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BIS(PENTABROMOPHENYL) ETHER

CAS No: 1163-19-5

EINECS No: 214-604-9

Summary Risk Assessment Report

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SUMMARY RISK ASSESSMENT REPORT

Summary report, 2003

France and United Kingdom

This document has been prepared by the French and UK rapporteurs on behalf of the European Union. The scientific work on the environmental part was prepared by the Building Research Establishment Ltd (BRE), under contract to the UK rapporteur.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance bis(pentabromophenyl) ether (decabromodiphenyl ether) that has been prepared by France and the UK 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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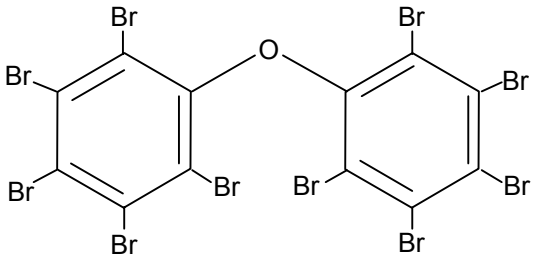
1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS Number: 1163-19-5
EINECS Number: 214-604-9
IUPAC Name: Bis(pentabromophenyl) ether (decabromodiphenyl ether)
Molecular weight: 959.2
Molecular formula: $C_{12}Br_{10}O$
Structural formula:



Synonyms: Decabromobiphenyl ether, DBDPE, DBBE, DBBO, DBDPO, decabromo biphenyl oxide, decabromo phenoxybenzene and benzene, 1,1'-oxybis, decabromo derivative

The name decabromodiphenyl ether is used in this assessment.

1.2 PURITY/IMPURITIES, ADDITIVES

The actual composition of the products from different producers/suppliers is regarded as confidential information. A typical composition for modern products would be 97-98% decabromodiphenyl ether with 0.3-3.0% of other brominated diphenyl ethers, mainly nonabromodiphenyl ether, and the composition of products supplied in the EU is consistent with these figures. The composition of older products (no longer supplied in the EU) or products from other sources may be different from these figures.

There were no stated additives incorporated into the commercially available forms of this substance.

1.3 PHYSICO-CHEMICAL PROPERTIES

The physico-chemical properties are summarised in **Table 1.1**.

Table 1.1 Physico-chemical properties of decabromodiphenyl ether

Property	Value/remark
Physical state (at normal temperature and pressure)	Fine crystalline powder (white to off white), particle size typically <5 µm
Melting point	300-310°C
Boiling point	decomposes at >320°C
Specific gravity	3.0
Vapour pressure	$4.63 \cdot 10^{-6}$ Pa at 21°C
Water solubility	<0.1 µg/l at 25°C
Log octanol-water partition coefficient	6.27 (measured by generator column method)
Flammability	not applicable
Autoflammability	not applicable
Explosive properties	none
Oxidising properties	none

1.4 CLASSIFICATION

Decabromodiphenyl ether is not classified for environmental or health effects.

2 GENERAL INFORMATION ON EXPOSURE

Production

There is currently no production of decabromodiphenyl ether in the EU. All of the decabromodiphenyl ether used in the EU is currently imported.

Uses

The main use of decabromodiphenyl ether is as a flame retardant additive for a range of polymer systems (particularly high impact polystyrene but also polypropylene, ethylene-vinyl acetate copolymers, other ethylene copolymers, ethylene-propylene-diene terpolymers, thermoplastic elastomers, polyester resins, styrenic rubbers, polycarbonates, polyamides and terphthalates). The end uses for these flame retarded polymers are generally in electrical and electronic equipment (e.g. computers, connectors, electrical boxes, wire and cable). Decabromodiphenyl ether is usually used at loadings of 10-15% weight in the polymers.

Another application is as a flame retardant for some types of drapery and upholstery fabric, where it is backcoated onto the fabric in a latex binder (up to 1,500 tonnes/year of decabromodiphenyl ether are used in this application in the EU).

The total EU demand for decabromodiphenyl ether was estimated as 8,210 tonnes/year in the mid-1990s and 7,500 tonnes/year in 1999. In addition, decabromodiphenyl ether may be imported into and exported from the EU in finished or semi-finished products, but, although it was not possible to estimate the amount, the net import into the EU was thought to be small compared with the total amount of decabromodiphenyl ether known to be used in the EU.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

Environmental releases

Information from a number of sources has been used to estimate releases from the stages in formulation and use of decabromodiphenyl ether. Emissions from the compounding and processing of plastics have been estimated using information from the plastics industry gathered for a draft Use Category Document in conjunction with the default release factors from the EU Technical Guidance Document. Emissions from the use in textiles have been estimated using information supplied for that industry. Emissions to the environment during the service life time of products containing decabromodiphenyl ether (e.g. leaching, volatilisation and particulate loss), and at disposal of these products, are also considered. The total EU emissions of decabromodiphenyl ether are estimated as 29.1 tonnes/year to air, 319.3 tonnes/year to wastewater treatment plants, 175.4-178.8 tonnes/year direct to surface water and 116.1-126.6 tonnes/year to urban/industrial soil. The total emissions are dominated by the estimated emissions over the service life of products and disposal of products.

