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Environmental risk evaluation report: 1,1'-(Ethane-1,2-diyl)bis[penta-bromobenzene]

CAS: 84852-53-9

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Steve Killeen

Head of Science

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Executive summary

Flame retardants are widely used to protect materials and products from catching fire. 1,1'-(Ethane-1,2-diyl)bis[pentabromobenzene] (EBP) is a brominated flame retardant. Its main applications in Europe are as an additive in a wide variety of polymers, and in coatings for fire-resistant fabrics. EBP is not manufactured in Europe, but it is imported in large quantities (more than 1,000 tonnes/year in total) from two known suppliers.

This assessment is the first detailed environmental risk assessment for EBP in the public domain. It adheres to the format of risk assessments set out by the Existing Substances Regulation.

No specific information is available about either direct releases of EBP from industrial applications or indirect releases from treated articles in service and at disposal. This assessment is therefore based on generic industry information and a number of assumptions. Overall, environmental releases are expected to be highest from textile backcoating applications because these are wet processes. Diffuse emissions from treated articles over their lifetime will undoubtedly occur, but are very difficult to quantify. The assessment takes account of these releases using a number of assumptions, but the releases are relatively small compared to the predicted local releases from industrial sites.

EBP is not readily biodegradable, and so it is assumed to be relatively persistent in the environment. It is poorly water soluble, and is expected to adsorb strongly to organic matter in sediment, sewage sludges and soil. The actual extent of both adsorption and other environmental partitioning behaviour (particularly bioaccumulation) is unclear in the absence of reliable data.

EBP is difficult to test in water due to its very low solubility, but appears to have a relatively low hazard potential. No effects have been observed in short-term aquatic toxicity tests on fish, *Daphnia* and algae, or two species of sediment-dwelling organism following long-term exposures. Relatively high concentrations of EBP in soil have produced some toxicity in some plants and earthworms. The substance is of low toxicity to mammals.

Long-term toxicity data for pelagic aquatic organisms and also for wastewater treatment plant (WWTP) micro-organisms are unavailable, but EBP is unlikely to pose any risks for surface water or WWTPs at any point in the substance's life cycle.

In the UK, EBP is currently used only in polymer processing. This application (combined with releases from EBP-treated articles) poses no direct environmental risks (including for humans exposed via the environment), based on a worst case scenario that may overestimate releases for the majority of industrial sites.

EBP is used in textile backcoatings in continental Europe. If such treatments were to occur in the UK, the local releases of the substance could be significantly higher from this activity than from polymer processing, even though the volume of use is much smaller. A tentative risk is identified for sediment and soil organisms from the formulation and application of textile backcoatings. Nevertheless, these findings should be viewed with caution, not least because tests showed no significant toxic effects and the emission scenarios are conservative.

Overall, the risks arising from direct toxic effects of EBP are low, especially in a UK context.

There are, however, concerns over bioaccumulation potential and the potential products of degradation processes that require further investigation. First, further studies on uptake and accumulation in wildlife are needed (preceded by a more reliable K_{ow} value, if possible). Second, the identity, properties and the rate of formation of EBP's principal metabolites and degradation products should be established, and their environmental impact assessed.

Both current European suppliers have made product stewardship commitments to reduce point source releases of EBP from downstream users, and one has responded to the conclusions of this assessment by commissioning more studies.

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Preface

Flame retardants are widely used to protect materials and products from fire. The Environment Agency has published a report on these substances (EA, 2003), which highlighted 1,2-bis(pentabromophenyl) ethane (also known as 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene] or EBP) as a candidate for priority review on the basis of its high supply tonnage.

EBP has the potential for widespread use in the United Kingdom (UK), not least because it is marketed as an alternative to decabromodiphenyl ether (decaBDE) in a number of applications (see Section 2). There are no detailed risk assessment reviews for EBP in the public domain. Consequently, the UK Government is working to provide more information on its potential risks to the environment and to human health following environmental exposure. The substance was included in the UK Co-ordinated Chemicals Risk Management Programme in July 2005.

The purpose of this report is to identify the properties that might lead to environmental or human health concerns. It also investigates the points in the substance's life cycle where risks might be occurring, although the report does not address human health risks following exposure of either consumers or workers. The data collection and peer review processes are described in Appendix 5.

This assessment is based on data provided voluntarily by industry. In general, information on specific UK uses and process releases was not available. However, given the nature of the open market, we have assumed that any use of the substance reported in Europe also takes place in the UK, unless there is reliable information to show that this is clearly not the case (e.g. if only a small number of locations are known to use a particular process). Similarly, estimates of EBP releases based on European sources are assumed to be applicable in the UK.

