

# HEXABROMOCYCLODODECANE

CAS-No.: 25637-99-4

EINECS-No.: 247-148-4

## SUMMARY RISK ASSESSMENT REPORT

*Final Report 2008*

Sweden

***FINAL APPROVED VERSION***

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## **PREFACE**

The report provides the comprehensive risk assessment of the substance hexabromocyclododecane. It has been prepared by the Sweden in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks 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 original risk assessment report that can be obtained from European Chemicals Bureau<sup>1</sup>. The present summary report should preferably not be used for citation purposes.

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<sup>1</sup> European chemicals Bureau – Existing Chemicals - <http://ecb.ei.jrc.it>



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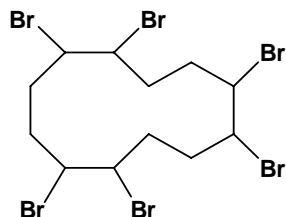
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## 1 GENERAL SUBSTANCE INFORMATION

### 1.1 Identification of the substance

CAS No.: 25637-99-4 (mixture of three diastereomers)  
 EINECS No.: 247-148-4  
 IUPAC name: HEXABROMOCYCLODODECANE  
 Molecular formula:  $C_{12}H_{18}Br_6$   
 Structural formula:



Molecular weight: 641.7  
 Synonyms: cyclododecane, hexabromo-

Two different CAS Numbers can describe Hexabromocyclododecane (HBCDD):

CAS No.	EINECS	Name
25637-99-4	2471484	Hexabromocyclododecane, and
3194-55-6	2216959	1,2,5,6,9,10-Hexabromocyclododecane

Technical HBCDD is manufactured in two forms, high-melting (HM) and low-melting (LM). It consists of three isomers ( $\alpha$ ,  $\beta$  and  $\gamma$ -isomers) each. The low-melting HBCDD consists of 70-80 %  $\gamma$ -isomer and 20-30 % of  $\alpha$ - and  $\beta$ -isomers. The high-melting HBCDD consists of 90 % or more of the  $\gamma$ -isomer

### 1.2 Purity/impurities, additives

The impurities in HBCDD are less than 4 % w/w. The stated impurities present are tetrabromocyclododecane and other brominated cyclododecanes.

### 1.3 Physico-chemical properties

A summary of the physico-chemical properties of technical HBCDD are shown in the following table.

Table 1-1 Physico-chemical properties of technical HBCDD

Property	Value
Chemical formula	$C_{12}H_{18}Br_6$

Molecular weight	641.7
Physical state	White odourless solid
Melting point	Ranges from approximately:172-184 °C to 201-205 °C; 190 °C is used as an average value in EUSES. 179-181 °C α-HBCDD 170-172 °C β-HBCDD 207-209 °C γ-HBCDD
Boiling point	Decomposes at >190 °C
Density	2.38 g/cm <sup>3</sup> ,2.24 g/cm <sup>3</sup> (two different studies)
Vapour pressure	6.3·10 <sup>-5</sup> Pa (21 °C)
Water solubility (20 °C)	66 µg/l (sum of α-, β- and HBCDD) 48.8 µg/l* α-HBCDD 14.7 µg/l* β-HBCDD 2.1 µg/l* γ-HBCDD
Partition coefficient n-octanol/water	Log Kow = 5.62 (technical product) 5.07 ± 0.09 α-HBCDD 5.12 ± 0.09 β-HBCDD 5.47 ± 0.10 γ-HBCDD
Henry's Law constant	0.75 Pa×m <sup>3</sup> /mol; Calculated from the vapour pressure and the water solubility (66µg/l)
Flash point	Not applicable
Auto flammability	Decomposes at >190 °C
Flammability	Not applicable-flame retardant!
Explosive properties	Not applicable
Oxidizing properties	Not applicable
Conversion factor	1 ppm = 26.6 mg/m <sup>3</sup> , 1 mg/m <sup>3</sup> = 0.037 ppm

\*Determined for the isomers present as a mixture not for the pure isomers.

## 1.4 Classification and labelling

Hexabromocyclododecane is currently not included in Annex I to Directive 67/548/EEC.

### Proposed classification

The classification for the environment is:

N; R50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Concentration limits:**

According to the proposal on specific concentration limits for very toxic substances (ECBI/65/99 Add.10), the reported L(E)C50 range of 10-100 µg/l will give rise to the following concentration limits of preparations

:

<i>Concentration limits of substance</i>	<i>Classification of preparation</i>
$C \geq 2.5 \%$	N; R50-53
$C \geq 0.25 \%$	N; R51-53
$C \geq 0.025 \%$	R52-53

This classification proposal has been endorsed by TCC&L (Summary record ENV 09/04 FU, 1204 r 1).

## 2 GENERAL INFORMATION ON EXPOSURE

### Production

HBCDD is presently only produced at one site in EU15, located in the Netherlands. The total annual (2005) EU15 production of HBCDD is around 6 000 tonnes. No information on export of HBCDD from the EU has been provided. Countries outside the EU15 known to produce HBCDD are the USA and Japan. HBCDD is imported to the EU15 from the USA (around 5 000 tonnes per year). Data from Japan indicate that the consumption of HBCDD in Japan is about 2 000 tonnes per year.

### Use

The main uses of HBCDD are in the polymer and textile industries. HBCDD can be used on its own or in combination with other flame retardants e.g. antimony trioxide. HBCDD is used in four principal product types, which are Expandable Polystyrene (EPS), Extruded Polystyrene (XPS), High Impact Polystyrene (HIPS) and Polymer dispersion for textiles.

According to industry information, the main use (90 %) of HBCDD is in polystyrene (PS). The predominant use of PS is in rigid insulation panels/boards for building and construction (EPS and XPS). About 2 % of the total use of HBCDD is in “high impact polystyrene” (HIPS). Most of the flame retarded HIPS-products are used in electrical and electronic appliances e.g. audio visual equipment cabinets (video and stereo equipment), distribution boxes for electrical lines in the construction sector, and refrigerator lining. Textiles with back-coating containing HBCDD can be used for e.g. flat and pile upholstered furniture (residential and commercial furniture), upholstery seatings in transportation, draperies, and wall coverings, bed mattress ticking, interior textiles e.g. roller blinds, automobile interior textiles and car cushions.