Environmental fate

The major characteristics of decabromodiphenyl ether relevant for the exposure assessment are that it is not readily or inherently biodegradable, it has a high log Kow value (6.27) and an estimated atmospheric half-life of 94 days. The high log Kow value indicates that decabromodiphenyl ether will adsorb strongly onto sludge and sediments and is not expected to be mobile in soil. The potential for uptake and accumulation of the substance by fish and other aquatic and terrestrial organisms appears to be low. However decabromodiphenyl ether has been found to be present, albeit at low concentrations, in predatory birds' eggs and some fish and marine mammals, and so appears to be available to organisms in the environment. There is also some evidence that decabromodiphenyl ether may (photo)degrade in the environment under certain conditions, possibly forming more toxic and accumulative products, but it is not possible to estimate the rate or extent of these reactions.

The predicted fate of decabromodiphenyl ether in wastewater treatment plants is 91.4% adsorbed onto sewage sludge, 0.3% released to air and 8.3% released to surface water. Thus the major emissions are estimated to occur to water and to land via sewage sludge.

Environmental concentrations

The methods in the Technical Guidance Document were used to estimate concentrations in water, sediment, air, soil and biota (fish). **Table 3.1** shows the PECs calculated for the various stages of the lifecycle of decabromodiphenyl ether. The calculated levels in air were predicted to be very low (<0.05 $\mu g/m^3$) for all lifecycle stages and are not presented here. It was not possible to estimate reliable concentrations of decabromodiphenyl ether in the earthworm food chain for secondary poisoning.

Table 3.1 Summary of PECs and PEC/PNEC ratios estimated for decabromodiphenyl ether

Media	Release source	PEC	PEC/PNEC ratio
Surface water	Polymer processing site	0.33 µg/l	
	Textiles – compounding site	2.6 µg/l	
	Textiles – application site	1.3 µg/l	
	Textiles – combined compounding/application site	3.8 µg/l	
	Regional sources	0.093-0.094 µg/l	
Sediment	Polymer processing site	10.8 mg/kg wet wt	≤0.073
	Textiles – compounding site	89.0 mg/kg wet wt	≤0.60
	Textiles – application site	46.1 mg/kg wet wt	≤0.30
	Textiles – combined compounding/application site	131 mg/kg wet wt	≤0.89
	Regional sources	5.66-5.72 mg/kg wet wt	≤0.039
Waste water treatment plant	Polymer processing site	8 µg/l	≤0.005
	Textiles – compounding site	42 µg/l	≤0.028
	Textiles – application site	84 µg/l	≤0.056
	Textiles – combined compounding/application site	126 µg/l	≤0.084
Soil	Polymer processing site – agricultural soil	3.30 mg/kg wet wt	≤0.038
	Textiles – compounding site – agricultural soil	34.0 mg/kg wet wt	≤0.39
	Textiles – application site – agricultural soil	17.1 mg/kg wet wt	≤0.20
	Textiles – combined compounding/application site – agricultural soil	51.0 mg/kg wet wt	≤0.59
	Regional sources – agricultural soil	27.0 mg/kg wet wt	≤0.31
	Regional sources – industrial/urban soil	17.8-19.0 mg/kg wet wt	≤0.20-≤0.22
Secondary poisoning – fish food chain	Polymer processing	0.72 µg/kg	$2.9 \cdot 10^{-7}$
	Textiles – compounding	4.4 µg/kg	$1.8 \cdot 10^{-6}$
	Textiles – application	2.4 µg/kg	$9.6 \cdot 10^{-7}$
	Textiles – combined compounding/application site	6.4-6.5 µg/kg	$2.6 \cdot 10^{-6}$

3.2 EFFECTS ASSESSMENT

Aquatic compartment (incl. sediment)

Short-term toxicity test data are available for both fish and algae. In both cases, no effects were seen at concentrations of decabromodiphenyl ether well in excess of its water solubility. No toxicity data is available with *Daphnia*, but by analogy with another highly brominated diphenyl ether (octabromodiphenyl ether), no effects would be expected to occur in tests with this species at concentrations up to the solubility limit of decabromodiphenyl ether.

Based on the currently available toxicity data, it is not possible to derive a PNEC for decabromodiphenyl ether as no effects are expected at concentrations up to the water solubility of the substance. The risk to surface water from this substance can be considered to be low.

