Substances classified as CMR of category 3 should be prohibited unless they are evaluated by the SCCP and found acceptable for use in cosmetic products. Through the amendment[5] of Directive 76/768/EEC, BBP is listed now in annex II to the directive and must therefore not form part of the composition of cosmetic products.

Only authorised substances should be used in the manufacture of all types of regenerated cellulose film intended to come into contact with foodstuffs. BBP has been deleted from the list of authorised substances due to the Directive 2004/14/EC[6] amending the directive on materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (93/10/EEC).

The Directive 2002/72/EEC relates to plastic materials and articles intended to come in contact with foodstuffs. Substances or groups of substances listed in annexes II to VI, can be used for the manufacture of plastic materials and articles, subject to the restrictions therein. However the list of additives established through Directive 2002/72/EEC shall be considered to be an incomplete list until the Commission decides that it shall become a positive Community list of authorised additives, to the exclusion of all others. BBP is not included in the current, but yet incomplete list of additives set out by the 2nd amendment [7] to the Directive 2002/72/EEC.

[4] DIRECTIVE 2005/84/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 December 2005 amending, for the 22nd time, Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)

[5] DIRECTIVE 2005/80/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 November 2005 amending Council Directive 76/768/EEC concerning cosmetic products, for the purposes of adapting Annexes II and III thereto to technical progress.

[6] DIRECTIVE 2004/14/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 January 2004 amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

[7] DIRECTIVE 2004/19/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 1 March 2004 amending for the 2nd time, Council Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 Environmental fate

BBP may be released into the environment during its production and subsequent life cycle stages, including disposal. Emissions to water and air are expected to be the most important entry routes of BBP. General characteristics of BBP which are relevant for the exposure assessment are given below.

Degradation

The contribution of hydrolysis and photolysis in water to the overall environmental degradation of phthalate esters, including BBP, is expected to be low. Photo-oxidation by OH radicals contributes to the elimination of BBP from the atmosphere. An atmospheric half-life of about 1.5 days has been estimated for the photo-oxidation reaction. The metabolic pathway of aerobic and anaerobic biodegradation of phthalates can be summarised as follows. First the di-ester is hydrolysed into the mono-esters (monobutyl phthalate and monobenzyl phthalate) by esterases with low substrate specificity. Subsequently the mono-esters are converted into phthalic acid. There is ample evidence that BBP is ready biodegradable under aerobic conditions fulfilling the 10-day window criterion. Anaerobic test indicate that biodegradation of BBP is slower in the anaerobic environment e.g. sediments or deeper soil or groundwater layers.

Distribution

The Henry's law constant of 0.176 Pa m^3*mol^{-1} indicates that BBP is not likely to volatilize from surface waters. BBP is emitted to air during production, formulation and processing due to elevated processing temperatures. In the air BBP is removed by both wet and dry deposition, but long distance transport is unlikely due to low volatility and short half life in the atmosphere.

The octanol/water partition coefficient (Kow) of BBP is high and consequently the equilibrium between water and organic carbon in soil or sediment will be in favour of the soil or sediment. A Koc of 10,500 l/kg can be calculated using the log Kow of 4.84.

Bioaccumulation

The measured bioconcentration factors (BCF) based on total radioactivity are in the range 135-663 l/kg. The BCF-value of 12 l/kg, taking only into account the accumulation of the parent compound, would mean that BBP is not considered to biomagnify. Based on the data from the Human Health Risk Assessment, it cannot be excluded that the metabolites can give endocrine/reproductive toxicity effects to other species like birds, fish etc, as they do to mammals. Therefore the BCF-value used should cover the BCF of the parent compound and the accumulation of the two monoester metabolites (MBuP and MBeP). The experimental BCF of 449 l/kg using ^{14}C-labelled BBP is therefore used for estimating secondary poisoning in EUSES.

3.1.2 PECs at production and processing

Exposure scenarios

The environmental exposure assessment of BBP is based on the expected releases of the substance during the following life cycle stages:

I Production
II Distribution (road tankers and ships)
IIIa Processing of PVC flooring by plastisol coating
IIIb-1 Formulation of PVC sealants
IIIb-2 Processing of PVC sealants
IIIc Processing of PVC coated textiles
IIId Processing of polymer films
IIIe-1 Formulation of general PVC
IIIe-2 Processing of general PVC
IIIf-1 Formulation of paints and inks
IIIf-2 Processing of paints and inks
IIIg-1 Formulation of adhesives
IIIg-2 Processing of adhesives
IIIh Formulation of non polymer
IVa Interior use of PVC products and polymer films
IVb Interior use of sealing
IVc Use of, paints and inks and adhesives
IVd Use of non polymer
V Incineration and landfill disposal of BBP containing polymer products

For these lives cycle stages local Predicted Environmental Concentrations (PECs) were calculated based on either generic (TGD defaults) or site-specific scenarios. The exposure scenario for IIIa (Processing of PVC flooring by plastisol coating) and IIIc (PVC coated textiles) is based on the ESD Plastics Additives from 2004. The recently updated ESD "Plastics" has passed the OECD process and is based on best available information.

In accordance with the ESD "Plastics" flooring sites were split into large sites with air treatment facilities in place and small sites without air treatment. Industry stressed that the estimation of plant size on the basis of BBP consumption may be misleading because BBP is usually not used alone but in a mixture with other plasticisers. Hence, small sites with respect to BBP are not necessarily small sites in terms of plasticiser use and industry has confirmed that the sites are actually not small sites in terms of plasticiser use. However, information from industry has also shown that there are actually sites without air treatment and hence the worst case ESD-scenario for small sites, which do not have air treatment in place, could not be omitted even though the sites may not be small sites in terms of the definition of the ESD with respect to total plasticiser use. According to industry the emissions to waste water are an overestimation, both for the large sites and for the small site scenario, but as no site specific emission data have become available emission factors are takes from the ESD.

The total BBP volume used for flooring in 2005 has been further reduced, but the scenarios used in the risk assessment are still relevant. In 2005 it is still valid to use the ESD emission factors for a small site since sites without air treatment have been identified.

Results are presented in **Table 3.1** and **Table 3.2** for production and processing, respectively.

Regional PECs are calculated to be 0.17 µg/l for water, 0.07 mg/kg wwt for sediment, $6.3 \cdot 10^{-4}$ µg/m^3 for air and $3.0 \cdot 10^{-3}$ mg/kg wwt for agricultural soil. In addition to these

estimated PECs also a number of EU monitoring data are available for BBP in various environmental compartments. Comparison of measured data and calculated PECs show that the regional PECs for all compartments are higher than the majority of monitoring data. Some measured values exceeding the regional PECs may be due to local sources or are data derived from older studies, where contamination can not be excluded. The calculated regional and local PECs are used further in the risk assessment.