Table 2-1 Summary of production and use of HBCDD

	number of sites	quantity handled tons / year	typical HBCDD content in end-product	typical form of HBCDD
Production of HBCDD in 2005	1	6 000	100 %	powder or granulate (>500 um)
Formulation of flame-retarded EPS beads	> 18	3 400	0.7 % (in EPS beads)	Powder (50-250 um)
Formulation of flame-retarded PS compound for HIPS	4	> 200	not available	powder
Formulation of flame-retarded PS compound for XPS	> 14	1 700	40 % (in compound)	powder, granulate
Formulation of polymer dispersion for textile back-coating	16	1 100 (assumption)	10 to 15 % (in the dispersion)	Micronised (3-4 um)
Industrial use of EPS beads to produce flame-retarded EPS	hundreds	3 400	0.7 % (in the EPS)	embedded in EPS
Industrial use of HBCDD in PS compound to produce flame-retarded HIPS	not available	> 200	1 to 3% (in the XPS)	powder or embedded in compound
Industrial use of HBCDD in PS compound to produce	17	1 700	1 to 3%	embedded in

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flame-retarded XPS			(in the XPS)	compound
Industrial use of HBCDD as powder to produce flame-retarded XPS	18	3 200	0.5 to 3 % (in the XPS)	powder, granules
Industrial use of HBCDD in polymer dispersion for textile back-coating	24	1 000	25 % or 6 to 15 % (in final layer)	micronised, in a dispersion
Disposal	not known, widely spread	not known	varying	varying

## 3 ENVIRONMENT

### 3.1 Environmental Exposure

#### Environmental releases

During the handling of HBCDD in all life cycle stages, releases of HBCDD to the environment can be expected. Site-specific information is available for many of the HBCDD uses with the exception of industrial use of EPS and HIPS.

Releases have been determined for all sites where site-specific data have been provided from Industry. In addition, generic local release estimations using default emission factors from Emission Scenario Documents have been performed in order to represent sites for which no information has been submitted.

The total EU 15 emissions of HBCDD are calculated to 8.7 tonnes/year, with 72 % released to waste water, 22% to surface water, and 6% to air. Most emissions (81%) are estimated to come from the industrial use of HBCDD in textile backcoating.

#### Environmental fate*Persistence*

Theoretically abiotic degradation of hexabromocyclododecane is possible. According to Kirk-Othmer ((1993)) HBCDD is rather easily dehydrobrominated. In practice abiotic degradation is probably of low significance because of the rather rigid ring-structure of HBCDD and its low water solubility. HBCDD is not readily biodegradable according to standard OECD degradation tests.

Based on results from standard degradation simulation studies, HBCDD seems to be persistent in aerobic soil.

The degradability of HBCDD in sediment varies with test concentration at least for  $\gamma$ -HBCDD. When tested at a concentration similar to what is measured close to polluted areas, the  $DT_{50}$  for  $\gamma$ -HBCDD was 100 days ( $20^{\circ}\text{C}$ ) corresponding to 190 days at  $12^{\circ}\text{C}$ . When tested at a concentration representing concentrations normally found in sediments not affected by point sources the half life was 21 and 32 days at  $20^{\circ}\text{C}$ , corresponding to 21 and 61 days at  $12^{\circ}\text{C}$ , in two different sediments, respectively. For  $\alpha$ -HBCDD which seems to be more persistent an aerobic  $DT_{50}$  of approximately 113 days in sediment at  $20^{\circ}\text{C}$  was determined. Recalculated to a more realistic environmental temperature ( $12^{\circ}$ ) this corresponds to a  $DT_{50}$  of 210 days. The measured data available from dated sediment cores indicates that HBCDD has degraded in these sediments more slowly than what would be expected based on some of the available experimental sediment degradation half-lives. Furthermore, HBCDD is found to be ubiquitously present in remote areas in abiotic samples and biota providing evidence, that the substance is persistent in the environment.

#### *Bioaccumulation*

Reliable experimental BCFs from two flow-through bioconcentration tests with fish are available. A representative BCF-value of 18100 was chosen. Furthermore, a large set of measured data in biota in the field show that HBCDD is biomagnified in the environment. It is concluded, that HBCDD has a very high bioaccumulation potential.

### Environmental concentrations

Environmental concentrations have been calculated for water, sediment, air, soil and biota for all life cycle stages of HBCDD, including 2 production plants and 40 to 50 plants preparing formulations of HBCDD or using HBCDD. These data can not easily be summarised, and the reader is referred to the full risk assessment report.

### 3.2 Effects

Table 3-1 Reliable acute and chronic ecotoxicity studies

Compartment/Species	Method	Results
<b>AQUATIC COMPARTMENT</b>		
<b>FISH</b>		
<i>Onchorhynchus mykiss</i>	OECD 203 and TSCA 40/797/1400, and ASTM Standard E729-88a	No mortalities or other effects around 2.5 µg/l.
<i>Onchorhynchus mykiss</i>	Flow-through OECD 210 and OPPTS 850.1400	NOEC: Hatching success ≥3.7 µg/l Swim-up ≥3.7 µg/l Larvae and fry survival ≥3.7 µg/l Growth ≥3.7 µg/l
<b>INVERTEBRATES</b>		
<i>Daphnia magna</i>	OECD 202. Static immobilisation test, and TSCA 40/797/1300, and ASTM Standard E729-88a	48 h EC <sub>50</sub> >3.2 µg/l
<i>Daphnia magna</i>	TSCA , OECD Flow through 21 day test.	NOEC 3.1 µg/l LOEC length 5.6 µg/l
<b>ALGAE</b>		
<i>Selenastrum capricornutum</i>	OECD 201 and TSCA40/797/1050	96 h EC <sub>50</sub> >2.5 µg/l
<i>Skeletonema costatum</i>	Marine algal bioassay method, different marine growth media (Not according to guidelines, results only used as supportive)	72 h EC <sub>50</sub> = 9 µg/l (lowest value)
<i>Thalassiosira pseudonana</i>		72 h EC <sub>50</sub> = 40 µg/l (lowest value)
Chlorella sp.		96h EC <sub>50</sub> >water solubility
<i>Skeletonema costatum</i>	OECD 201, ISO 10253:1995 and EU Directive 92/69/EEC – Method C.3. One test concentration at the limit of respective water solubilities of each diastereomer.	NOEC <40.6 µg/l EC <sub>50</sub> >40.6
<i>Skeletonema costatum</i>	OECD 201. EC50 obtained from a limit test with one test concentration (54.5 µg/l) at the limit of respective water solubilities of each diastereomer.	NOEC >10 µg/l EC <sub>50</sub> = 52 µg/l
<b>SEWAGE TREATMENT PLANT, MICRO-ORGANISMS</b>		
Activated sludge	Respiration inhibition OECD 209	EC <sub>50</sub> = 15 mg/l; Limit test with one test concentration, EC <sub>50</sub> is an estimated value.
<b>SEDIMENT COMPARTMENT</b>		
<b>INVERTEBRATES</b>		
<i>Hyalella azteca</i> (Amphipod)	Sediment toxicity test 28-day exposure period under flow-through conditions.	LOEC >1000 mg/kg dw of sediment NOEC 1000 mg/kg dw of sediment.
<i>Lumbriculus variegatus</i> (Worm)	28-day sediment bioassay	LOEC = 28.7 mg/kg dw NOEC = 3.1 mg/kg dw Normalized: NOEC = 8.61 mg/kg dw
<i>Chironomus riparius</i> (Mosquito)	28-day sediment bioassay Egg production of F generation	LOEC = 159 mg/kg dw NOEC = 13.6 mg/kg dw Normalized: NOEC = 37.8 mg/kg dw
<b>TERRESTRIAL COMPARTMENT</b>		
<b>PLANTS</b>		
Plants: corn ( <i>Zea mays</i> ), cucumber ( <i>Cucumis sativa</i> ), onion ( <i>Allium</i> )	Seedling emergence, survival, height 21 days OECD 308 (proposal for revision), 850.4100 and 850.4225	NOEC >5000 mg/kg dry soil