The sediment phase is much more relevant for this substance than the water phase, and long-term toxicity data are available for decabromodiphenyl ether with the oligochaete *Lumbriculus variegatus* in two sediment types. No effects were seen in these studies at any concentration tested (up to 3,841 and 4,536 mg/kg dry weight in the two studies respectively). Based on these data, a PNEC for the sediment compartment of ≥384 mg/kg dry weight (equivalent to ≥148 mg/kg on a wet weight basis) was derived.

Decabromodiphenyl ether is of low toxicity to microorganisms. No effects on activated sludge respiration were seen at a concentration of 15 mg/l. Based on these data, a PNEC for wastewater treatment plants of ≥1.5 mg/l can be derived for decabromodiphenyl ether.

Terrestrial compartment

Terrestrial toxicity data are available for decabromodiphenyl ether with plants and earthworms (*Eisenia fetida*). No effects were seen at the highest concentrations tested (up to 5,349 mg/kg dry weight for six species of plants and 4,910 mg/kg dry weight for earthworms). Based on these data, a PNEC for the soil compartment of ≥98 mg/kg dry weight (equivalent to ≥87 mg/kg on a wet weight basis) was derived.

Atmosphere

The predicted atmospheric concentrations of decabromodiphenyl ether are all very low. Neither biotic nor abiotic effects are considered likely because of the limited release and low volatility of the substance.

Secondary poisoning

The information available indicates that decabromodiphenyl ether has a low potential for bioconcentration and bioaccumulation. However decabromodiphenyl ether has recently been found to be present in predatory birds' eggs, fish and marine mammals, indicating that it can be taken up from the environment. The available mammalian toxicity data allow a PNEC of 2,500 mg/kg food to be derived for decabromodiphenyl ether for secondary poisoning. However, it has recently been reported that decabromodiphenyl ether causes behavioural disturbances in neonatal mice at concentrations much lower than this PNEC (doses equivalent to 18.3-167 mg/kg food) but the toxicological significance of these findings is unclear.

Also of concern with regard to secondary poisoning is the possible formation of lower brominated diphenyl ethers as a result of photolysis/degradation of decabromodiphenyl ether in the environment. The available evidence indicates that the more toxic and accumulative lower brominated congeners, if formed, would only be minor products of these reactions, but there is some uncertainty over the actual significance of these processes in the environment, and not all the products from these reactions are known.

3.3 RISK CHARACTERISATION

Aquatic compartment (incl. sediment)

The worst-case PEC/PNEC ratios are summarised in **Table 3.1**. Based on the currently available toxicity data, it is not possible to derive a PNEC for the aquatic compartment as no effects are expected at concentrations up to the water solubility of the substance. The risk to the aquatic (surface water) compartment from decabromodiphenyl ether itself can be considered to be low.

The risk to the sediment compartment and wastewater treatment plants is low based on the PEC/PNEC ratios.

Terrestrial compartment

The worst-case PEC/PNEC ratios are summarised in **Table 3.1**. Based on these data, the risk to the terrestrial compartment for the use of decabromodiphenyl ether can be considered to be low.

Atmosphere

Neither biotic nor abiotic effects are considered likely because of limited release and low volatility of decabromodiphenyl ether. The predicted atmospheric concentrations are all very low (<0.05 $\mu g/m^3$).

Secondary poisoning

The PEC/PNEC ratios given in **Table 3.1** indicate that the risk of secondary poisoning from decabromodiphenyl ether can be considered to be low based on the PEC/PNEC approach.

Additional uncertainties

The current approach to risk assessment implies that there is no risk of secondary poisoning, and the PEC/PNEC ratios are much less than 1 (in fact below 10^{-5}) for the commercial decabromodiphenyl ether product. Although it appears to be persistent in the environment, the commercial substance is considered to have a low bioaccumulation potential based on the available laboratory data. It also shows no toxicity towards aquatic organisms up to the limit of water solubility, and effects in other organisms are only observed at relatively high concentrations, based on standard laboratory tests.

Nevertheless, the most recent analytical monitoring surveys indicate that it is present at (relatively) low concentrations in fish, marine mammals and predatory birds' eggs (those of bird-eating Peregrine Falcons and fish-eating Common Terns). These findings appear to contradict the conventional wisdom that molecules such as decabromodiphenyl ether are too large to pass through biological membranes and should not accumulate in organisms. There are uncertainties with some of the analytical data that indicate the presence of decabromodiphenyl ether at or near the detection limit of the method. Some of the positive determinations may also have been influenced by the presence of decabromodiphenyl ether in the gut contents rather than in body tissues, or analytical artefacts. Nevertheless, the finding of decabromodiphenyl ether in lipid tissues of some higher mammals and birds' eggs indicates that decabromodiphenyl ether may be bioavailable in the environment. How the uptake into organisms occurs, whether by food, air and/or water, is currently uncertain.