Table 3.1 Local PECs for different compartments at production sites (1997 data)

Compartment	Site A	Site B	Site C
	PEC	PEC	PEC
Surface water [µg/l]	0.50	0.18	0.31
Sediment [mg/kg wwt]	0.14	0.07	0.10
Oral fish [mg/kg]	0.22	0.08	0.14

Table 3.2 Local PECs for water, soil, air and secondary poisoning, and input parameters for life cycle stage III in 2004

Scenario	IIIa-1	IIIa-2	IIIb-1	IIIb-2	IIIc	IIId	IIIe-1	IIIe-2	IIIf-1	IIIf-2	IIIg-1	IIIg-2	IIIh
Type of use	Plastisol flooring Large site	Plastisol flooring Small site	Sealants		PVC coated textiles	PVC Films and sheet	General PVC		Paints and inks		Adhesives		Non polymer use
Industry and Use category	11 Polymer 47 Softener	11 Polymer 47 Softener	11 Polymer 47 Softener		13 Textiles 47 Softener	11 Polymer 47 Softener	11 Polymer 47 Softener		12 Pulp, paper, board 47 Softener		0 Others 47 Softener		0 Other 0 Other
Life cycle step	Processing	Processing	Formulation	Processing	Processing	Processing	Formulation	Processing	Formulation	Processing	Formulation	Processing	Formulation
PECair [µg/m³]	1.52	2.38	0.69	0.14	0.34	0.21	0.02	0.03	0.14	0.14	0.07	0.002	0.45
PECstp [mg/l]	0.27	0.43	0.002	0	0.06	0.04	0.004	0.03	0.03	0.002	0.01	0.01	0.10
PEC surface water [µg/l]	27.1	42.3	0.41	0.17	6.23	3.81	0.54	2.69	3.08	0.38	1.63	1.18	9.75
PEC sediment [mg/kg wwt]	6.20	9.67	0.09	0.04	1.43	0.87	0.12	0.61	0.71	0.09	0.37	0.27	2.23
PEC agr soil [mg/kg wwt]	8.79	13.7	0.08	0.001	1.98	1.19	0.12	0.82	0.95	0.07	0.48	0.33	3.13
Oral worm [mg/kg]	15.4	24.0	0.15	0.0	3.47	2.08	0.22	1.44	1.67	0.12	0.84	0.58	5.47
Oral fish [mg/kg]	5.05	7.84	0.12	0.08	1.20	0.75	0.14	0.18	0.61	0.08	0.35	0.15	1.84

3.2 EFFECTS ASSESSMENT

3.2.1 Aquatic compartment

Both short-term and long-term aquatic toxicity data are available for BBP. The PNEC for the aquatic compartment is derived from the 28-day NOEC of 75 µg/l for reproduction of the invertebrate *Mysidopsis bahia,* a marine crustacean. This value is supported by chronic studies in fish and algae which gave NOECs of similar value. An assessment factor of 10 will be used for the extrapolation because long term NOECs for three trophic levels are available.

The $PNEC_{surface\ water}$ is 7.5 µg/l.

For $PNEC_{marine}$ an assessment factor of 100 has to be applied because only long-term toxicity NOECs are available from freshwater and saltwater species for three trophic levels and effect data from additional taxonomic groups (e.g. molluscs, echinoderms) are missing, resulting in $PNEC_{marine}$= 0.75 µg/l.

However the $PNEC_{aquatic}$ is provisional. As a group, phthalates have been suspected to cause endocrine disruption in wildlife. Endocrine disrupting effects have been shown in experimental systems for BBP. There has been suspicion about estrogenic and anti-androgenic effects caused by BBP in fish. A fish reproduction study has been requested in order to investigate possible endocrine effects of BBP.

As there are no experimental data for the toxicity of BBP to sediment-dwelling organisms, the equilibrium partitioning method is used for the derivation of a PNEC in freshwater-sediment: $PNEC_{freshwater\text{-}sediment}$ = 1.72 mg/kg wwt.

Marine-sediment: $PNEC_{marine\text{-}sediment}$ = 0.17 mg/kg wwt.

A $PNEC_{microorganisms}$ has not been derived as there was no effect on respiration in activated sludge at the solubility limit of BBP (2.8 mg/l).

3.2.2 Terrestrial compartment

As no negative effects were seen in the acute toxicity test with earthworm *(Eisenia foetida)* no $PNEC_{soil}$ could be derived. Moreover, when only one terrestrial study is available for soil organisms, the equilibrium partitioning method should also be applied for deriving a $PNEC_{soil}$ (TGD), resulting in a value of 1.39 mg/kg wwt.

3.2.3 Atmospheric compartment

Toxicity of airborne BBP to plants was assessed in two separate vapour phase phytotoxicity tests with three species mustard, (*Sinapsis alba*), Chinese cabbage, (*Brassica chinesis*) and white clover (*Trifolium repens*). The exposure period was 21 days and the species were exposed to 1 and 10 µg/m^3 nominal test concentration, measured endpoints were fresh/dry weight of plant parts and visual observation of abnormalities. At a mean maximum vapour concentration of 5.7 µg/m^3 no effects were observed. No $PNEC_{plant\text{-}air}$ could therefore be derived.

3.2.4 Secondary poisoning

The oral NOAEL of 50 mg/kg bw from a rat reproduction toxicity study is used for the derivation of the PNEC for predators (conversion factor = 20, assessment factor = 30), resulting in a $PNEC_{oral}$ of 33 mg/kg in food.

3.3 RISK CHARACTERISATION

3.3.1 General discussion

Table 3.3 and **Table 3.4** present the local PEC/PNEC ratios for the production and processing stages of BBP, respectively.