Compartment/Species	Method	Results
<i>cepa</i> ), ryegrass, ( <i>Lolium perenne</i> ), soybean ( <i>Glycine max</i> ), and tomato ( <i>Lycopersicon esculentum</i> )	(public drafts)	
<b>INVERTEBRATES</b>		
<i>Eisenia fetida</i> (Earthworm)	Survival and reproduction, 56 days OECD prosal and 207 and OPPTS 850.6200	NOEC 128 mg/kg dry soil Normalized: NOEC 59 mg/kg dry soil (EC <sub>50</sub> 771 mg/kg dry soil)

### 3.2.1 Aquatic compartment

Long term studies are in general considered more relevant than short term studies, particularly for substances with low water solubility. Reliable long term studies are available for all three trophic levels. The lowest NOEC, the 21d-NOEC 3.1 µg/l for *Daphnia magna*, will be used for derivation of PNEC, using an assessment factor of 10. Thus, the predicted no effect concentration for the aquatic compartment is 0.31 µg/l.

For intermittent releases to the aquatic environment the lowest L(EC)<sub>50</sub> of at least three short-term tests from three trophic levels is recommended in the revised TGD, with applying an assessment factor of 100 for calculation of PNEC. The lowest EC<sub>50</sub> is the one from the algae growth inhibition test with *Skeletonema costatum* (52 µg/l), and the resulting PNEC 0.52 µg/l.

The EC<sub>30</sub> of 15 mg/l obtained for effects on microorganisms in a respiration inhibition test is taken as an estimate of the EC<sub>50</sub> for the PNEC derivation, using an assessment factor of 100. Thus PNEC<sub>STP</sub> is 0.15 mg/l.

Toxicity data are available from chronic studies with three sediment-dwelling species with different feeding regimes. The lowest NOEC, 8.6 mg/kg dry weight was obtained for reduced number of total worms in a 28 days test with *Lumbriculus variegates*. Using an assessment factor of 10, the PNEC<sub>sed</sub> becomes 0.86 mg/kg dry weight.

#### 3.1.2 Terrestrial compartment

There are studies on terrestrial organisms from three trophic levels available. Applying an assessment factor of 10 results in a PNEC<sub>soil</sub> of 5.9 mg/kg dry soil.

#### 3.1.3 Atmosphere

There is no effect data for the atmospheric compartment.

#### 3.1.4 Non compartment specific effects relevant to the food chain

Due to accumulation of HBCDD in organisms such as fish (BCF = 18 000) fish feeding mammals and birds are exposed to HBCDD. In addition, predators feeding on marine mammals and birds are another group of animals that may be highly exposed to HBCDD.



A 2-generation study in rats has recently been performed where HBCDD was administered via the diet by mixing HBCDD-particles with ground dry feed, at concentrations of 150, 1,500, and 15,000 ppm (dry weight). A high and dose-dependent pup mortality during lactation was observed in the F2 generation (increased by 35 % in the high dose group and 15 % in the mid dose group), although only being statistically significant in the high dose group. Overall, a NOAEL of 150 ppm dry weight can be deduced based on ecologically relevant effects at 1,500 ppm. As no assessment factor is needed for duration correction when the data come from a 2-generation study, the total assessment factor to be used is 30, and the PNEC 5 mg HBCDD/kg wwt food.

However, in line with the TGD it is acknowledged that a regional assessment of secondary poisoning for PBT substances can not be done with any certainty.

### **3.3 Risk characterisation**

#### Aquatic compartment

For individual sites involved in EPS formulation, XPS formulation, formulation of polymer dispersions for textiles, industrial use of XPS and sites involved in textile back coating the PEC/PNEC ratio is  $> 1$  in either surface water or sediment or in both compartments indicating that there is a need for limiting the risks at these sites. For textile back coating there is a general concern based on measured concentrations in sediment downstream three different locations giving PEC/PNEC ratios  $>1$ .

However, for production, micronising and industrial use EPS and HIPS the PEC/PNEC ratios for HBCDD in both surface water and sediment are  $< 1$  indicating that there is at present no need for further information and/or testing and for risk reduction measures beyond those, which are being applied already. This also applies for individual sites in other use areas.

For most sites there is no concern for sewage treatment plants. However, for some sites with industrial use of XPS having intermittent releases to waste water and for 1 textile backcoating site the PEC/PNEC ratios were  $>1$ .

#### Terrestrial compartment

Whereas the PEC/PNEC ratio is  $< 1$  thus indicating no concern for most use areas, the PEC/PNEC ratio is  $>1$  for the generic local scenario for the industrial use of XPS compound and textile backcoating and also for a few individual site in these use areas.

#### Atmospheric compartment

There is no concern for any scenario.

#### Secondary poisoning

In the light of HBCDD being a PBT substance and considering the large uncertainties both in the derivation of PECs and in the derivation of PNEC it is not considered appropriate to draw conclusions for the individual sites. Since for PBT-substances the major concern is that accumulation of such substances in the foodchain may result in unpredictable effects in the long term it is appropriate to draw an overall conclusion iii) for secondary poisoning, i.e., there is concern for secondary poisoning.

### Marine environment

For individual sites involved in EPS formulation, XPS formulation, formulation of polymer dispersions for textiles, industrial use of XPS and sites involved in textile back coating the PEC/PNEC ratio is  $> 1$  in either surface water or sediment or in both compartments indicating that there is a need for limiting the risks at these sites. For textile back coating there is a general concern based on measured concentrations in sediment downstream three different locations giving PEC/PNEC ratios  $>1$ .