There is also some evidence that the concentrations of decabromodiphenyl ether may be increasing in sediments. If this is a true trend, then the increasing number of apparently positive findings of decabromodiphenyl ether in organisms in the environment in the more recent studies might reflect a more general increase in the amount of decabromodiphenyl ether in the environment. Other possible explanations for the findings from the more recent studies are that:

- the uptake rate by these organisms is very slow (i.e. the levels may be increasing with time),
- more sensitive analytical methods are being used (so are able to detect lower concentrations of decabromodiphenyl ether), or
- simply a wider variety of species is being sampled.

It is not currently possible to distinguish between these different possibilities.

The levels found in fish, etc., are below those that are predicted to cause effects on fish-eating species using the PEC/PNEC approach. However, the sample sizes are small, and the trend in these levels is unknown. It is also possible that higher concentrations could be found in other organisms. Coupled with questions over analytical problems, levels need to be confirmed.

It is not possible to assess the effects of the concentrations of decabromodiphenyl ether present in, for example, birds' eggs using the current approaches. The mere presence of a chemical in biota is not necessarily a cause for concern, and there is no evidence at this point in time of biomagnification taking place or actual environmental harm arising from this substance at these levels. However, there is some evidence from recent non-standard behavioural tests on mice that neonatal exposure may cause irreversible behavioural disturbances (as determined by disruption of habituation) in adult mice.

The toxicological significance of these findings (in terms of population survival) is unclear. However, the dose range is below those at which no effects were observed in standard mammalian toxicity tests (behavioural effects have been noted at levels 500 times lower than the standard NOAEL obtained from a 2-year chronic study in rats - a NOAEL has not been established for the behavioural effect).

Even if the study represents a reproducible effect, the interpretation of such an effect in the context of this assessment is unclear, especially in terms of assessment factors and comparison with actual tissue levels (rather than dose). However, it does imply that the standard toxicity tests might not have picked out subtle effects that could be significant at sensitive life stages. This raises some concern about the presence of the substance in birds' eggs. This substance is persistent and so it is also possible that slow uptake may be occurring over extended timescales, so that levels in biota may increase with time. It is therefore possible that the current PEC/PNEC approach for secondary poisoning may not be appropriate for decabromodiphenyl ether in terms of both the PEC and the PNEC, and could underestimate the risk. This issue needs further investigation.

A second aspect of concern is that although the substance is persistent, there is evidence that it can degrade under some conditions. For example, photolysis on solid surfaces has been demonstrated under laboratory conditions. Lower brominated diphenyl ether congeners have been identified among the degradation products from these studies (some products remain unidentified). It is known that some lower brominated diphenyl ethers (e.g. tetra- and pentabromodiphenyl ether) are potentially much more bioaccumulative and toxic than decabromodiphenyl ether. The available experimental evidence indicates that the lower brominated diphenyl ethers, if formed, are likely to be only minor products, but the overall environmental degradation rate has not been determined and the environmental significance of any degradation pathway remains uncertain.

There is currently no evidence that significant degradation to lower brominated diphenyl ether congeners is actually occurring in the environment. If debromination of decabromodiphenyl ether to lower brominated congeners, in particular 2,2',4,4'-tetrabromodiphenyl ether (the most common congener present in biota in the environment) is a significant process, then it may be possible to derive some information on the process from trends in the available monitoring data for that substance. However, such an analysis is complicated by the fact that this congener is present in substantial amounts in the commercial pentabromodiphenyl ether product and the use of this product in the EU has declined in the EU in recent years. Thus, any possible trend in the amount of 2,2',4,4-tetrabromodiphenyl ether (or other lower brominated diphenyl ether congeners) linked to the use of decabromodiphenyl ether is likely to be masked as a result of the changing use pattern. There is evidence that the concentrations of lower brominated diphenyl ether

congeners in human breast milk in Europe has fallen recently following an increase up to the late 1990s but the recent trend in the levels of these congeners in other biota in Europe is less clear.

Since some of the products may be more bioaccumulative and toxic than the parent compound, any significant formation would be a cause for concern. The current database in inconclusive on this point, and further work might be needed.

Four possible areas of further work are as follows.

a) A more widespread monitoring project to determine whether the finding in top predators (including birds' eggs) is a widespread or localised phenomenon, and trends (if possible).

b) Further toxicity testing. The existence of a mammalian toxicity data set means that testing could be considered on birds (e.g. an avian reproduction test (OECD 206), with appropriate tissue analysis). Alternatively, a study that administers the substance by injection of eggs could be done to determine whether adverse developmental effects are detectable. Overall, the benefit of further vertebrate testing is open to question due to expected difficulties in achieving sufficiently high exposures. This leaves the toxicity issue with some unresolved uncertainty.

c) An investigation of the rate of formation of degradation products under environmentally relevant conditions over a suitably prolonged time period.

d) Further toxicological work on the non-diphenyl ether degradation products, to determine if they pose a hazard or risk.