Table 3.3 Local PECs and PEC/PNEC for different compartments at production sites (1997 data)

Compartment	Site A		Site B		Site C	
	PEC	PEC/PNEC	PEC	PEC/PNEC	PEC	PEC/PNEC
Surface water [µg/l]	0.50	0.07	0.18	0.02	0.31	0.04
Sediment [mg/kg wwt]	0.14	0.08	0.07	0.04	0.10	0.06
Oral fish [mg/kg]	0.22	0.006	0.08	0.002	0.14	0.004

Table 3.4 Local PEC/PNECs for water, soil and secondary poisoning, and input parameters for life cycle stage III in 2004

Scenario	IIIa-1	IIIa-2	IIIb-1	IIIb-2	IIIc	IIId	IIIe-1	IIIe-2	IIIf-1	IIIf-2	IIIg-1	IIIg-2	IIIh
Type of use	Plastisol flooring Large site	Plastisol flooring Small site	Sealants		PVC coated textiles	PVC Films and sheet	General PVC		Paints and inks		Adhesives		Non polymer use
Industry and Use category	11 Polymer 47 Softener	11 Polymer 47 Softener	11 Polymer 47 Softener		13 Textiles 47 Softener	11 Polymer 47 Softener	11 Polymer 47 Softener		12 Pulp, paper, board 47 Softener		0 Others 47 Softener		0 Other 0 Other
Life cycle step	Processing	Processing	Formulation	Processing	Processing	Processing	Formulation	Processing	Formulation	Processing	Formulation	Processing	Formulation
Surface water	3.61	5.64	0.05	0.02	0.83	0.51	0.07	0.36	0.41	0.05	0.22	0.16	1.30
Soil	6.32	9.86	0.06	0.001	1.42	0.86	0.09	0.59	0.68	0.05	0.35	0.24	2.25
Fish	0.15	0.24	0.004	0.002	0.04	0.02	0.004	0.005	0.02	0.002	0.01	0.005	0.06
Worm	0.46	0.72	0.005	0.0003	0.10	0.06	0.007	0.04	0.05	0.004	0.03	0.02	0.16

3.3.2 Aquatic compartment (incl. sediment)|

STP

Conclusion (ii).

No $PNEC_{microorganism}$ could be derived. However, predicted concentrations in STPs in all life cycle steps are well below the highest concentration tested (water solubility, 2.8 mg/l) which gave no adverse effects towards microorganisms. Therefore **Conclusion (ii)** is anticipated.

Surface water

Conclusion (i).

A long-term fish study on reproductive and endocrine effects has to be performed.

The PEC/PNEC ratios for all life cycle steps are presented in **Table 3.3** and **Table 3.4** and result in the following conclusions:

Production and Distribution (Life cycle stage I and II)

Conclusion (ii).

The exposure scenarios for the production sites are based on site specific information and on default values. The PEC/PNEC ratios for the aquatic compartment are below 1, thus a risk to the aquatic environment is not expected. However, the **Conclusion (ii)** has to be seen as provisional until possible endocrine effects in fish have been resolved.

Processing/Formulation (Life cycle stage III)

Conclusion (ii).

The exposure scenarios for processing of BBP are based on default parameters from the TGD or the ESD “Plastics”. PEC/PNEC ratios for the aquatic compartment are below 1 for the use categories IIIb, IIIc, IIId, IIIe, IIIf and IIIg at life cycle stage III. Thus a risk to the aquatic environment is not expected. However, the **Conclusion (ii)** has to be seen as provisional until possible endocrine effects in fish have been resolved.

Conclusion (iii).

Two use categories show PEC/PNEC ratios > 1. These are the use categories IIIa (flooring large and small sites) and IIIh (formulation of confidential use). The exposure scenario for IIIa is based on the ESD Plastics Additives from 2004. The recently updated ESD “Plastics” has passed the OECD process and is based on best available information. Further site specific data have not been obtained. The exposure scenario for IIIh is based on information from Industry. The PEC/PNEC ratios for the aquatic compartment are above 1, thus a risk to the aquatic environment has to be expected.

Use and Disposal (Life cycle stages IV and V)

Conclusion (ii).

These exposure scenarios are based on several assumptions and on default parameters. The PEC/PNEC ratios for the aquatic compartment are below 1, thus a risk to the aquatic environment is not expected. However, the **Conclusion (ii)** has to be seen as provisional until possible endocrine effects in fish have been resolved.

Marine risk assessment

Under the marine risk assessment a PBT assessment has to be carried out. BBP is regarded as readily biodegradable meeting the 10 d window and the BCF is less than 2000, the B and P criteria are therefore not met. The T criterion is fulfilled since BBP is classified as toxic for reproduction (category 2 and 3) (see also Section **Error! Reference source not found.**). Only one out of three criteria is fulfilled and therefore BBP is not considered as a PBT-substance.

The $PNEC_{marine}$ is 0.75 µg/l. The monitoring study of Vethaak et al. (2002) includes two sampling locations one from the North Sea and the other one from the estuary of the river Ems Dollard, where the measured concentrations are above the $PNEC_{marine}$ (1.8 µg/l and 1.0 µg/l). The first sampling location (estuary of the river Ems Dollard) is influenced by freshwater and can therefore be covered by the inland risk assessment according to TGD, resulting in a PEC/PNEC ratio below 1.

The other sampling location is the only one out of four different locations in the North Sea exceeding the $PNEC_{marine}$. Therefore the measured high concentration of BBP seems to be an outlier and no request for further data is considered necessary at this stage **Conclusion (ii)**. However, a definite conclusion should await the results of the long-term fish study on reproductive and endocrine effects.

Sediment

The $PNEC_{sediment}$ is 1.72 mg/kg wwt. PEC and PNEC were calculated with the equilibrium partitioning method from the $PNEC_{aquatic}$ therefore the same conclusions as for water can be drawn.

3.3.3 Atmospheric compartment

A $PNEC_{air}$ could not be derived from the vapour exposure plant study. Therefore only a qualitative risk assessment is performed. The maximum PECs for air were estimated for flooring at a small site and for sealant formulation with concentrations of BBP of 2.4 and 1.0 µg/m^3. These concentrations are below the highest tested average concentration of 5.7 µg/m^3, for which no effects were observed. Measured air concentrations of BBP at flooring processing sites and sealant formulation sites are all below 0.4 µg/m^3. A **Conclusion (ii)** seems therefore adequate.

3.3.4 Terrestrial compartment

The PNEC for the terrestrial compartment is 1.39 mg/kg wwt derived by the equilibrium partitioning method. For the risk characterisation this value is compared with the PEC in agricultural soil for production, formulation and processing of BBP.

Production and Distribution (Life cycle stage I and II)

A risk assessment of local concentrations through sludge application to soil is not considered necessary for life cycle stage I and II.

Processing/Formulation (Life cycle stage III)

Conclusion (ii).

The exposure scenarios for processing of BBP are based on default parameters from the TGD or the ESD "Plastics". PEC/PNEC ratios for the terrestrial compartment are below 1 for the use categories IIIb, IIId, IIIe, IIIf and IIIg at life cycle stage III. Thus a risk to the terrestrial environment is not expected. However PNECsoil is calculated with the equilibrium partitioning method based on PNECaquatic. The **Conclusion (ii)** has therefore to be seen as provisional until possible endocrine effects in fish have been resolved.

Conclusion (iii).