However, for production, micronising and industrial use EPS and HIPS the PEC/PNEC ratios for HBCDD in both surface water and sediment are  $< 1$  indicating that there is at present no need for further information and/or testing and for risk reduction measures beyond those, which are being applied already. This also applies for individual sites in other use areas.

### PBT-assessment

HBCDD is a PBT substance, thus leading to concern.

The basis for the PBT-assignment is as follows. HBCDD does not unequivocally fulfil the specific P-criterion, with some reliable studies indicating that biodegradation can occur. It does, however, not degrade rapidly and monitoring data indicate a significant degree of environmental transport and overall stability. The BCF of HBCDD is 18 100 and thus the vB criterion is fulfilled. Also the T-criterion is fulfilled according to available data. HBCDD is ubiquitous in the environment, being also found in remote areas far away from point sources. The highest concentrations of HBCDD are detected in marine top-predators such as porpoise and seals showing that HBCDD bioaccumulates up the foodchain. Based on an overall assessment the TCNES subgroup on identification of PBT and vPvB substances have concluded that HBCDD has PBT properties according to the PBT criteria of the TGD.

In addition, HBCDD has a high potential for long-range environmental transport. Its half-life in the atmosphere is  $> 2$  days and it has been found in remote areas in abiotic samples (air, deposition, sediment) and biota (polar bears, bird eggs, seals) in the majority of samples of the last years.

## 4 HUMAN HEALTH

### 4.1 Exposure assessment

Due to the use of HBCDD in products in the society, humans may be exposed from different sources:

- at the workplace at the production of HBCDD,
- at the industrial use (formulation and industrial use of HBCDD as an additive and at the industrial uses of articles containing HBCDD ;
- from use of consumer products; and,
- indirectly via the environment via food, soil, water and air.

All known uses of HBCDD are as flame retarding additive in polymers. HBCDD is used foremost in extruded polystyrene (XPS) and expanded polystyrene (EPS) used mainly in building insulation, high impact polystyrene (HIPS), and in back-coating for textile.

HBCDD is a solid substance at room temperature (melting point  $>170$  °C) and is most often handled as a solid powder or a compacted (pelletised) powder in the industry.

The human population can be exposed to HBCDD by inhalation of vapour and airborne dust, ingestion and by dermal contact. In addition there is a risk that babies can be exposed during pregnancy and due to breast-feeding.

Following exposure routes are considered to be relevant for the risk assessment:

- Inhalation of vapour and airborne dust and via dermal contact at the production of HBCDD, the industrial uses and the industrial end-uses
- Via inhalation of HBCDD emitted from articles as vapour and adsorbed to domestic dust and dermal exposure during private end-use (consumers)
- Exposure via the environment via inhalation of vapour and particles and via oral routes when exposed by food and water.

Humans may be exposed to HBCDD for different periods during lifetime including single short-term exposure and persistent exposure for a lifetime.

#### 4.1.1 Occupational exposure

The following data were used for occupational exposure assessments.

- measured data of HBCDD
- physico-chemical data of HBCDD as the physical state, powder dimension and the vapour pressure at different temperatures
- qualitative and quantitative data regarding methods and use pattern of the product, temperature at which production processes take place; and the amount of HBCDD used in the different products.

There are three industry sectors where occupational exposure to HBCDD may occur;

- Manufacture of HBCDD
- Industrial use of HBCDD as an additive (formulation and processing in the polymer- and textile industry)

- Industrial use of semi-finished or end-products containing HBCDD

The exposure is assessed without taking account of the possible influence of personal protective equipment (PPE) as the information of the effectiveness of PPE to reduce exposure to HBCDD in practical situations is limited.

The following exposure scenarios are considered:

- the filling of bags at the manufacture of HBCDD
- charging HBCDD to processes producing end-products or semi-products containing HBCDD (micronisation of HBCDD, production of XPS and EPS, and textile coating)
- sewing

The identified reasonable worst-case exposures for occupational exposure to HBCDD, representing the three scenarios (typical exposures within brackets) are shown in the table below Table 4-1.

Table 4-1. Identified reasonable worst-case exposures for occupational exposure.

Scenario	Product grade	Inhalation		Dermal <sup>c</sup>			Multiple routes exposure
		mg/m <sup>3</sup>	mg/kg/day	mg/day	dermal abs (%)	mg/kg/day	mg/kg/day
FILLING. Filling of bags at the production of HBCDD <sup>a</sup>	Fine powder (via micronisation)	10 (5)	1.42	4200	4	2.4	3.82
	Powder	1.9 (0.95)	0.27	840 (	4	0.49	0.76
	Granules	0.19 (0.1)	0.03	84	2	0.02	0.05
ADDING. Industrial use of HBCDD as an additive <sup>a</sup>	Formulation of textile.	3.1 (1.55)	0.44	120	4	0.07	0.51
	Fine powder						
	Formulation of polystyrene (EPS, XPS and HIPS), standard grade powder	2.5 (1.25)	0.36	84	4	0.05	0.41
	Formulation of polystyrene (EPS, XPS and HIPS), granules or masterbatch	0.22 (0.11)	0.031	8.4	2	0.002	0.033
SEWING (Occupational). Industrial end-use <sup>b</sup>		0.5 (0.25)	0.08	84	4	0.06	0.14

#### 4.1.2 Consumer exposure

HBCDD is used in several products, some of which are available to consumers.

Some examples of end-products containing HBCDD are:

- flat and pile upholstered furniture (residential and commercial furniture)
- upholstery seatings in transportation, draperies, and wall coverings

- bed mattress ticking
- interior textiles e.g. roller blinds
- automobile interior textiles
- car cushions
- insulation boards (against cold or warm) of transport vehicles e.g. lorries and caravans
- insulation boards in building constructions e.g. houses' walls, cellars and indoor ceilings and "inverted roofs" (outdoor)
- parking decks
- insulation boards against frost heaves of road and railway embankments
- packaging material
- electrical and electronic equipment e.g. distribution boxes for electrical lines
- video cassette housings
- polyvinyl chloride wire, cable and textile coating
- protecting paints for military purposes

Other exposure can occur due to misuse of products containing HBCDD e.g. when children play with articles containing HBCDD not intended to play with.

Any foreseeable misuses of HBCDD have not been identified.