There is a high level of uncertainty associated with the suitability of the current risk assessment approach for secondary poisoning and the debromination issue. The combination of uncertainties raises a concern about the possibility of long-term environmental effects that cannot easily be predicted. There is insufficient confidence in the PEC and PNEC estimates to reach either conclusion (ii) or (iii) for this endpoint. In order to be able to reduce the uncertainties to an acceptable level, further research could be attempted. It is noted, however, that much of the information required above would take some considerable time to be generated or gathered, and might not be sufficiently comprehensive to remove all uncertainty. There is evidence that decabromodiphenyl ether is highly persistent, and of particular note, the major components of the commercial product have been detected, albeit at relatively low levels and from a limited sample, in predatory birds' eggs and marine mammals. The trend in these levels is unknown. It is not possible to say whether or not on a scientific basis there is a current or future risk to the environment. However, given the persistent nature of the substance, it would be of concern if, once the further information had been gathered, the analysis indicated a risk to predators, since it could then be difficult to reduce exposure.

In summary, although it is concluded that further information should be gathered in order to refine the risk assessment, in light of:

- the persistence of the substance,
- the time it would take to gather the information and
- the fact that there is no guarantee that the studies would provide unequivocal answers,

consideration should be given at a policy level to the need to investigate risk management options now in the absence of adequate scientific knowledge.

[N.B. A number of technical experts from EU member states consider that this uncertainty is sufficient to warrant risk reduction measures directly (conclusion (iii)) based on the information currently provided in this assessment.]

Another area of potential concern for both direct toxicity and secondary poisoning is the possible formation of brominated dibenzo-*p*-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (e.g. incineration, landfill (where fires could occur) or accidental fires). Overall it can be concluded that decabromodiphenyl ether, as a source of bromine, can contribute to the formation of halogenated dibenzo-*p*-dioxins and debenzofurans generated during such processes. It is not possible from the available data (and it is beyond the scope of this risk assessment) to quantify the actual contribution that decabromodiphenyl ether makes to the total "toxic" products (fires etc. can generate products other than halogenated dibenzo-*p*-dioxins and dibenzofurans that are considered toxic (e.g. polycyclic aromatic compounds)). Formation of halogenated dibenzo-*p*-dioxins and dibenzofurans in some of these processes is well known and emission control technology is available for incinerators and metal recycling facilities that can reduce emissions to acceptable levels. Although incineration or metal recycling could take place at installations without suitable emission reduction equipment, it should be noted that in most situations decabromodiphenyl ether is unlikely to be the only source of halogenated dioxins/furans. Emission control technology cannot be applied to landfill or other accidental fires. Recycling of plastics containing the substance does not appear to contribute to brominated dibenzo-*p*-dioxin or furan formation.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

Occupational exposure

Occupational exposure may occur during manufacture, industrial processing in the plastic industry, the textile industry, equipment and upholstery manufacture and end uses of flame retarded products. Formulation and use of hot melt adhesives containing decabromodiphenyl ether may also be a source of occupational exposure.

Decabromodiphenyl ether is a solid with a very low vapour pressure. Inhalation of dust and skin contact are the predominant routes of exposure. In situations where exposure to mist may occur as a result of heating (extrusion, moulding), the presence of extraction ventilation is likely to minimise exposure. Exposure is expected to be very low after inclusion in the polymer or textile coating matrix.

A few dust exposure measurements are available which are not sufficient for the risk assessment. There are no measured data on dermal exposure. Consequently the occupational exposure assessment is based on EASE model estimation and expert judgement. The results for the different scenarios are summarised in **Table 4.1**.

Table 4.1 Summary of occupational exposure

Scenario	External inhalation exposure (mg/m^3)	External dermal exposure ($mg/cm^2/day$)
1 Manufacture (bagging and cleaning activities)	5	1
2 Coumpounding and master batching - bag emptying - extrusion	 5 extremely low	 1 negligible
3 Moulding	extremely low	negligible
4 Textile industry (bag emptying)	5	1
5 Formulation of hotmelt adhesive (bag emptying)	5	1
6 Equipment and upholstery manufacture	extremely low	negligible
7 End uses of flame retarded products	negligible	negligible

Consumer exposure

Decabromodiphenyl ether has no direct consumer use but is incorporated as a flame retardant in consumer plastics and in upholstery textiles.

There are no measured data into the indoor environment. Measurements of PBDPO in the air at offices show concentration of at most 97 pg/m^3 and confirm that exposure from the polymer matrix is very low.

For application in upholstery, although no data on leaching are available, dermal exposure after direct contact at home is expected very low given the low frequency and duration of any contact.

In summary, based on scattered pieces of evidence and in agreement with previous risk assessment, it is felt that consumer exposure to decabromodiphenyl ether is likely to be negligible.