Three use categories show PEC/PNEC ratios > 1. These are the use categories IIIa (flooring large and small sites), IIIc (PVC coated textiles) and IIIh (formulation of confidential use). The exposure scenarios for IIIa and IIIc are based on the ESD "Plastics". The recently updated ESD "Plastics" has passed the OECD process and is based on the best available information. Further site specific data have not been obtained. The exposure scenario for IIIh is based on information from industry. The PEC/PNEC ratios for the terrestrial compartment are above 1, thus a risk to the terrestrial environment has to be expected.

Use and Disposal (Life cycle stages IV and V)

Conclusion (ii).

These exposure scenarios are based on several assumptions and on default parameters. The PEC/PNEC ratios for the terrestrial compartment are below 1, thus a risk to the terrestrial environment is not expected. However PNECsoil is calculated with the equilibrium partitioning method based on PNECaquatic. The **Conclusion (ii)** has therefore to be seen as provisional until possible endocrine effects in fish have been resolved.

3.3.5 Secondary poisoning

The $PNEC_{oral}$ is determined to 33.3 mg/kg in food for birds and mammals. For the risk characterisation this value is compared with the PECs in fish and worm for the various exposure scenarios. PEC_{fish} was determined using a BCF of 449 l/kg, while PEC_{worm} was determined using a BCF of 831 l/kg.

All life cycle stages show PEC/PNEC ratios <1 indicating a **Conclusion (ii)**.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

Occupational exposure may occur during the production of BBP, in industrial use of BBP containing products and in professional end use of semi- and end products containing BBP.

The main routes of occupational exposure are by inhalation and dermal contact. Ingestion is not considered to be relevant for occupational exposure.

Due to the very low vapour pressure of BBP, evaporation and hence the air concentration of BBP is very low at ambient temperatures. Vapour pressures ranges for BBP from 0.00004 Pa to 0.00799 Pa are documented in literature. This corresponds to an air saturation concentration of 0.005 to 1 mg/m^3. Thus the air concentration of BBP due to evaporation will not exceed 1 mg/m^3 at ambient temperatures. Exposure to BBP vapours via inhalation is expected to be much lower, except in processes where the temperature is elevated. However, the air concentration of BBP would be higher if aerosols are generated.

The following scenarios are considered for occupational exposure to BBP:

Scenario 1 Production of BBP

- Scenario 1A: Filling of tank trucks and rail tankers
- Scenario 1B: Drumming
- Scenario 1C: Process sampling (manually sampling)
- Scenario 1D: Cleaning and maintenance

Scenario 2 Industrial use of BBP containing products

- Scenario 2A: Plastisol coating
  - Scenario 2A1: Flooring with the plastisol spread coating process
  - Scenario 2A2: Processing of PVC floats
- Scenario 2B: Processing of sealants
- Scenario 2C: Calendering and extrusion of PVC polymers
  - Scenario 2C1: Flooring with the calendering process
  - Scenario 2C2: Films with the extrusion process

Scenario 3 Professional end use of semi- and end products containing BBP

The exposure scenarios are described without taking into account the possible use and hence influence of personal protective equipment (PPE).

Few measurements regarding workers exposure to BBP have been found in the literature. For this reason all available data have been used, even when the information on the performance of the measurements has been limited.

To be able to assess the risk at the workplace for the exposure scenarios where no measured data was available. The EASE (Estimation and Assessment of Substance Exposure) model has been used to estimate the exposure. In the EASE calculations the parameter for saturated vapour pressure is set to 0.00112 Pa.

Table 4.1 Summary of exposure levels for occupational exposure of BBP. The values taken forward to the risk characterisation are emphasised

Workplace operation	Inhalation (mg/m^3)	Dermal (mg/day)
Scenario 1: Production of BBP		
1A: Filling of and rail tankers	Reasonable worst case: 0.54	420 *(E)*
1B: Drumming	Reasonable worst case: 1.0 Short term value: 2.6	420 *(E)*
1C: Process sampling (manually)	Reasonable worst case value: 1.0 (E)	420 *(E)*
1D: Cleaning and maintenance	Reasonable worst case value: 1.0 (E)	84 *(E)*
Scenario 2: Industrial use of BBP-containing products		
2A1: Flooring with the plastisol spread coating process	Typical value: 0.035 Reasonable worst case: 1.2	–
2A2: Processing of PVC floats	Typical value: < 0.005	840 *(E)*
2B: Processing of sealants	< 0.1 The exposure under scenario 2B is less than for scenario 2A1	840(E)
2C1: Flooring with the calendering process	Typical value: 0.4 Reasonable worst case: 3.0	420 *(E)*
2C2: Processing of films with the extrusion process	< 0.03	-
Scenario 3: Professional end use of semi- and end products containing BBP		
Scenario 3 (values taken from scenario 2)	Typical value: 0.4 Reasonable worst case: 3.0 From scenario 2C1	420 *(E)* From scenario 2C1 840 *(E)* From scenario 2A2
3A: Use of polysulfide sealants for glass insulation	Negligible	0-42 *(E)*
3B: Use of polyurethane sealants/fillers/grouting agent	Typical value: < 0.005	<< 84-840 *(E)*

4.1.1.2 Consumer exposure

BBP is used in several products, some of which are available to consumers. BBP alone is not available to consumers as a product. To cover the use of BBP, attention is given to products

with high potential for consumer exposure such as I) food and food packaging/infant formula, II) indoor air and III) baby equipments/children toys.

According to updated information, the use of BBP in the manufacture of regenerated cellulose film has decreased during the recent years and is no longer allowed. This is due to EU Directive 2004/14/EC amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, where BBP has been deleted from the positive list. BBP may still be used in other types of food packaging materials of plastics. However, the actual extent of such use is unknown.

The exposure estimates used in the risk characterisation are given in **Table 4.2.**

Table 4.2 Summary of consumer exposure

Exposure scenario	Adults		Children	
	Inhalation mg/kg bw/day	Oral mg/kg bw/day	Inhalation mg/kg bw/day	Oral mg/kg bw/day
Food and food packaging		0.0003		0.00083
Infant formula/food and food packaging				0.00102
Indoor air	0.000083		0.000083	
Baby equipment/children toys				0.00095

4.1.1.3 Humans exposed via the environment

BBP may be released to the environment through waste water and air effluents at the sites where it is produced, processed, formulated as well as during use and after disposal.

For local and regional BBP exposure assessment, production and processing/formulation are considered. For regional BBP exposure distribution is considered as well. The indirect human local exposure values based on EUSES calculations ranged from 0.0002 to 0.0295 mg/kg bw/day, and the highest indirect regional exposure values based on EUSES calculations was 0.00013 mg/kg bw/day.