Risk assessments generally use data from tests conducted on the substance itself. However, in the case of EBP, there is significant uncertainty in the actual numerical value of some important parameters. In such instances, this report considers data from laboratory tests on analogue substances and from predictive modelling, aiming to establish a weight of evidence for selecting an appropriate value.

The layout of this report follows the format (with a few small modifications) of a risk assessment carried out under Council Regulation (EEC) 793/93, known as the Existing Substances Regulation (ESR). Readers familiar with such assessments should be able to quickly find the information they are seeking.

Note: Despite the best efforts of the consulted companies and the Environment Agency, the exposure assessment relies on a number of assumptions and so might not be wholly realistic. It is also possible that some other uses of EBP exist that are not known to the Environment Agency or the main suppliers of the substance. The report draws its conclusions based on current knowledge, but the information it contains should be read with care to avoid possible misinterpretations or misuse of the findings. Anyone wishing to cite or quote this report should contact the Environment Agency beforehand.

1 General substance information

The public version (2000 edition) of the International Uniform Chemical Information Database (IUCLID[1]) contains no data on EBP. The following information has been compiled from industry product literature and Internet searches, as well as an IUCLID file provided by Albemarle (2005).

1.1 Identification of the substance

CAS number 84852-53-9

EINECS number 284-366-9

IUPAC name 1,2-Bis(pentabromophenyl) ethane

EINECS name 1,1'-(Ethane-1,2-diyl)bis[pentabromobenzene]

Molecular formula C14 H4 Br10

Molecular weight 971.23 g/mole

Structural formula (C6Br5)CH2CH2(C6Br5)

SMILES code C(c(c(c(c(c1Br)Br)Br)c1Br)Cc(c(c(c(c2Br)Br)Br)Br)c2Br

Combined nomenclature (CN) code ex 2903 69 90 (used for EU customs purposes)

Synonyms
Ethane 1,2-bis(pentabromophenyl) [EBP]
1,1'-(1,2-Ethanediyl)bis[2,3,4,5,6-pentabromobenzene]
Benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo-]
Ethylene bis(pentabromophenyl) [also EBP]
Decabromodiphenyl ethane
Firemaster® 2100
Saytex® 8010
Planelon BDE
S8010

The name tenbromo disphenol ethane (*sic*) (TDE) is also used on some Asian (particularly Chinese) suppliers' websites. Older test reports provided by Albemarle Corporation also use the trade name Saytex 402, although this is now obsolete.

[1] IUCLID contains unvalidated tonnage, use pattern, property and hazard information for industrial and consumer chemicals, submitted by industry under the Existing Substances Regulation, EC no. 793/93. The public version is available from the European Chemicals Bureau website, http://ecb.jrc.it/. A confidential version is available to regulatory authorities. A file is available for this substance in the confidential IUCLID, but it only contains outdated tonnage information and a brief statement about use.

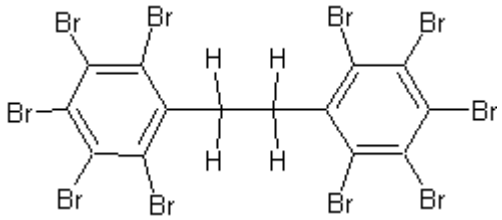

Figure 1.1 Structure of EBP

1.1.1 Structural analogues

Although data on the chemical and physical properties of EBP are best taken from laboratory tests on the substance itself, where there is some uncertainty in a particular result – or where there are no data at all – it can sometimes be useful to consider measurements obtained for similar chemicals. In this context, substances with two linked aromatic rings are more relevant than substances that have a single benzene ring.

Unlike the polybromodiphenyl ethers (PBDEs), there is no family of commercially available congeneric brominated diphenyl ethane products in this case.

There are three related substances, listed in Table 1.1, that are logged in the European Chemical Substances Information System (ESIS), which is part of the European Chemicals Bureau website.

Table 1.1 Structurally similar 'existing' substances

EINECS name	EINECS no.	CAS no.	Supply level
Decabromodiphenyl ether	214-604-9	1163-19-5	HPVC
1,1'-[Ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]	253-692-3	37853-59-1	LPVC
1,1'-[Ethane-1,2-diylbisoxy]bis[pentabromobenzene]	262-680-7	61262-53-1	Neither HPVC nor LPVC

HPVC: high production volume chemical (supplied at 1,000+ tonnes/year at least once by a company in 1990-4)
LPVC: low production volume chemical (supplied at 10+ tonnes/year at least once by a company in 1990-4)

Decabromodiphenyl ether (decaBDE) has been extensively reviewed under the ESR (EC, 2002; ECB, 2004; and EA, 2007). It has an oxygen atom between the two aromatic rings rather than an ethane bridge. This structural difference means that EBP has greater molecular flexibility but lower polarity.