Humans exposed via the environment

The maximum total daily human dose of decabromodiphenyl ether from all sources is estimated by the EUSES model to be around 12 µg/kg bw/day for production, 8 µg/kg bw/day for polymer processing, 9 µg/kg bw/day for textile (compounding), 8 µg/kg bw/day for textile (application), and 11 µg/kg bw/day at a regional level. The majority of the dose is predicted to come from root crops.

4.1.2 Effects assessment

Toxicokinetics, metabolism and distribution

Decabromodiphenyl ether can be absorbed through the gastro-intestinal tract (approximately 6-9.5%) and is distributed to the blood, the liver and the adipose tissue. Given the low rate of oral absorption in rats, a low bioaccumulation potential might be anticipated. Some decabromodiphenyl ether is absorbed intact from the intestine and excreted mainly in the faeces, intact or in the form of metabolites (e.g. debrominated hydroxylated diphenyl oxides). Only trace amount of bromine compounds was found in tissues and the brain of neonatal mice exposed on postnatal day 3, 10 or 19. However the toxicological significance of this last finding is unclear. A maximal dermal absorption of 1% may be assumed. Although pulmonary exposure may occur due to the small particle size (<5 µm), the limited available data do not allow determination of pulmonary absorption.

Acute toxicity

Decabromodiphenyl ether has a low oral, dermal and inhalation acute toxicity in animals. Oral administration in corn oil indicates a rat LD50 greater than 5,000 mg/kg. No clinical signs of toxicity were observed up to 2,000 mg/kg and no deaths were seen up to 5,000 mg/kg. A dermal LD50 greater than 2,000 mg/kg has been demonstrated in rabbits using decabromodiphenyl ether applied neat under occlusive wraps. No deaths were observed up to 2,000 mg/kg. Local and general signs of toxicity were not reported but necropsies were not performed in this dermal toxicity study. Following inhalation administration in rat at 2 and 48.2 mg/l during one hour, no deaths were seen; only minor ocular signs and dyspnea were observed from 2 mg/l concentration. The reliability of these data is limited by the absence of information on particle size distribution.

Irritation / Corrosivity / Sensitisation

Decabromodiphenyl ether is not a dermal or an ocular irritant and does not exhibit a chloroacnegenic activity. There is no indication of skin sensitisation.

Repeated dose toxicity

The lowest NOAEL of 1,120 mg/kg/day for systemic toxicity (including non neoplastic lesions exclusively) is derived from a chronic 2-year dietary study in rats. At the highest dose tested (2,240 mg/kg/day) in males, non neoplastic lesions in the liver (increased incidence of thrombosis and degeneration), spleen fibrosis and lymphoid hyperplasia of the mandibular lymph nodes were observed. In the same study, a LOAEL of 1,120 mg/kg/day is determined for local effects based on the slight increase of the forestomach acanthosis observed from 1,120 mg/kg/day. No effects on thyroid homeostasis were found in either sex of two species after 13 weeks treatment

with decabromodiphenyl ether up to approximately 7,000 and 11,000 mg/kg/day in mice and 2,800 and 3,800 mg/kg/day in rats and only mild effects (follicular cell hyperplasia and marginally increased incidence of thyroid follicular cell adenomas or carcinomas) were found in one species after a life time exposure from 3,200 mg/kg/day in male mice.

Mutagenicity

With regard to mutagenesis, on the whole, results from different *Salmonella* can be considered as negative. Decabromodiphenyl ether does not exhibit any cytogenetic effects *in vitro* or *in vivo*. It is noticeable that some of these tests present some limitations. However given the absence of alert-structure for genotoxicity, the negative results obtained in the mutagenicity tests with decabromodiphenyl, octabromodiphenyl and pentabromodiphenyl ethers, no concern about mutagenicity may be assumed.

Carcinogenicity

With regard to carcinogenesis, a LOAEL for carcinogenicity of 1,120 mg/kg/day is stated based on the increased incidence of liver neoplastic nodules from the lowest tested dose (1,120 mg/kg/day) in a dietary study in rats. On thyroid, marginal increase in incidence of thyroid tumours supported by an increased incidence of follicular cell hyperplasia is observed in mice but not in rats. It is recognised that there are marked species differences in thyroid gland biochemistry and physiology and that the rodent thyroid gland is markedly more active and operates at a considerably higher level with respect to thyroid hormone turnover as compared to primate. Finally, it should be reminded that decabromodiphenyl ether presents a non-genotoxic profile as well as other polybrominated congeners such as octabromodiphenyl ether and pentabromodiphenyl ether and is devoid of alert-structure for genotoxicity.

Toxicity for reproduction

With regard to reproductive toxicity, no effects on fertility were seen in a 1-generation reproduction oral study in rats up to 100 mg/kg/day administered in the diet, though the absence of parental toxicity indicates that higher dose levels could have been tested. However, no histological changes were seen in the reproductive organs in rats and mice treated for 2 years in a dietary study with up to 50,000 ppm decabromodiphenyl ether (equivalent to approximately 2,240-2,550 and 6,650-7,780 mg/kg/day, respectively). Thus no concern for fertility is assumed.