The release of HBCDD from products containing HBCDD is depending on (1) the concentration of HBCDD in the product (2) the mobility of HBCDD in the matrix, (3) the relative surface area of the product and (4) the physical conditions of the surrounding media. The mobility of HBCDD in latex in e.g. textile coatings is assumed to be greater than the mobility in XPS and EPS and the mobility of HBCDD in HIPS is assumed to be greater than in XPS and EPS. The relative surface area depends on the conformation of the matrix and the use of the product. The concentration of HBCDD in textile latex coating is assumed to be about 25 % (however, lower when expressed as % of weight of the whole textile), in HIPS 3 % and in XPS and EPS about 1 %. We assume that latex coating on textile results in greatest relative release of HBCDD from products. Due to the low vapour pressure the release to air from products is assumed to be relatively low.

These scenarios for consumer's exposure to HBCDD have been taken into account;

- TEXTILE IN FURNITURE (AND CURTAINS)  
Subscenario. Oral exposure to dust  
Subscenario. Inhalation exposure  
Subscenario. Oral exposure by mouthing of textile
- INDOOR AIR. Exposure from XPS construction boards
- MATTRESS TICKING. Lying down in a bed on a mattress with flame-retarded ticking.

For the three textile backcoating scenarios, the oral exposure of dust and the inhalation of airborne dust are considered insignificant and are consequently not brought forward to the risk characterisation.

For the scenario with a child mouthing textiles the daily exposure is assumed to be 30 µg/kg bwt/day HBCDD if the back-coated side is available. If only the textile side is available, the exposure would become 3 µg/kg/day.

For the two other consumer scenarios, indoor air and mattress ticking, the calculated exposure levels are 0.002 and 0.01 µg/kg/day, respectively, which is considered insignificant and therefore not brought forward to the risk characterisation.

### 4.1.3 Man exposed indirectly via the environment

HBCDD may be released to the environment through wastewater and air effluents from manufacture, formulation, industrial use, use and disposal of HBCDD containing products. Since HBCDD is a rather persistent and bioaccumulating substance emitted from both point sources and diffuse sources, it could be expected that the exposure to man via food is an important route of exposure.

Multiplying the concentrations in the intake media by the daily intake rates of each medium and summing the contribution of each medium will estimate the total daily intake.

In the risk characterisation, the food basket studies will be used rather than the EUSES-modelling, thus resulting in a regional intake of 20 ng/kg/day, representing both fish and vegetable oils and fats.

For the *local* scenarios, only few comparisons can be made between predicted and monitored concentrations in fish, involving the production sites and some textile industries. These comparisons indicate that EUSES may overpredict the fish concentrations considerably, e.g., the highest local modelled fish concentration is 700 mg/kg fish (textile backcoating) whereas the highest measured fish concentration is 9.5 mg/kg (outside a production plant).

For the risk characterisation, EUSES-data has to be used for the local scenarios, considering that the exposure most likely is overestimated by at least a factor of 10.

## 4.2 Effect assessment

Information on the toxicokinetics of HBCDD is limited. No data are available on absorption via inhalation. An *in vitro* dermal absorption study has been performed, and a dermal absorption value of 4 % has been selected. When the substance is *properly* dissolved in the vehicle, it is probably readily absorbed from the gastro-intestinal tract with the highest concentrations subsequently reached in adipose tissue and muscle, followed by liver and to a much lower extent the lung, kidney, blood and brain. Although the exact extent of oral absorption is unknown, it is probably in the order of 50-100 %. Higher concentrations are achieved in females than in males, but the substance is accumulating in both sexes. Among the three diastereoisomers of HBCDD present in the technical product, the accumulation of the  $\alpha$ -diastereomer is much higher than of the others, especially at higher exposure levels. The time to reach steady-state seems to be in the order of months. HBCDD can be metabolised, and three polar metabolites as well as unextractable substance in faeces and urine have been detected after exposure to  $\gamma$ -HBCDD, although the overall extent of metabolism of technical HBCDD is unknown. In environmental biodegradation studies, the only biodegradation pathway so far identified is a step-wise reductive debromination of HBCDD, via tetrabromocyclododecene and dibromocyclododecadiene, to 1,5,9-cyclododecatriene, which seemed to be the final degradation product in the environmental samples.

For an initial period of 3 days post dosing, elimination of HBCDD and its metabolites occurs mainly via faeces with a minor part excreted in urine. Elimination from body fat appears to be markedly slower than from other tissues, with an elimination half-life of the three diastereoisomers possibly being in the order of weeks to months.

Acute toxicity The minimum lethal dose is greater than 20 g/kg for both dermal and oral routes of administration, and greater than 200 mg/l from inhalation for 4 hours. Therefore, the acute toxicity is not considered further in the risk characterisation.

Irritation The substance is mildly irritating to the eye, but should not be classified as an eye irritant according to EU criteria. HBCDD is not irritating or corrosive to skin.

Sensitisation Available data indicates that at least certain commercial (Japanese) brands of HBCDD are potential skin sensitizers. However, the HBCDD available on the EU-market has been negative in both a Magnuson-Kligman test and in a Local Lymph Node assay, leading to the conclusion that there is no concern for sensitisation for the HBCDD occurring in the EU. Sensitisation will not be considered further in the risk characterisation. No information is available on respiratory sensitisation.

Repeated dose toxicity No repeated dose studies with inhalation or dermal exposure as route of administration are available. A 90-days toxicity study with oral exposure to a suspension of HBCDD particles has shown effects on the liver, the thyroid and the prostate. As from doses of 100 mg/kg/day, a dose-dependent increase in liver weight that was not accompanied by any clear pathological signs was noted, as well as effects on the thyroid hormone system. The liver weight increase was slowly reversible upon cessation of exposure. All other repeated dose studies on HBCDD have also shown the liver to be the target organ. In addition, the prostate weight was statistically increased at exposure to 1000 mg/kg/day. A LOAEL of 100 mg/kg/day is deduced for repeated dose toxicity based on liver weight increases (18-24 %). In addition, a disturbed thyroid hormone system (T4↓ and TSH↑) was observed after 90 days oral exposure to HBCDD, potentially being secondary to the liver effect. The use of a suspension of HBCDD particles in most toxicity studies has likely led to a low absorption rate. Therefore, based on an assumed conservative oral absorption of 10-20 % for this suspension, the study LOAEL of 100 mg/kg/day is transformed into a corrected LOAEL of 10-20 mg/kg/day.

The most recent 28 days study is performed using a benchmark model design and oral administration of dissolved HBCDD. The study mainly shows effects on the liver, the thyroid, and the pituitary. Overall, a NOAEL/BMD-L of 22.9 mg/kg/day for liver weight increase is proposed for repeated dose toxicity. Enzyme induction is a likely cause to the liver weight increase, and enzyme induction is clearly relevant also to humans.