The two other substances have an oxygen atom between the ethane bridge and the aromatic rings. A safety data sheet is available for 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (Chemtura, 2006), but a detailed review has not been located. Since both of these substances appear to be of low commercial importance, they are not considered further in this assessment in any detail (no data searches have been performed).

1.2 Purity/impurities, additives

1.2.1 Purity/impurities

Spectra and original study reports have not been reviewed.

EBP is a relatively pure substance. Albemarle (2005) states that the commercial substance has a typical purity of ≥98.5% w/w. However, in discussions with the Environment Agency, Albemarle confirmed that current production batches are typically 97% w/w pure, with the remainder consisting largely of nonabromodiphenyl ethane congeners. “Over-brominated” species (where bromine atoms are present on the ethane bridge) are present as very minor impurities. These impurity levels are consistent with the composition given in some older study reports.

Kierkegaard *et al*. (2004) also tentatively identified traces of octabromodiphenyl ethane congeners in standard solutions of the commercial product.

Ranken *et al*. (1994) summarise an analysis of a pilot plant sample for seven polybrominated dibenzodioxins and furans. None were detected (the limit of detection varied from 0.01 to 0.49 ppb, depending on the congener).

1.2.2 Additives

There are no reported additives used to stabilise the substance. Great Lakes (2003) reports no particular stability concerns.

1.3 Physico-chemical properties

The following section provides a summary of the chemical and physical properties of the substance. Apart from the key studies, no test reports have been reviewed. The information is taken from product technical information datasheets and safety data sheets unless otherwise indicated. Robust study summaries are available for some of the data in Albemarle (2005).

Data from predictive models and analogue substances are given where there are doubts about the reliability in the values of key properties as measured directly on EBP.

1.3.1 Physical state (at n.t.p.)

The substance is described as an odourless white or off-white powder (Albemarle, 2001; Great Lakes, 2003).

1.3.2 Melting point

Melting point ranges of 348-353°C and 351-355°C (no methods given) are cited by Great Lakes (undated & 2003 respectively).

Albemarle (2001) cites an initial melting point of 350°C (measured by differential scanning calorimetry). Albemarle (2005) gives a melting point of 345°C (no method quoted). These

values are from non-GLP, non-guideline studies on the commercial product (Albemarle, personal communication).

Some of the estimation models in this assessment require a melting point input parameter. Given the range of measurements above, the lowest value of 345°C will be used in these models.

1.3.3 Boiling point

This property is irrelevant to this assessment given the high melting temperature. The substance would probably degrade before boiling occurs.

1.3.4 Relative density

No information is available on relative density, although there is no practical consequence for this assessment.

The bulk density at 25°C is 0.711 g/mL (loose) or 1.111 g/mL (packed) (no method given) according to Great Lakes (undated). Albemarle (2001) cites a specific gravity of 3.25 and a bulk density of 0.868 g/mL (aerated) or 1.760 g/mL (packed) using the Hosokawa powder tester method.

1.3.5 Vapour pressure

Vapour pressure is an important parameter, since it helps to establish the extent to which a substance moves between air and other media (such as water).

Measured data

The vapour pressure of the commercial product has been measured as <1 x 10^{-4} Pa at 20°C using OECD guideline 104 (spinning rotor gauge method) in accordance with GLP (Van Hoven *et al.*, 2002). The measured value for EBP was the same as the mean background vapour pressure of the blank tube. Hexachlorobenzene was used as the reference material; its mean measured vapour pressure was 1.48 x 10^{-3} Pa, which compares favourably with published values. A copy of the study report was provided for this review, and the test is valid.

Predicted data

Using the chemical structure of EBP, the MPBPWIN v1.41 model (modified Grain method) (US EPA, 2000)[2] calculates a vapour pressure of 2.5 x 10^{-11} Pa at 25°C. An even lower value is produced if the approximate melting point of 345°C is included in the input parameters. The SPARC[3] model also predicts a very low vapour pressure of 5.4 x 10^{-17} Pa at 25°C, with the SMILES code as the input.