Human exposure to BBP can also be calculated from urinary excretion of the BBP metabolite monobenzyl phthalate (MBeP). In such studies the total exposure to BBP, from all sources, and via all exposure routes are measured. The level of MBeP measured in the urine was shown to be higher in children compared to adults. Based on the analysis of BBP metabolites in urine of adults and children (1-2 years and 6-11 years) in USA and EU, the daily intake of BBP has been calculated for these 3 groups. For children 1-2 years $4.9 \cdot 10^{-3}$ mg/kg bw/day (geometric mean) and 0.0182 mg/kg bw/day (maximum value from 19 children), for children 6-11 years (95^{th} percentile) $5.46 \cdot 10^{-3}$ mg/kg bw/day, and for adults the calculated level (95^{th} percentile) was $3.5 \cdot 10^{-3}$ mg/kg bw/day. These values will be put forward to the risk characterisation.

4.1.2 Effect assessment

Toxicokinetics, metabolism and distribution

In rats, the kinetics of BBP after oral administration was dose-dependent. Excretion of radiolabelled BBP in the urine was between 70% and 80% when BBP was given at doses from 2 mg/kg p.o. to 200 mg/kg p.o., whereas 22.4% were excreted in the urine after administration of 2,000 mg/kg p.o. The excretion of radioactivity in the feces was 20% after intravenous administration which indicates that the absorption in the dose range between 2 mg/kg p.o. and 200 mg/kg p.o. is nearly complete. After dermal application approximately 5% of the applied dose was absorbed each day. After 7 days approximately 30-40% of the applied amount seemed to be absorbed and reached the systemic circulation. BBP is rapidly metabolised and after 7 days 30% of the applied dose was excreted in the urine or faeces. 45% of the applied dose was found at the skin area of application. For the risk characterisation 5% dermal absorption is used.

The extent of systemic availability of the substance administered by inhalation is not known as specific data are lacking.

BBP is metabolized to monobutyl phthalate (MBuP) and monobenzyl phthalate (MBeP). This metabolism may take place in the gut wall and/or liver. In adult and immature rats, the ratio of monobutyl phthalate to monobenzyl phthalate found in the urine was 3:1. Both metabolites were found in the bile. Reabsorption from gut lumen may take place. There is no evidence of tissue accumulation. The percentage of excreted metabolites (MBuP and MBeP) in the urine in adult rats was shown to be higher compared to immature rats. The excretion of BBP metabolites in urine has also been studied in humans. Contrary to the metabolism of BBP in rats, BBP is mainly metabolised to MBeP in humans. However, limited data on the metabolism of BBP in humans are available. No half-life of BBP in the body has been calculated. However, the available data indicate a half-life of less than 24 hours.

In the risk characterisation, 100% absorption is assumed for both inhalation and oral exposure, whereas the absorption for dermal exposure is set at 5%.

Acute toxicity

The acute toxicity of BBP in animals is low. The oral LD_{50} values of BBP ranged from 2,330-20,400 mg/kg bw/day in rats and were 4,170 mg/kg bw/day (female) and 6,160 mg/kg bw/day (male) in mice. The dermal LD_{50} value in rabbits was greater than 10,000 mg/kg bw/day, whereas in rats the dermal LD_{50} value was 6,700 mg/kg bw/day. The LD_{50} values of BBP from i.p. administration were in the same range as from oral or dermal exposure. No information on acute toxicity after inhalation exposure is identified. The wide range of oral LD_{50} values in rats may be due to the relatively low water solubility of BBP. The lowest LD_{50} value was obtained when BBP was administered in a corn oil vehicle.

Irritation

With respect to the irritation potential of BBP, animal studies performed according to current Test Guidelines for both skin and eye irritation ere available, whereas in humans only skin irritation was studied. From these studies it appears that BBP is not irritating to the skin, however, a slight eye irritation was reported in rabbits using the Draize procedure. No data on respiratory irritation from animal or human studies are available.

Sensitisation

As regards the sensitizing effect of BBP both animal and human studies were located. In an ear swelling test in mice and guinea pigs, BBP was negative. However, the test has not been fully evaluated and no standard protocols are available. In two human studies no sensitisation of BBP was reported. No data on respiratory sensitisation from animal studies are available. In a case-control study an association was found between cases of persistent allergic symptoms in children and the concentration of BBP in dust collected from their homes compared to children without such symptoms. However, in this study very small differences were found in the concentrations of BBP in house dust from controls and cases of allergic symptoms in children, and the children were exposed to other phthalates (DBP, DEHP etc) as well. Furthermore, demographic factors and pet ownership was not considered in this study. Due to the limitations in study design, no clear conclusion can be drawn from the study on the relationship between BBP in house dust and allergic symptoms in children. Based on the available data and according to EU criteria BBP does not need to be classified as a sensitiser.

Repeated dose toxicity

With respect to repeated dose toxicity, a NOAEL of 151 mg/kg bw/day was derived from a well performed 13 week study with oral administration of BBP to rats. This NOAEL value is used in the risk characterisation for consumers and indirect exposure via the environment for oral exposure to BBP. A NOAEL of 218 mg/m^3 was derived from a 13 week inhalation study in rats performed in compliance with GLP. This NOAEL value is used in the risk characterisation for workers for inhalation exposure to BBP, and for indoor air exposure to BBP for consumers. In the oral repeated dose toxicity study histopathological changes, gross morphological changes, and increased kidney weight and an urinary pH decrease were reported at the next highest BBP dose; 381 mg/kg bw/day in male rats. In the inhalation repeated dose toxicity study a significant increased kidney and liver weight was reported at 789 mg/m^3 in male and female rats, and a decrease in serum glucose in male rats.

Mutagenicity

A variety of *in vitro* and *in vivo* genotoxicity studies are available for BBP. BBP showed no evidence of mutagenicity in *Salmonell typhimurium* or mouse lymphoma cells. BBP did not induce sister chromatid exchanges (SCE) or chromosomal aberrations (CA) in CHO hamster cells. BBP did not induce sex-linked recessive lethals *in Drosophila melanogaster* or dominant lethal mutations in mice.

BBP induced morphological transformation in Syrian hamster embryo cells, but not in the BALB/3T3 cell transformation system. Positive results were obtained in a mouse bone marrow test for SCE, however the responses were week, and the SCE test was not repeated. Taking into consideration the non-genotoxic properties of other phthalate esters, BBP can be considered as a non-genotoxic substance.