A NOAEL from a 90 days study would normally be preferred in the risk characterisation, but the uncertainties introduced in the evaluation of the 90 days study by the dosing of HBCDD-particles to the animals, leads to the choice of a NOAEL of 22.9 mg/kg/day from the recent 28-days study.

Mutagenicity The preponderance of evidence from available studies indicates that HBCDD lacks significant genotoxic potential in vitro and in vivo.

Carcinogenicity Based on the only available lifetime bioassay, it is not possible to assess the carcinogenic potential of HBCDD. However, the available data (including mutagenicity) gives no reason for further exploration of this endpoint.

#### Reproductive toxicity

A NOEAL of 10 mg/kg/day has been deduced in a two generation reproductive toxicity study in rats. The NOAEL is based on a high and dose-dependent pup mortality during lactation observed in the F2 generation (increased by 35 % in the high dose group and 15 % in the mid dose group), although only being statistically significant in the high dose group. In addition, a dose-dependent decrease in fertility index was observed in both generations (8-14 % in the mid and high dose groups)(with a statistically significant trend in F0), and a reduced number of primordial follicles in the mid and high dose groups was also evident (30 %, only measured in F1).

Two ordinary *developmental toxicity* studies have failed to demonstrate any fetotoxicity, teratogenic potential, or adverse effects from HBCDD on development postpartum.

A study on *developmental neurotoxicity* in adult mice exposed to HBCDD as pups at day 10 postpartum has been conducted. The study indicated that HBCDD may cause statistically significant changes in spontaneous behaviour, learning and memory defects. An indicative LOAEL of 0.9 mg/kg/day can be deduced from this latter study. The study is published, but would benefit from being confirmed by other laboratories.

### 4.3 RISK CHARACTERISATION

The toxicity to exposure ratio for different human populations and scenarios has been used to derive the MOS. The lowest and the most reliable NOAELs established in studies in animals have been used.

An oral absorption of 100 % is assumed for *dissolved* HBCDD. Data on absorption by inhalation exposure is lacking, and for the purpose of modelling, the efficiency of inhalation uptake can be considered equal to uptake by the oral route (100 %). A value of 4 % is assumed to be applicable for uptake of powder by the dermal route. Depending on the particle size occurring in the exposure situation, a value of 2 % is used when granules are used.

The endpoints of concern are:

- **repeated dose toxicity** for which a NOAEL/BMD-L of 22.9 mg/kg/day based on an increased liver weight is deduced from an 28 days oral study using a benchmark model design.
- **reproductive toxicity, for which a NOAEL** of 10 mg/kg/day has been deduced in a two generation reproductive toxicity study in rats. The NOAEL is based on a high and dose-dependent pup mortality during lactation in the F2 generation, a reduced fertility index and a reduced number of primordial follicles.

There are indications of developmental neurotoxicity in adult mice exposed to HBCDD as pups. However, this study by Eriksson et al (2006) is not performed according to current guideline and GLP and therefore this potential developmental neurotoxicity needs to be examined further and conclusion (i) is reached for all exposure scenarios. However, similar results on developmental neurotoxicity have been published for decabromodiphenyl ether by the same authors using the same method. For decabromodiphenyl ether it has been agreed to perform a new toxicokinetics/developmental neurotoxicity study according to a modified OECD guideline and GLP. The results from this new decabromodiphenyl ether study will serve as a guidance on how to interpret the data from the Eriksson study, and may also serve as a basis on how to proceed with further testing of neurotoxicity. While awaiting these results and taking into account that HBCDD is a PBT substance, a **conclusion (i) on hold** with regard to a developmental neurotoxicity study is reached for all exposure scenarios.

#### 4.3.1 Workplace

Occupational exposure to HBCDD occurs primarily by dermal and respiratory routes of exposure. Exposure by multiple exposure routes is considered to more accurately represent total



exposure levels for each population, and is estimated as the sum of the highest exposures from each route during a working day.

Dermal exposure levels used for manufacture and industrial use have been derived from EASE, whereas most inhalation exposure levels are based on measured data. In the case of sewing (industrial use), the exposure level was estimated by the rapporteur. The mean particle sizes for the different applications vary considerably between the producers. In general, the size of the fine powder used by the textile industry is in the range of 2-19 µm, the powder 20-150 µm, and the granules 560-2400 µm. The extent of use of personal protective equipment (PPE) seems to vary between the occupational settings using HBCDD. However, in setting the reasonable worst case exposure levels, it is assumed that no PPE is used. Risk characterisation is only performed for the endpoint repeated dose toxicity.

Three scenarios have been identified for which there will be a risk characterisation:

- manufacture of HBCDD, where exposure mainly occur during filling operations with HBCDD powder or granules
- industrial use of HBCDD, i.e., production of fire-proofed products (e.g., polystyrene), where exposure mainly occur during adding of HBCDD powder or granules to the formulation. HBCDD may also be added as a masterbatch.
- end use of HBCDD during sewing textiles treated with HBCDD. Other end-uses, such as handling of polystyrene-boards are assumed to result in very low exposure levels, and, therefore, there is no scenario for this use.

The minimal MOS-values for comparison with the obtained MOS-values are 20 for repeated dose toxicity and 50 for reproductive toxicity.

Table 4-2. Compilation of data from the occupational risk characterisation based on realistic worst-case exposure concentrations. For inhalation exposure estimates, the typical exposure (in mg/m<sup>3</sup>) is given within brackets.

Scenario	Product grade	Inhalation			Dermal			Multiple routes exposure		
		mg/m <sup>3</sup> mg/kg/day	MOS rdt	Concl rdt	mg/day mg/kg/day	MOS rdt	Concl rdt	mg/kg/day	MOS rdt	Concl rdt
FILLING. Filling of bags at the production of HBCDD <sup>a</sup>	Fine powder	10 (5) 1.42	16	(iii)	4200 2.4	10	(iii)	3.82	6	(iii)
	Powder	1.9 (0.95) 0.27	85	(ii)	840 0.49	47	(ii)	0.76	30	(ii)
	Granules	0.19 (0.1) 0.03	763	(ii)	84 0.02	1145	(ii)	0.05	458	(ii)
ADDING. Industrial use of HBCDD as an additive <sup>a</sup>	Formulation of textile. Fine powder	3.1 (1.55) 0.44	52	(ii)	120 0.07	327	(ii)	0.51	45	(ii)
	Formulation of polystyrene (EPS, XPS and HIPS), standard grade powder	2.5 (1.25) 0.36	64	(ii)	84 0.05	458	(ii)	0.41	56	(ii)

Scenario	Product grade	Inhalation			Dermal			Multiple routes exposure		
	Formulation of polystyrene (EPS, XPS and HIPS), granules masterbatch	0.22 (0.11) 0.031	739	(ii)	8.4 0.002	1145 0	(ii)	0.033	763	(ii)
SEWING (Occupational). Industrial end-use <sup>b</sup>		0.5 (0.25) 0.08	286	(ii)	84 0.06	382	(ii)	0.14	164	(ii)

<sup>a</sup> When two numbers exist in a box, the first one gives the concentration (mg/m<sup>3</sup> or mg/day) and the second, lower one the internal intake in mg/kg/day.