The validity of these predictions is unclear. Boethling and Mackay (2000) indicate that for estimated vapour pressures in the range 1 - 10^{-4} Pa the error is up to 99%.

[2] There is a more recent version of this software, but the Environment Agency understands that the differences are minor.

[3] http://ibmlc2.chem.uga.edu/sparc/

Data from structural analogues

DecaBDE has a melting point of around 300-310^{o}C and a vapour pressure of 4.63 $\times$ 10^{-6} Pa at 21^{o}C (EC, 2002). Since EBP has a higher melting temperature, it would be logical to expect its vapour pressure to be lower.

Selected value

It is very difficult to accurately measure the vapour pressure of a substance that is essentially involatile. Direct testing of EBP has only provided a limit value. Both predicted values and structural analogue data suggest that the vapour pressure will be substantially lower.

A vapour pressure of ~1 x 10^{-6} Pa at 25°C will be assumed for this assessment, implying that the substance is of low volatility. However, the vapour pressure could be even lower, and the impact of using a lower value is considered in Appendix 1.

1.3.6 Water solubility

Measured data

A water solubility of approximately 0.00072 mg/L (0.72 µg/L) has been measured at 25°C on the commercial product using a column elution method (OPPTS 830.7860) in accordance with GLP (Van Hoven *et al.*, 1999a). A copy of the study report was provided for this review is considered valid with restrictions by the Environment Agency because:

- In this test the dry substance was mixed with the solid support for 30 minutes, rather than applied in a solvent. It is therefore possible that the surface area available for contact with the water phase was not as high as it could have been.
- The saturated concentration measured in the samples was between the limits of detection and quantitation of the analytical method.
- Albemarle (2005) suggests that EBP is highly adsorbing to glass surfaces.

Given these qualifications, the measured value of water solubility is compared with data from other sources.

Predicted data

Several QSAR estimates have been performed using three software tools (VCCLabs ALOGPS V.2.1[4], SPARC[5] and WSKOW v1.41/WATERNT v1.01 (US EPA, 2000)[6]) with the SMILES code as the input. The results are presented in Table 1.2.

Table 1.2 Predicted water solubility values (S) for EBP

Model	Predicted log S	Units	Basis
ALOGpS	-7.66	µg/L	Based on K_{ow} of 'similar' molecules
IA_logS	-7.53	µg/L	Neural network based on molecular indices
AB/LogS	-10.65	ng/L	Estimated from 5 chlorinated aromatics
QLogS	-14.39	ng/L	Molecular fragments
WSKOW	-11.96	mg/L	Molecular fragments
WATERNT	-6.01	mg/L	Molecular fragments
SPARC	-20.56	Mole fraction	Not clear – 'fundamental chemical structure theory'

These values are all substantially lower than the measured value. It is not clear whether EBP fits within the prediction domain of the models.

Data from structural analogues

DecaBDE has a water solubility below 0.1 µg/L at 25°C (EC, 2002). This is a maximum value since the substance could not be detected in the water phase (the stated detection limit was 0.1 µg/L). EBP has less scope for hydrogen bonding than decaBDE, so its solubility should also be lower.

A water solubility of ~0.01 µg/L has been reported for decachlorobiphenyl (Mackay *et al.*, 2006).

Selected value

The substance has a very low water solubility that is difficult to measure experimentally. **The measured value of 0.72 µg/L has been used in this assessment**, although there is evidence from predictive models and analogues that the true value could be much lower.

1.3.7 n-Octanol–water partition coefficient

The octanol-water partition coefficient (K_{ow}) is a measure of the hydrophobicity of a chemical. It is used to predict environmental partitioning behaviour as well as aquatic toxicity.

[4] http://146.107.217.178/lab/alogps/start.html

[5] http://ibmlc2.chem.uga.edu/sparc/

[6] There is a more recent version of this software, but the Environment Agency understands that the differences are minor.

Measured data

A K_{ow} value has been measured for commercial EBP at 25°C using a column elution method (OPPTS 830.7560) in accordance with GLP (Van Hoven *et al*, 1999b). A copy of the study report was provided for this review. A generator column was prepared by loading an inert support material with ten millilitres of a saturated solution of the substance in n-octanol (which was prepared by mixing and sonication for 10 minutes, followed by centrifugation of the supernatant, then a final filtration through a 0.2 micron filter). Aqueous solutions of the test compound were produced by pumping water through the generator column. The aqueous solution leaving the column represented the equilibrium concentration of the test chemical that had partitioned from the n-octanol phase into the water phase. A log K_{ow} value of 3.55 was estimated by dividing the concentration of the substance in the n-octanol stock solution by the concentration measured in n-octanol-saturated water samples eluted from the column. This latter concentration (0.544 µg/L) was the mean of three measurements, all of which were below the limit of quantitation of 0.8 µg/L and above the limit of detection of 0.415 µg/L). Given this analytical uncertainty, the K_{ow} value was reported as an estimate.