For developmental effects, no adverse treatment related effect was observed such as external or internal malformations or variations, foetal weight, sex ratio, total resorption and late resorption up to 1,000 mg/kg/day. Therefore, no concern for developmental toxicity is assumed.

Neurotoxicity

With regard to neurotoxicity, decabromodiphenyl ether causes behavioural disturbances in neonatal mice exposed at a single dose of 2.22 to 20.1 mg/kg/bw on post-natal day 3. This effect was not seen in mice exposed on post-natal day 10 or 19. The study has certain limitations compared with regulatory guidelines and thus uncertainty as regards interpretation of the results remains. Moreover only an abstract of this study and a personal communication from the authors are available with limited details. Therefore**,** no conclusion can be drawn from this endpoint.

Breast-feeding

With regard to breast-feeding, following pregnancy, hexabromodiphenyl ether and other polybromodiphenyl ethers such as tetrabromodiphenyl ether and pentabromodiphenyl ethers have been identified in breast milk but such measurements were not carried out on decabromodiphenyl

ether or on octabromodiphenyl ether. However, considering the toxicokinetic profile of decabromodiphenyl ether, a rather low excretion in breast milk might be anticipated.

4.1.3 Risk characterisation

Workers

For the purpose of the risk characterisation, it is assumed that inhalation of dust and skin exposures are the main routes of exposure. Oral exposure is not considered to be a significant route of exposure under normal working practices.

For the inhalation route, assuming a full-shift exposure of 5 mg/m^3, 10 m^3/working day, a 70 kg worker and 100% absorption, the estimated body burden 0.7 mg/kg/day is achieved. For the dermal route, assuming maximum skin exposure of 1 mg/cm^2/day, a skin surface exposed of 840 cm^2, a worker's weight of 70 kg and a maximum skin absorption of 1%, the calculated body burden amounts 0.12 mg/kg/day.

Considering the estimated internal exposure and comparing the NOAEL of 1,120 mg/kg/day for chronic toxicity, MOSs have been calculated. For occupational exposure, these MOSs can be considered sufficient. For liver neoplastic nodules observed in a carcinogenic study, considering the estimated internal exposure and comparing the LOAEL of 1,120 mg/kg/day, MOSs have been calculated and are considered sufficient for occupational exposure.

Consumers

Since consumer exposure is likely to be negligible, no resulting risk for consumer is estimated.

Humans exposed via the environment

The exposure assessment has shown that the main route of intake is by the oral route.

Considering the highest estimated total daily intake of 12 μg/kg bw/day and comparing the NOAEL of 1,120 mg/kg/day for chronic toxicity and the LOAEL of 1,120 mg/kg/day for liver neoplastic nodules observed in a carcinogenic study, MOSs have been calculated. The estimated MOSs are considered sufficient for exposure of this population via the environment.

Combined exposure

Combined environmental exposure and occupational exposure will not influence the characterisation of the risks.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

Decabromodiphenyl ether gives no reason for concern in relation with its physico-chemical properties. There is no need for further information and/or testing.

5 RESULTS

5.1 INTRODUCTION

Decabromodiphenyl ether was produced at one site within the EU but production at this site ceased in 1999. The decabromodiphenyl ether currently used in the EU is imported.

Decabromodiphenyl ether is used in the plastics and textile industries as a flame retardant. In the plastics industry, it is used as an additive flame retardant in a wide range of plastic types. In the textile industry, decabromodiphenyl ether is generally backcoated onto the textile in a latex binder. The commercially supplied decabromodiphenyl ether is a mixture of brominated diphenyl ethers, consisting mainly of decabromodiphenyl ether, with small amounts (0-3%) of other brominated diphenyl ethers such as nonabromodiphenyl ether. The product is a solid of very low water solubility and vapour pressure.

5.2 ENVIRONMENT

Local releases to the environment may occur from polymer processing and use in textile finishing. In addition, volatilisation and leaching of the flame retardant from articles, and also release of particulates containing decabromodiphenyl ether, may occur during the lifetime of the article (and at disposal for particulates). These releases have been quantified in the risk assessment and used to calculate PECs for various environmental compartments.

For the aquatic compartment, the risk from exposure via surface water is thought to be low. Exposure of organisms via sediment is thought to be much more relevant for this substance and, although the available measured levels in sediment are lower than the predicted levels, the risk to sediment dwelling organisms was also found to be low. No risk was identified for sewage treatment processes or the terrestrial compartment. No adverse effects are expected on the atmosphere from the production and use of decabromodiphenyl ether.