**Table 4-3** Compilation of data from the occupational risk characterisation for reproductive toxicity, based on realistic worst-case exposure concentrations. For inhalation exposure estimates, the typical exposure (in mg/m<sup>3</sup>) is given within brackets.

Scenario	Product grade	Inhalation			Dermal			Multiple routes exposure		
		mg/m <sup>3</sup> mg/kg/day	MOS repro	Concl repro	mg/day mg/kg/day	MOS repro	Concl repro	mg/kg/day	MOS repro	Concl repro
FILLING. Filling of bags at the production of HBCDD <sup>a</sup>	Fine powder	10 (5) 1.42	7	(iii)	4200 2.4	4	(iii)	3.82	3	(iii)
	Powder	1.9 (0.95) 0.27	37	(iii)	840 0.49	20	(iii)	0.76	13	(iii)
	Granules	0.19 (0.1) 0.03	333	(ii)	84 0.02	5000	(ii)	0.05	200	(ii)
ADDING. Industrial use of HBCDD as an additive <sup>a</sup>	Formulation of textile. Fine powder	3.1 (1.55) 0.44	23	(iii)	120 0.07	143	(ii)	0.51	20	(iii)
	Formulation of polystyrene (EPS, XPS and HIPS), standard grade powder	2.5 (1.25) 0.36	28	(iii)	84 0.05	200	(ii)	0.41	24	(iii)
	Formulation of polystyrene (EPS, XPS and HIPS), granules masterbatch	0.22 (0.11) 0.031	323	(ii)	8.4 0.002	5000	(ii)	0.033	333	(ii)
SEWING (Occupational). Industrial end-use <sup>b</sup>		0.5 (0.25) 0.08	125	(ii)	84 0.06	167	(ii)	0.14	71	(ii)

### 4.3.2 Consumers

HBCDD is used in several products, some of which are available to consumers, e.g. textiles in furniture, automobile interior textile, construction boards, mattress ticking and videocassettes.

In most applications HBCDD is present non-bound within a polymer matrix, hence, it may migrate from the polymer and be released. Release of HBCDD from the surface of the product into atmosphere from plastic products may be a potential way of exposure. Due to the low vapour pressure the release to air from products is assumed to be relatively low. Direct contact with products containing HBCDD may give rise to dermal exposure.

Consumers may be exposed to HBCDD by dermal, oral and respiratory routes of exposure. Exposure by multiple exposure routes is considered to more accurately represent the intake for each population. The extent of exposure by multiple exposure routes is calculated as the sum of the highest exposure from each route during a day.

It is assumed that direct exposure to consumers occurs mainly during contact with textiles containing HBCDD, but exposure via indoor air is also a possibility. The information used for indoor air is based on estimations of the release of HBCDD from construction boards.

The minimal MOS-values for comparison with the obtained MOS-values are 40 and 100 for repeated dose toxicity and reproductive toxicity, respectively. All MOS-values are  $\geq 330$ , and there is thus no concern for consumers.

### 4.3.3 Man indirectly exposed via the environment

HBCDD may be released to the environment through wastewater and air effluents from production, formulation, industrial use, use and disposal of HBCDD containing products. Available information indicates that release from diffusive sources, such as use of end-products and from disposal, could be important.

The minimal MOS-values for comparison with the obtained MOS-values are 40 and 100 for repeated dose toxicity and reproductive toxicity, respectively.

It should be noted, that there is limited biodegradation of HBCDD in the environment and it has bioaccumulating properties. There are limited data on indirect exposure to HBCDD, with most monitoring/screening being performed in Scandinavia, and recently, in the UK and the Netherlands. Low levels of HBCDD has been found in different fish species and in food items, such as salmon, egg, milk, vegetable oils and fats, and fat from domestic animals (chicken, beef and lamb). Based on these data the intake of HBCDD via food has been estimated to be 0.00002 mg/kg/day, which will be used rather than the EUSES-prediction of regional exposure.

All MOS-values are  $\geq 330$ , and there is thus no concern for the regional exposure of man via the environment.

Predicted daily local exposure via the environment is estimated by EUSES, however it seems that EUSES would overestimate the local scenarios with at least a factor of 10.

For some local scenarios, the calculated MOSes are low, and would formally lead to concern. However, considering the overestimation of the exposure by at least a factor of 10, there is no concern expressed for any local scenario.

## 5 OVERALL RESULTS OF THE RISK ASSESSMENT

### 5.1 Environment

#### 5.1.1 Aquatic compartment

##### *STP*

There is no concern for the majority of the sites including the generic scenarios for most use areas. However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to some sites with industrial use of XPS having intermittent releases to waste water and for 1 textile backcoating site including the generic textile backcoating scenario.

##### *Surface water*

There is no concern for the many of the sites including the generic scenarios for many use areas.

However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to some sites involved in EPS formulation including the generic scenario, one site involved in formulation of XPS compound and the generic scenario, the generic local scenario for formulation of polymer dispersions for textiles, individual sites involved in industrial use of XPS compound and HBCDD powder including the generic local scenario for industrial use of XPS compound and finally, sites involved in textile backcoating including the generic scenario.

##### *Freshwater sediment*

There is no concern for the many of the sites including the generic scenarios for many use areas. However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to some sites involved in EPS formulation including the generic scenario, on-site involved in XPS formulation including the generic scenario, one site involved in formulation of polymer dispersions for textiles including the generic scenario, individual sites involved in industrial use of XPS compound and HBCDD powder including the generic local scenario for industrial use of XPS compound and sites involved in textile backcoating including the generic scenario. A general conclusion (iii) is drawn for textile backcoating. based on measured concentrations in sediment downstream three different locations giving RCRs >1.

#### 5.1.2 Terrestrial compartment

There is no concern for the majority of the sites including the generic scenarios for most use areas. However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to the generic scenario for industrial use of XPS compound, three sites using HBCDD powder in the production of XPS and one site involved in textile backcoating including the generic scenario.