Carcinogenicity

Butyl benzyl phthalate was tested for carcinogenicity by oral administration in one experiment in mice and in three experiments with rats, including a dietary restriction study. No increases in the incidence of tumours were observed in mice. An increased incidence of mononuclear cell leukemias was reported in female rats at high doses (12,000 ppm corresponding to 720 mg/kg bw/day) of BBP. The increase was within the historical controls and frequency was actually similar to the frequencies found in the two control groups in the

second experiment. A marginally increased incidence of pancreatic adenomas and transitional epithelial papilloma of the urinary bladder was found in female rats. BBP is considered to be non-genotoxic. Overall, BBP is considered as a non-carcinogenic substance.

Toxicity to reproduction

Several studies are available addressing both fertility and developmental toxicity of BBP.

Based on the available data on fertility/effects on the reproductive organs a NOAEL at 100 mg/kg bw/day from a 2-generation study in rats is used in the risk characterisation. In another recent 2-generation study significantly reduced mating and fertility indices were reported in F1 parents to make F2 offspring at 750 mg/kg bw/day. The NOAEL for fertility was 250 mg/kg bw/day from this study.

For developmental effects a NOAEL at 50 mg/kg bw/day for offspring is used in the risk characterisation. This NOAEL value is based on a dose-related significant reduction in absolute and adjusted AGD in both F1 and F2 offspring from 250 mg/kg bw/day. At the next higher dose, 750 mg/kg bw/day a significant increase in F1 and F2 male pups with one or more nipples and/or areolae was reported. The NOAEL for maternal toxicity was 750 mg/kg bw/day and was based on organ weight changes (liver and kidney) and histopathological lesions graded as minimal in the liver at 750 mg/kg bw/day.

Several *in vivo* studies are available which indicate an anti-androgen-like activity of BBP or its major metabolites in rats. Effects reported in the studies included a decreased AGD, increases in male offspring with reproductive tract malformations, as well as effects on testicular migration following BBP exposure from 270 mg/kg bw/day *in utero*.

In a human study the relation between exposure to phthalates and semen quality was evaluated. An association was found between high levels of mono butyl phthalate and/or mono benzyl phthalate in the urine and altered semen quality. Due to the mixed exposure to various phthalates it is difficult to conclude that the effect observed on semen quality was related only to BBP exposure. The phthalates were only measured in a single spot urine sample in a relative small group of men (168) derived from subfertile couples.

An association between prenatal and postnatal exposure to phthalates and whether the exposure had any influence on reproductive organ development in newborn boys was studied in two epidemiological studies. In the first study an association between maternal exposures to BBP as well as other phthalates and lower anogenital index (AGI) in boys was reported. In the second study a marginally association was found between intake of milk contaminated with BBP and postnatal surge of reproductive hormones (SHBG, LH, testosterone and inhibin B) in newborn boys however, this was not significant.

These data support the hypothesis that prenatal phthalate exposure at environmental levels may affect male reproductive development in humans. However, due to the small sample size, (85 boys in the first study and 130 boys in the second study), further studies with larger sample size would have to be performed before clear conclusions can be drawn.

In conclusion, BBP is found to adversely affect the reproductive organs in experimental animal studies which may affect fertility. Furthermore, the substance is found to be a developmental toxicant and to possess anti-androgen like properties in experimental animal studies.

Classification according to Annex I (29th ATP) of Directive 67/548/EEC[8]

Human Health: Repr. Cat. 2; R61: May cause harm to the unborn child, Repr. Cat 3; R62: Possible risk of impaired fertility. Symbol: T; Toxic

4.1.3 Risk characterisation

4.1.3.1 Workers

The main routes of workers exposure are expected to be by inhalation or dermal contact. The highest exposure levels are expected when performing processes at elevated temperatures and working operations creating aerosols.

The knowledge of the toxicokinetics of BBP, especially following these routes, is limited. The assessments of the hazardous properties of BBP are based on animal data, as no significant human data are available.

The concerned endpoints related to worker exposure to BBP are repeated dose toxicity and reproductive toxicity relating to fertility and developmental effects in offspring.

The lack of measured exposure data and uncertainty in the descriptions of the available measured data, adds a significant uncertainty to the assessment of the risk related to the exposure of BBP. Worst case exposure scenarios have therefore been used in the risk assessment of BBP. In calculating the internal exposure a 100% bioavailability (uptake) is used as a default value for the inhalatory route, while dermal absorption is considered to be 5% as a worst case estimate. The calculated internal exposures to BBP for the different scenarios are probably overestimated.

Acute toxicity

Acute toxicity of BBP in animals is low. Comparison with the anticipated occupational exposure levels it is concluded that BBP is of no concern for workers with respect to acute effects.

Conclusion (ii).

Irritation/corrosivity

BBP was found to have no skin irritating effect in humans. It is concluded that BBP is of no concern for workers with regard to irritation/Corrosivity.

Conclusion (ii).

Sensitisation

As regards the sensitising effect of BBP both animal and human studies were located. In an ear swelling test in mice and guinea pigs, BBP was negative. No skin sensitisation was

[8] The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provosions relating to the classification, packaging and labelling of dangerous substance (OJ L 216/3, 16.06.2004, p. 123).

reported in two human studies with BBP. In a case-control study an association was found between cases of persistent allergic symptoms in children and the concentration of BBP in dust collected from their homes compared to children without such symptoms. Due to the limitations in study design, no clear conclusion can be drawn from the study. It is concluded that sensitisation is of no concern for workers

Conclusion (ii).

Repeated dose toxicity

A NOAEL level of 218 mg/m^3 was identified from a 90-day inhalation study. As this level might be of concern for workers, MOS values were calculated for the different scenarios for the inhalation, the dermal and the combined route. **Table 4.3** shows the Margin of Safety (MOS) values for the combined route (inhalation- and dermal route).

Table 4.3 MOSs calculated for the combined route for the endpoint repeated dose toxicity. NOAEL is 218 mg/m^3 or 62.8 mg/kg bw/day (Monsanto, 1982)

Scenario	Internal combined exposure (mg/kg bw/day)	MOS	Conclusion
Scenario 1: Production of BBP			
Reasonable worst case	0.44	143	(ii)
Scenario 2: Industrial use of BBP-Containing products (2C1)			
Typical value	0.36	174	(ii)
Reasonable worst case	0.73	86	(ii)
Scenario 3: Professional end-use of semi- and end-products containing BBP			
Typical value	< 0.36	> 174	(ii)
Reasonable worst case	< 0.73	> 86	(ii)

The MOS-values varied from 73 to > 545 and a **Conclusion (ii)** is drawn for all scenarios and routes for the endpoint repeated dose toxicity.

Mutagenicity

The almost uniformly negative mutagenic effects of BBP in several test systems, indicates that this effect is of no concern for workers.

Conclusion (ii).