The available information indicates that the risk of secondary poisoning, as determined by the conventional PEC/PNEC ratio, resulting from use of decabromodiphenyl ether is low. There are, however, considerable uncertainties in the secondary poisoning assessment, and a strict PEC/PNEC approach may not be appropriate for this substance. In addition, the possibility of degradation in the environment to give more toxic lower brominated diphenyl ethers cannot be completely ruled out over extended time periods with the available data. The combination of uncertainties raises a concern about the possibility of long-term environmental effects that cannot easily be predicted. Although further information is necessary to help clarify the concern, the inherent difficulties and time required to complete the work mean that there may be a need at a policy level to consider precautionary risk reduction action for this endpoint.

Overall results of the risk assessment

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

This conclusion applies to the risk of secondary poisoning from all sources of decabromodiphenyl ether. The current PEC/PNEC approach indicates that there is no risk of secondary poisoning. The PEC/PNEC ratios are much less than 1 (in fact below 10^{-5}) for the commercial decabromodiphenyl ether product. It is possible that the current PEC/PNEC approach for secondary poisoning may not be appropriate in terms of both the PEC and the PNEC, and could underestimate the risk. This issue needs further investigation.

Two possible areas for further work are as follows:

a) A more widespread monitoring project to determine whether the finding in top predators (including birds' eggs) is a widespread or localised phenomenon, and trends (if possible).

b) Further toxicity testing. The existence of a mammalian toxicity data set means that testing could be considered on birds (e.g. an avian reproduction test (OECD 206), with appropriate tissue analysis). Overall, the benefit of further vertebrate testing is open to question due to expected difficulties in achieving sufficiently high exposures. This leaves the toxicity issue with some unresolved uncertainty.

A second aspect of the concern for secondary poisoning is that although the substance is persistent, there is evidence that it can degrade under some conditions to more toxic and bioaccumulative compounds. The current database is inconclusive on this point, and further work could be done as follows:

c) An investigation of the rate of formation of degradation products under environmentally relevant conditions over a suitably prolonged time period (e.g. years) - for example, an extended monitoring programme to determine trends in degradation product levels in various environmental compartments. This could be coupled with analysis of the parent compound to detect whether it is building up in the environment or has achieved equilibrium. A controlled field study (or studies) might be the way forward, with controlled continuous input of the substance and regular monitoring of other components.

d) Further toxicological work on the non-diphenyl ether degradation products, to determine if they pose a hazard or risk.

There is a high level of uncertainty associated with the suitability of the current risk assessment approach for secondary poisoning and the debromination issue. The combination of uncertainties raises a concern about the possibility of long-term environmental effects that cannot easily be predicted. It is not possible to say whether or not on a scientific basis there is a current or future risk to the environment. However, given the persistent nature of the substance, it would be of concern if, once the further information had been gathered, the analysis indicated a risk to predators, since it could then be difficult to reduce exposure. In summary, although it is concluded that further information should be gathered in order to refine the risk assessment, in light of:

- the persistence of the substance,
- the time it would take to gather the information and
- the fact that there is no guarantee that the studies would provide unequivocal answers,

consideration should be given at a policy level to the need to investigate risk management options now in the absence of adequate scientific knowledge.

[N.B. A number of technical experts from EU member states consider that this uncertainty is sufficient to warrant risk reduction measures directly (conclusion (iii)) based on the information currently provided in this assessment.]

The possible long-term increase in levels as a result of releases from waste sites might need to be considered further in any future revision of this risk assessment report.

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 applies to the environmental assessment of risks to the aquatic (surface water, sediment and waste water treatment plants), terrestrial and atmospheric compartments by the conventional PEC/PNEC approach for decabromodiphenyl ether itself from all sources.

5.3 HUMAN HEALTH

5.3.1 Human health (toxicity)

Chronic toxicity and liver neoplastic nodules observed in a carcinogenicity study are considered to be the critical endpoints in the risk assessment.

Workers

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.

Consumers

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.

Humans exposed via the environment

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.

5.3.2 Human health (risks from physico-chemical properties)

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.

Results of discussion at the policy level

Following the agreement of the risk assessment conclusions reached on a technical basis as presented in this report, Member States noted the uncertainties expressed regarding the risk characterisation for secondary poisoning. They also noted the conclusion that further information would be required to remove these uncertainties and refine the risk assessment. Member States were concerned that it would take a significant time to gather the information and that the resulting refined risk assessment could then indicate a risk to predators. Furthermore, increasing levels in the environment and the possible formation of more bioaccumulative and toxic compounds via degradation could occur while the data were being gathered. Consequently Member States agreed that emission reduction measures should be considered without delay for the sources of this exposure. In the light of this agreement, a risk reduction strategy for this substance will be developed in parallel to the performance of the proposed testing listed under the conclusion (i). Depending on the strategy adopted, the further testing might have to be adjourned in the interests of animal welfare and cost versus benefit unless expert advice is provided which indicates that tests may be relevant to the control measures which emerge.