This test method is reportedly suitable for substances that have very low solubility in both water and organic solvents; it has been used in the same laboratory to determine the K_{ow} values for several other important brominated flame retardants including decaBDE (Albemarle, personal communication). The Environment Agency agrees that the method was suitable in principle, but considers the result to be unreliable for a substance that contains many bromine atoms. Given that the concentration in the water phase was very close to the measured water solubility (i.e. at or close to saturation), a higher stock solution concentration could have led to a higher K_{ow} value using this technique.[7]

Predicted data

Several QSAR estimates have been performed using three software tools (VCCLabs ALOGPS V.2.1[8], SPARC[9] and CLOGP (the latter result provided by Albemarle as a personal communication) with the SMILES code as the input. The results are presented in Table 1.3.

All of the predicted log K_{ow} values are at least 4 orders of magnitude higher than the measured value. The highest values are generally based on molecular fragment methods, and are likely to be outside the model domains (e.g. the KOWWIN v1.67 model (US EPA, 2000) gives good estimates of log K_{ow} in the range 0 - 5 (TGD, 2003)). TGD (2003) also points out that predicted log K_{ow} values above 10 are only relevant in qualitative terms (it is currently not possible to measure a log K_{ow} above about 8.2).

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[7] This method might also underestimate the K_{ow} if the column flow rate is too fast, as microdroplets of n-octanol may be washed from the column. However, the data provider states that the laboratory took steps to avoid this problem.

[8] http://146.107.217.178/lab/alogps/start.html

[9] http://ibmlc2.chem.uga.edu/sparc/

Table 1.3 Predicted K_{ow} values for EBP

Model	Predicted log K_{ow}	Basis
QlogP	-	Not checked: software returned correlation coefficient (-0.84) instead of a K_{ow} value
ALOGPs	7.86	Based on K_{ow} of 'similar' molecules
IA_logP	8.71	Neural network based on molecular indices
AB/LogP	>10	From 4 chlorinated aromatics (including a hexachlorobiphenyl) with log K_{ow} in the range 7.1-7.54
MiLogP	10.36	Molecular fragments
CLOGP	11.37	Molecular fragments
COSMOFrag	11.39	Molecular fragments
XLOGP	11.93	Molecular fragments
KOWWIN	13.64	Molecular fragments
SPARC	14	'Fundamental chemical structure theory' (presumably molecular fragments)

A more reliable estimate of the log K_{ow} may be obtained using the measured water solubility of ~0.72 µg/L. For example, a log K_{ow} of around 7.2 can be estimated using the following equation from the WSKOW program within EPIWIN (US EPA, 2000):

$$\log S = 0.693 - 0.96 \log K_{ow} - 0.0092 (MP - 25)$$

where S = solubility in moles/L (7.41×10^{-10}); MP = melting point in °C (345)

If the 'true' solubility were lower then the estimated K_{ow} would increase accordingly (the melting point makes a small contribution to the overall estimate, so changes to that value do not make much difference).

Data from structural analogues

DecaBDE has measured log K_{ow} values spanning the range 6.27 (using the same generator column method as EBP) to 9.7 (based on a relationship between log K_{ow} and reverse-phase HPLC retention time) (EC, 2002; ECB, 2004). A log K_{ow} of 12.11 was calculated from the chemical structure using the KOWWIN v1.67 model (US EPA, 2000), demonstrating that this model is not a good predictor for this type of structure. Since EBP is less polar than decaBDE, it is unlikely to have a significantly lower K_{ow} value.

A measured log K_{ow} value of 6.07 is available for hexabromobenzene (SRC PhysProp, http://www.syrres.com/esc/physprop.htm). Since EBP has the same basic structure, but with one bromine atom substituted with the much larger pentabromophenyl ethane moiety, it is expected to have a higher log K_{ow}.

According to Chemtura (2006) the related substance 1,1'-[ethane-1,2-diylbisoxy]-bis[2,4,6-tribromobenzene] (CAS no. 37853-59-1) has a log K_{ow} value of ~3.3. The reliability of this result is unknown, and there are few other physico-chemical property data available for this substance for comparison. Since EBP contains more bromine atoms, it would be expected to be more hydrophobic.