Carcinogenicity

There have been some indications of a carcinogenic effect of BBP in rats but not in mice; however no genotoxic effects were evident. BBP is considered to be a non-genotoxic and non-carcinogenic substance. The substance is considered to be of no concern for the anticipated occupational exposure levels.

Conclusion (ii).

Reproductive toxicity

Fertility

A NOAEL at 100 mg/kg bw/day for effects on the reproductive organs/fertility from a 2-generation study in rats was used in the risk assessment (Nagao et al., 2000). This value was used to perform a risk characterisation for workers. MOS values for the different exposure scenarios were calculated for the inhalatory route, the dermal route and for the combined route (see **Table 4.4**).

Table 4.4 Calculated MOS values for the combined route for the endpoint fertility toxicity. NOAEL is 100 mg/kg bw/day (Nagao et al. 2000)

Scenario	Internal Internal combined exposure (mg/kg bw/day)	MOS	Conclusion
Scenario 1: Production of BBP			
Reasonable worst case	0.44	227	(ii)
Scenario 2: Industrial use of BBP-Containing products (2C1)			
Typical value	0.36	278	(ii)
Reasonable worst case	0.73	137	(ii)
Scenario 3: Professional end-use of semi- and end-products containing BBP			
Typical value	< 0.36	> 278	(ii)
Reasonable worst case	< 0.73	> 137	(ii)

Developmental toxicity

BBP and its major metabolites have been reported to give potential toxic effects on development following exposure in rats. The NOAEL of 50 mg/kg bw/day for offspring is used in the risk assessment. MOS values for the different exposure scenarios were calculated for the inhalatory, the dermal and the combined route (see **Table 4.5**).

Table 4.5 Calculated MOS values for the combined route for the endpoint developmental toxicity. NOAEL is 50 mg/kg bodyweight/day (Tyl *et al*. 2004)

Scenario	Internal combined exposure (mg/kg bw/day)	MOS	Conclusion
Scenario 1: Production of BBP			
Reasonable worst case	0.44	113	(ii)
Scenario 2: Industrial use of BBP-Containing products (2C1)			
Typical value	0.36	139	(ii)
Reasonable worst case	0.73	68	(ii)
Scenario 3: Professional end-use of semi-and end-products containing BBP			
Typical value	< 0.36	> 139	(ii)
Reasonable worst case	< 0.73	> 68	(ii)

Based on an evaluation of available toxicological and exposure data it is concluded that there is no concern for BBP with respect to any of the considered endpoints or scenarios.

Conclusion (ii) for all scenarios and endpoints.

However it should be noted that BBP in the future might replace other phtalates for industrial uses, and in such cases risk assessments for the new working scenarios should be added to this risk assessment report.

4.1.3.2 Consumers

Consumers may be exposed to BBP by intake of food contaminated from food packaging and/or infant formula, from indoor air due to the use of BBP in both PVC and non-PVC polymetric material found in homes, and by the use of baby equipment and children toys. The critical endpoints associated with consumer exposure to BBP are repeated dose toxicity and reproductive toxicity including both fertility and developmental effects in offspring. The NOAELs for the different endpoints are presented in table 4.6. In table 4.7 the MOS values for the various consumer exposure scenarios are included. **Conclusion (ii)** is derived for all exposure scenarios.

Table 4.6 Derived NOAEL values

NOAEL	mg/kg bw/day
Repeated dose toxicity, oral	151
Repeated dose toxicity, inh.	218
Reproductive effects, fertility	100
Reproductive effects	50

The conclusions for consumers related to toys and childcare articles reflect the exposure situation at the time of data collection for the RAR. BBP is not intentionally used in toys and childcare articles in EU but may be present as impurities in trace amounts. The possible situation that BBP might be used as a substitute for other phthalates in toys and childcare articles has not been taken into account.

Table 4.7 Summary of the MOS values for the various exposure scenarios

Exposure scenarios	MOS values Repeated dose toxicity	MOS values Fertility	MOS values Development
Food and foodpackaging	503,000	330,000	167,000
Infant formula and food and foodpackaging	148,000	98,000	49,000
Indoor air	3,000,800	1,200,000	600,000
Baby equipment and children toys	160,000	105,000	53,000

4.1.3.2 Humans exposed via the environment

The indirect human local exposure values based on EUSES calculations ranged from 0.0002 to 0.0295 mg/kg bw/day, and the indirect regional exposure values based on EUSES calculations was 0.00013 mg/kg bw/day.

Human exposure to BBP was also calculated from urinary excretion of the BBP metabolite monobenzyl phthalate (MBeP). For adults the calculated level (95^{th} percentile) was $3.5 \cdot 10^{-3}$ mg/kg bw/day, for children 6-11 years (95^{th} percentile) $5.46 \cdot 10^{-3}$ mg/kg bw/day, and for children 1-2 years $4.9 \cdot 10^{-3}$ mg/kg bw/day (geometric mean) and 0.0182 mg/kg bw/day (maximum value from 19 children).

The critical endpoints associated with exposure via the environment for adults and children to BBP are repeated dose toxicity and reproductive toxicity including both fertility and developmental effects in offspring. The NOAEL for repeated dose toxicity is 151 mg/kg/day. The NOAEL for fertility is 100 mg/kg bw/day, and the NOAEL for developmental toxicity in offspring is 50 mg/kg bw/day in rats. In table 4.8 the MOS values for adults and children exposed via the environment are described. **Conclusion (ii)** is derived for all exposure scenarios.

Table 4.8 MOS values for humans exposed via the environment

Scenarios	Human intake mg/kg bw/day	MOS repeated dose toxicity	MOS fertility	MOS development
Local estimated by EUSES	0.0295	5,000	3,400	1,700
Regional estimated by EUSES	0.00013	1,161,000	770,000	385,000
Calculated from metabolites in urine for adults	0.0035	43,000	29,000	14,000
Calculated from metabolites in urine for children 6-11 years	0.00546	28,000	18,000	9,000
Calculated from metabolites in urine for children 1-2 years	0.0046 (geometric mean) 0.0182(maximum value)	33,000 (geometric mean) 8,300 (maximum value)	22,000 (geometric mean) 5,500 (maximum value)	11,000 (geometric mean) 2,750 (maximum value)

4.1.3.3 Combined exposure

The combined exposure to BBP is the sum of all the specific sources (occupational exposure, consumer exposure, and indirectly exposure via the environment), and by all routes of exposure (oral, dermal or by inhalation). However, since occupational exposure values will totally dominate the exposure levels for adults, it is not considered relevant to make a separate calculation for combined exposure for adults including occupational exposure.