### 5.1.3 Atmosphere

**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

### 5.1.4 Secondary poisoning

#### Aquatic predators, Terrestrial predators, Marine predators, Marine top predators

In the light of HBCDD being a PBT substance and considering the large uncertainties both in the derivation of PECs and in the derivation of PNEC it is not considered appropriate to draw conclusions for the individual sites. Since for PBT-substances the major concern is that accumulation of such substances in the foodchain may result in unpredictable effects in the long term it is appropriate to draw an overall conclusion (iii) for secondary poisoning.

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

### 5.1.5 Marine environment

#### *Marine Surface water*

There is no concern for the many of the sites including the generic scenarios for many use areas.

However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to some sites involved in EPS formulation including the generic scenario, one site and the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, individual sites involved in industrial use of HBCDD powder in XPS and use of XPS compound including the local generic scenario for industrial use of XPS compound, and some sites involved in textile backcoating including the generic scenario.

#### *Marine Sediment*

There is no concern for the many of the sites including the generic scenarios for many use areas. However, conclusion (iii) - there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account - applies to some sites involved in EPS formulation including the generic scenario, one site and the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, individual sites involved in industrial use of HBCDD powder in XPS and use of XPS compound including the generic local scenario for industrial use of XPS compound, and some sites involved in textile backcoating including the generic scenario. In addition, measurements in marine sediment associated to a producer of EPS beads (EPS formulation) gives a RCR >1 which indicates that there are concerns for this site and that there may be a general concern for this use area.

### 5.1.6 PBT-assessment

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

HBCDD does not unequivocally fulfil the specific P-criterion, with some reliable studies indicating that biodegradation can occur. It does however not degrade rapidly and monitoring data indicate a significant degree of environmental transport and overall stability. The BCF of HBCDD is 18 100 and thus the vB criterion is fulfilled. Also the T-criterion is fulfilled according to available data. HBCDD is ubiquitous in the environment, being also found in remote areas far away from point sources. The highest concentrations of HBCDD are detected in marine top-predators such as porpoise and seals showing that HBCDD bioaccumulates up the foodchain. Based on an overall assessment the TCNES subgroup on identification of PBT and vPvB substances have concluded that HBCDD has PBT properties according to the PBT criteria of the TGD.

## 5.2 HUMAN HEALTH

**(i) on hold** There is a need for further information and/or testing.

There are indications of developmental neurotoxicity in adult mice exposed to HBCDD as pups. However, this study by Eriksson et al (2006) is not performed according to current guideline and GLP and therefore this potential developmental neurotoxicity needs to be examined further and conclusion (i) is reached for all exposure scenarios.

However, similar results on developmental neurotoxicity have been published for decabromodiphenylether by the same authors using the same method. For decabromodiphenylether it has been agreed to perform a new toxicokinetics/developmental neurotoxicity study according to a modified OECD guideline and GLP. The results from this new decabromodiphenylether study will serve as guidance on how to interpret the data from the Eriksson study, and may also serve as a basis on how to proceed with further testing of neurotoxicity. While awaiting these results a **conclusion (i) on hold** with regard to a developmental neurotoxicity study applies.

### WORKERS

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 because of:

- concern for repeated dose toxicity effects on the liver as a consequence of inhalation and/or dermal exposure during filling HBCDD fine grade powder in production.
- concern for reproductive toxicity during filling HBCDD fine and standard grade powder in production, and during adding HBCDD fine and standard powder at industrial use of HBCDD as an additive.

CONSUMERS

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

HUMANS EXPOSED VIA THE ENVIRONMENT

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

HUMAN HEALTH (physico-chemical properties)

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

## 6 GLOSSARY

<b>Standard term / Abbreviation</b>	<b>Explanation/Remarks and Alternative Abbreviation(s)</b>
<i>Ann.</i>	Annex
AF	assessment factor
BCF	bioconcentration factor
bw	body weight / <i>Bw</i> , <i>b.w.</i>
°C	degrees Celsius (centigrade)
CAS	Chemical Abstract System
CEC	Commission of the European Communities
CEN	European Committee for Normalisation
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
d	day(s)
d.wt	dry weight / <i>dw</i>
DG	Directorate General
DT <sub>50</sub>	period required for 50 percent dissipation (define method of estimation)
DT <sub>50lab</sub>	period required for 50 percent dissipation under laboratory conditions (define method of estimation)
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
DT <sub>90field</sub>	period required for 90 percent dissipation under field conditions (define method of estimation)
EC	European Communities
EC	European Commission
EC <sub>50</sub>	median effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
EU	European Union
EUSES	European Union System for the Evaluation of Substances
<i>f</i> <sub>oc</sub>	Fraction of organic carbon
G	gram(s)



PNEC(s)	Predicted No Effect Concentration(s)
$PNEC_{water}$	Predicted No Effect Concentration in Water
(Q)SAR	Quantitative Structure Activity Relationship
STP	Sewage Treatment Plant
TGD	Technical Guidance Document <sup>2</sup>
UV	Ultraviolet Region of Spectrum
UVCB	Unknown or Variable composition, Complex reaction products or Biological material
v/v	volume per volume ratio
w/w	weight per weight ratio
w	gram weight
GLP	Good Laboratory Practice
h	hour(s)
ha	Hectares / <i>h</i>
HPLC	High Pressure Liquid Chromatography
IARC	International Agency for Research on Cancer
$C_{50}$	median immobilisation concentration or median inhibitory concentration 1 / <i>explained by a footnote if necessary</i>
ISO	International Standards Organisation
IUPAC	International Union for Pure Applied Chemistry
kg	kilogram(s)
kPa	kilo Pascals
$K_{oc}$	organic carbon adsorption coefficient
$K_{ow}$	octanol-water partition coefficient
$K_p$	Solids water partition coefficient
l	litre(s)
log	logarithm to the basis 10
$L(E)C_{50}$	Lethal Concentration, Median
LEV	Local Exhaust Ventilation

<sup>2</sup> Commission of the European Communities, 1996. Technical Guidance Documents in Support of the Commission Directive 93/67/EEC on risk assessment for new substances and the Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. Commission of the European Communities, Brussels, Belgium. ISBN 92-827-801[1234]

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m	Meter
µg	microgram(s)
mg	milligram(s)
MAC	Maximum Accessibility Concentration
MOS	Margins Of Safety
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OEL	Occupational Exposure Limit
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal
pH	potential hydrogen <i>-logarithm</i> (to the base 10) of the hydrogen ion concentration {H <sup>+</sup> }
pKa	<i>-logarithm</i> (to the base 10) of the acid dissociation constant
pKb	<i>-logarithm</i> (to the base 10) of the base dissociation constant
Pa	Pascal unit(s)
PEC	Predicted Environmental Concentration
STP	Sewage Treatment Plant
WWTP	Waste Water Treatment Plant