Selected value

From the molecular structure it can be assumed that EBP will be a very hydrophobic compound. There are technical challenges in measuring an accurate K_{ow} for this type of substance. Although a suitable technique was used, the measured value is considered unreliable[10]. The evidence from the analogue compounds and QSAR predictions suggests that the **log K_{ow} is significantly higher than 3.55 (i.e. in the region of 7 – 8 or more)**. Given the spread of possible values, it is not considered appropriate to prefer one over another. Instead, a more reliable measurement is needed. The use of K_{ow} to estimate other properties is considered further in the relevant sections on the environmental fate and behaviour of EBP (Section 3.2) and Appendix 1.

1.3.8 Hazardous physico-chemical properties

Hazardous physico-chemical properties are relevant to this assessment from the point of view of laboratory hazards that might limit testing options, and possible controls that might be required for process equipment (e.g. to exclude air if a substance is pyrophoric).

Since the substance is used as a flame retardant (see Section 2), it is not expected to be flammable. Great Lakes (2003) states that the substance is not flammable, but is combustible if exposed to an external flame.

The chemical structure of this compound does not suggest that explosive or oxidising properties are likely.

1.3.9 Other relevant physico-chemical properties

Particle size

Little information is available on particle size distribution. Albemarle (2001) simply cites an average particle size of 5.6 micrometers, without stating the method.

pKa

Since the substance has no ionisable groups, a pKa value is not relevant.

Solubility in other solvents

Albemarle (2005) reports that the solubility in organic solvents (acetone, methanol, toluene, chlorobenzene and dimethyl formamide) is below 0.01 weight per cent (<100 mg/L) at 25°C. No method is quoted. Great Lakes (undated) reports the same limit value for some of these solvents, as well as methylene chloride, hexane and methyl ethyl ketone at 20°C (again no method is quoted).
In addition, a concentration of 1.9 mg/L has been measured in an n-octanol solution as part of another study, although this is not a definitive value for the n-octanol solubility (see Section 1.3.7).

[10] The data provider disagrees with this analysis, and considers the measured result to be valid without restriction.

^{14}C-EBP was found to be insoluble in any solvent compatible with an intravenous administration route (MRI, 2004; the study is summarised in Section 4.4.1.1.1).

1.3.10 Summary of physico-chemical properties

A summary of the physico-chemical data used for the risk assessment is given in Table 1.4. Data for which the Environment Agency has reviewed test reports for reliability are indicated with an asterisk.

Table 1.4 Physico-chemical properties

Property	Value used for the risk assessment
Physical state at n.t.p.	Powder
Molecular weight	971.23 g/mol
Melting point	~345ºC
Vapour Pressure*	~1 x 10^{-6} Pa at 25ºC
Water solubility*	~0.72 µg/L at 25ºC
n-Octanol-water partition coefficient, log K_{ow}*	~7-10 at 25ºC, though use with caution
Particle size	5.6 µm (average)

* Full study report reviewed.

These properties make the substance difficult to test in aquatic systems and to model (e.g. the EUSES program (see Section 3) advises a minimum water solubility value of 1 µg/L).

2 General information on exposure

2.1 Production and supply volumes

EBP was reportedly introduced to the market in the mid-1980s (UBA, 2001). However, the principal European supplier has indicated that EBP only became commercially important during the early 1990s (Albemarle, personal communication).

There is currently no known European production facility for EBP. Two companies – Albemarle Corporation and Chemtura Corporation (until recently Great Lakes Chemical Corporation) – manufacture it in the United States. Only Albemarle is recorded on the ESIS database as an importer into the EU. The same source indicates that the substance is supplied below 1,000 tonnes/year. However, this figure reflects sales in the early-to-mid 1990s; European sales have more recently been estimated at around 2,500 tonnes/year (UBA, 2001).

Previous consultation for the Environment Agency's flame retardant review (EA, 2003) suggested a trend of increasing consumption of EBP in Europe. The information gathered for this assessment confirms that:

- both Albemarle and Chemtura sell the substance in the EU;
- the substance is supplied above 1,000 tonnes/year in the EU;
- sales during 2001-2004 have increased since the previous estimate by UBA (2001).

Actual sales figures have been kept confidential due to the small number of suppliers involved, although further details are available in a confidential annex to this report. The total amount of EBP used in the UK is below 1,000 tonnes/year.