Due to the different BBP exposure scenarios for children and adults, two combined exposures estimated are performed, one for children (0 to 2 years) and one for adults:

I. Children exposure to BBP from toys, infant formula, indoor air and indirectly via the environment (air, water and food).
II. Adult exposure to BBP as a consumer, indoor air and indirectly via the environment (air, water and food).

The critical effects of BBP considered are repeated dose toxicity and reproductive toxicity including both fertility and developmental effects in offspring.

The MOS values for repeated dose toxicity, fertility and developmental effects in offspring for combined local exposure (scenario IIIa small site) for children (0-2 years), are considered sufficient, indicating no concern for local exposure to BBP.

Conclusion (ii).

The MOS values for repeated dose toxicity, fertility and developmental effects in offspring for combined regional exposure to BBP as measured by EUSES, and as calculated from urinary excretion of MBeP (Brock et al., 2002; Anderson et al., 2001) for children (0-2 years) are considered sufficient, indicating no concern for exposure to BBP from regional exposure.

Conclusion (ii).

Also the MOS values for repeated dose toxicity, fertility and developmental effects in offspring for combined regional and local exposure to BBP for adults are considered sufficient, indicating no concern for exposure to BBP.

Conclusion (ii).

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

Flammability, explosive properties and oxidising properties are not considered to form a hazard. There is no need for further information and/or testing with regard to physicochemical properties.

Conclusion (ii).

5 RESULTS

5.1 ENVIRONMENT

Conclusion (i) There is a need for further information and/or testing.

A long-term fish study on reproductive and endocrine effects has to be performed.

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

This conclusion is reached for the following life cycle steps/environmental compartments

- Production and distribution (Life cycle I and II) for all environmental compartments
- For the use categories IIIb, IIIc, IIId, IIIe IIIf and IIIg at life cycle step III (processing and formulation) for surface water (including sediment)
- For the use categories IIIb, IIId, IIIe IIIf and IIIg at life cycle step III (processing and formulation) for the terrestrial compartment
- For use and disposal (Life cycle IV and V) for all environmental compartments
- For the atmosphere (all life cycle steps)
- For STP at all production, formulation and processing sites
- For secondary poisoning (all life cycle steps)

Conclusions (ii) for surface water (including sediment) and the terrestrial compartment have to be seen as provisional until possible endocrine effects in fish have been resolved.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion is reached for the following life cycle steps/environmental compartments:

- For the use categories IIIa (flooring large and small site) and IIIh (non polymer use “confidential”) at life cycle step III (processing and formulation) for surface water (including sediment)
- For the use categories IIIa (flooring large and small site), IIIc (PVC coated textiles) and IIIh (non polymer use “confidential”) at life cycle step III (processing and formulation) for the terrestrial compartment

The exposure assessment for flooring (IIIa) and PVC coated textiles (IIIc) are based on the ESD “Plastics” (OECD, 2004). The recently updated ESD has passed the OECD process and is based on best available information. Further site specific data have not been obtained. The exposure scenario IIIh is based on information from Industry. The PEC/PNEC ratios for the aquatic (including sediment) and the terrestrial compartment are above 1, thus a risk to the aquatic and terrestrial environment has to be expected.

Flooring sites were split into large sites with air treatment facilities in place and small sites without air treatment (in accordance with the ESD on Plastics Additives from 2004). Industry stressed that the estimation of plant size on the basis of BBP consumption may be misleading because BBP is usually not used alone but in a mixture with other plasticisers. Hence, small

sites with respect to BBP are not necessarily small sites in terms of plasticiser use and industry has confirmed that the sites are actually not small sites in terms of plasticiser use. However, information from industry has also shown that there are actually sites without air treatment and hence the worst case ESD-scenario for small sites, which do not have air treatment in place, was not omitted even though the sites may not be small sites in terms of the definition of the ESD with respect to total plasticiser use.

According to industry emissions to waste water are an overestimation, both for the large sites and for the small site scenario, but as no site specific emission data have become available emission factors are takes from the ESD.

Conclusion (iii) is based on BBP consumption data from 2004. For 2005 there are only two producers left and industry provided estimations of the expected use volume of BBP for all use categories. These figures are confidential as there are only two producers left.

The total BBP volume used for flooring in 2005 has been further reduced, but the scenarios used in this risk assessment are still relevant. In 2005 it is still valid to use the ESD emission factors for a small site since sites without air treatment have been identified.

Applying the expected use volumes for 2005 to "PVC coated textiles" (IIIc) no risk to soil is to be expected.

5.2 HUMAN HEALTH

Human Health (toxicity)

Workers

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Consumers

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

It should be noted that the conclusion for "consumers" related to toys and childcare articles reflects the exposure situation at the time of data collection for this RAR. BBP is not intentionally used in toys and childcare articles in the EU but may be present as impurity in trace amounts. The possible situation that BBP might be used as a substitute for other phthalates in toys and childcare articles in the future has not been taken into account.

Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

It should be noted that recent epidemiological studies have indicated an association between maternal exposures to BBP as well as to other phthalates and the length of the anogenital distance (AGD) in newborn boys. These data support the hypothesis that prenatal phthalate exposure at environmental levels may affect male reproductive development in humans. However, due to small sample size in the studies, this issue will have to be further

investigated, and new studies in the future should be taken into account in the risk assessment of BBP.

European Commission

EUR 22773 EN/2 **European Union Summary Risk Assessment Report**
benzyl butyl phthalate (BBP)

Editors: S. Pakalin, K. Aschberger, O. Cosgrove, A. Paya-Perez, S. Vegro.

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The report provides the summary of the comprehensive risk assessment of the substance benzyl butyl phthalate (BBP). It has been prepared by Norway in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to humans and the environment, laid down in Commission Regulation (EC) No. 1488/94.

Part I - Environment

This part of the evaluation considers the emissions and the resulting exposure to the environment in all life cycle steps. Following the exposure assessment, the environmental risk characterisation for each protection goal in the aquatic, terrestrial and atmospheric compartment has been determined.

The environmental risk assessment concludes that there is concern for surface water (including sediment) and the terrestrial compartment from some use categories and there is a need for further information and for testing (long-term fish study on reproductive and endocrine effects). There is no concern for the atmosphere and sewage treatment plants.

Part II – Human Health

This part of the evaluation considers the emissions and the resulting exposure to human populations in all life cycle steps. The scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks have been identified.

The human health risk assessment concludes that there is no concern for workers, consumers humans exposed via the environment and for human health (physico-chemical properties).

The conclusions of this report will lead to risk reduction measures to be proposed by the Commission's committee on risk reduction strategies set up in support of Council Regulation (EEC) N. 793/93.