An Internet search shows that several companies in Asia (particularly China) also offer EBP for sale, but the scale of any direct imports from these sources into the EU is not known. The same applies to the scale of imports of the substance in semi-finished and finished articles (e.g. computer casings, textiles, etc.) or within a "master batch" (i.e. compounded plastic pellets that are ready for further processing, such as extrusion, and that already contain EBP as a flame retardant additive).

There is no known natural source of EBP.

2.2 Uses

2.2.1 General information on uses

EBP is advertised by the suppliers as a general-purpose (additive) flame retardant for a variety of polymer applications and for textiles. It is used together with antimony trioxide as a synergist in the ratio 2:1 to 3:1 (UBA, 2001). It is not sold directly to the general public. The total number of industrial user sites is not known.

The applications of EBP are very similar to those of decaBDE (Albemarle, personal communication). In the absence of specific information to the contrary, it is assumed that the uses are the same for the purposes of this assessment. Some additional information for decaBDE is therefore summarised in the following sections, based on the published risk assessment reports for decaBDE.

2.2.2 Polymer applications

Consultation for this report indicates that the major use of EBP in Europe and the UK (accounting for at least 90% of the tonnage supplied) is as an additive flame retardant for polymers. Key performance features highlighted in the technical product literature include:

- high flame retardant efficiency, improving cost and physical properties;
- excellent colour and good UV stability, giving better in-service performance and good initial colour/low yellowness index;
- high thermal stability;
- reduced tendency to bloom, giving less plate-out/better plastic appearance.

EBP's properties make it suitable for applications involving high temperature, a requirement for colour stability or where recycling is anticipated. An additional benefit claimed by Albemarle is that the substance can be used in the formulation of products to meet European dioxin laws (see Appendix 2). EBP is also advertised as a good cost and performance alternative to decaBDE[11].

The substance can be used with a variety of polymers, including (Great Lakes, undated & 2002):

- acrylonitrile-butadiene-styrene (ABS);
- high impact polystyrene (HIPS);
- polypropylene and polyethylene;
- polycarbonate;
- polybutylene terephthalate and polyethylene terephthalate;
- PVC;
- thermoplastic elastomers;

[11] EBP is not used to replace penta- or octabromodiphenyl ether, both of which were banned from use in the EU in 2004. It is also noted that other substances and polymer systems can be used as substitutes for decaBDE applications (Albemarle, personal communication).

- epoxy resins;
- unsaturated polyesters.

EBP can also be used in polyamide (Albemarle, undated-a).

A summary of applications is given in Table 2.1. It has not been possible to obtain a breakdown of the amounts of EBP used in each application.

Table 2.1 Applications advertised for EBP by Great Lakes (Chemtura) in 2005[12]

Key applications	Basic description
Adhesives	Adhesives can contribute significantly to the flammability of a substrate or composite. Adhesives may also be the optimum components in which to add a flame retardant because the composite's overall physical properties will not be compromised. Sealant use has also been mentioned (Great Lakes, undated).
Building insulation and Roofing materials	For energy conservation, etc.
Cable	Including: • appliance cables used in the internal wiring of equipment and machines, as well as any external connecting cables and power cords; • building cable, including data/communication cable, providing low voltage power distribution within a building; • plenum-rated cable (i.e. power or data cable that can be used within spaces that are also used for carrying environmental air supplies, which has very stringent flame spread and smoke production requirements); • plastic conduit used to carry and protect cables within an installation; • power cable used in heavy machines, feeders, and branch circuits found in industrial, commercial, and electric utility applications (designed for high voltages).
Coatings	Polymeric coatings are used for a variety of substrates to improve aesthetics, protect surfaces, and improve physical properties.
Electronic components	Including: • connectors, relays and switches; • consumer electronics (e.g. TV cabinet backs, etc.)
Transportation	Plastics are increasingly used to reduce manufacturing costs and weight. Flame retardant additives are used for applications where prolonged heat exposure or flammability is a concern, e.g. for electrical components, cable insulation and upholstery textiles.

Albemarle (2001 & 2005) provides very similar information, with an emphasis on electrical and electronic applications (particularly those made from HIPS (such as television cabinet backs), other styrenic resins or thermoplastic polyolefins) and wire and cable insulation.

Typical loading rates are not provided in the product literature, but are expected to be similar to decaBDE, i.e. 10-15% by weight (EC, 2002). Albemarle (undated-b) states that the

[12] http://www.e1.greatlakes.com/fr/products/jsp/firemaster_2100.jsp

recommended loading of EBP required in HIPS to achieve the highest UL-94[13] rating (V-0) is 12% w/w (the same as for decaBDE). A loading rate of 8-9% can achieve the V-2 rating. This source also provides information on UV stability of treated HIPS, stating that the level of performance should be able to respond to the needs of a significant market segment in the office automation/business electronics market. However, the substance is reported as being unsuitable for HIPS applications that require the most stringent standards of UV stability.

EBP has also been detected in a water pipe insulating tube consisting of two different types of plastics (an inner insulating layer and an outer protective layer) (Kierkegaard *et al*., 2004).

2.2.3 Textile applications

EBP is an additive flame retardant for textiles used for furniture and furnishings (Great Lakes, 2002; Albemarle, 2005). The quantities are relatively low compared to polymer applications (further details are provided in the confidential annex).

No information is available about specific applications, but they are likely to be similar to those for decaBDE (i.e. latex-based backcoatings for drapery and upholstery fabric[14]), and the following details relate to that substance (EC, 2002).

Textile companies that handle flame retardants include:

- compounders (formulators or 'dispersers'), who mix and then supply the flame retardant formulation to users;
- finishers, who apply the flame retardant coating to the fabric;
- self-compounders, who both mix their own flame retardant formulation and apply it to the fabric.

There were around 8 UK companies involved in compounding or self-compounding in the 1990s. Around 10 contract coaters bought in textiles and applied flame retardant treatments as required. In addition, there were two known in-house weaver/coaters operating in the UK.

In a typical compounding (formulation) process, antimony trioxide and the brominated flame retardant are pre-mixed as a dispersion in water. The dispersion contains around 70% solids and is made up in batches, a batch being prepared typically every other day. Large tanks store the dispersion which is piped directly into the mixing vessel to produce the final formulation. The water dispersion is added to emulsion polymers in these vessels and mixed. Once mixed, the final product is poured into smaller containers (drums, kegs, tanks, etc.), depending on customer requirements.

The flame retardant formulations are applied to fabrics by backcoating. In this process, a running roll applies the formulation to the back of the textile. The textile then passes through an oven at a temperature of 130-140°C for a few seconds to drive off the water. The equipment coats around 20 linear metres/minute (most fabric in the UK is 1.4 metres in width).

[13] The ability to pass the Underwriters Laboratories' UL-94 flammability test is a very common criterion required for business and consumer electronics applications.

[14] http://www.e1.greatlakes.com/fr/markets/jsp/textiles.jsp states that in some cases the yarn used to make the fabric is flame retarded during its production (e.g. for synthetic carpets, although this is not currently a major use in Europe).

Typical loadings for various fabrics are thought to be in the range 30-80 g dry coating per square metre of fabric; the brominated flame retardant makes up around 30-40% of the dry coating weight.

2.2.4 Information from product registers

The SPIN (Substances in Preparations in Nordic Countries) database (http://www.spin2000.net/spin.html) provides data on the use of chemical substances in Norway, Sweden, Denmark and Finland. The information is derived from the Product Registries of the contributing countries. A search of the online database in October 2005 found records for EBP use in Sweden in 1999-2003, but no further details were available.

2.3 Controls recommended by suppliers

Albemarle (2005) provides the following information:

- No special storage is required. However, strong acids/bases and temperatures above 320ºC should be avoided.
- Local exhaust at the source of dust, and mechanical ventilation is recommended during handling, as well as use of standard personal protective equipment.
- Dispose according to local and national regulations.

Great Lakes (2003) provides the following information:

- The substance should be kept in cool, dry, ventilated storage and closed containers, away from heat, sparks and open flames.
- No special conditions are given for handling in the workplace (beyond good industrial practice).
- The material should be incinerated or otherwise disposed of as solid waste in accordance with local regulations.
- Empty packaging may contain product residues and due consideration should be given prior to disposal.
- If accidentally spilled or released, no material should enter drains or watercourses. The substance should be swept up immediately, placed in a marked container and disposed of in accordance with local waste disposal regulations.

2.4 Life cycle in Europe

The anticipated EU life cycle of EBP (by analogy with decaBDE) is given in Figure 2.1.

EBP is only used in polymer manufacturing in the UK. Some UK sites appear to have trialled the use of EBP in textile applications in recent years, but this no longer takes place (further details are provided in the confidential annex). EBP is used in textile applications where there is pressure to replace decaBDE (largely in Germany, where a voluntary industry agreement in place) (TFA, 2006). However, the market has a potential to grow as countries consider introducing legislation for furniture fabrics, and if market conditions for other brominated flame retardants (e.g. decaBDE) were to change in future.

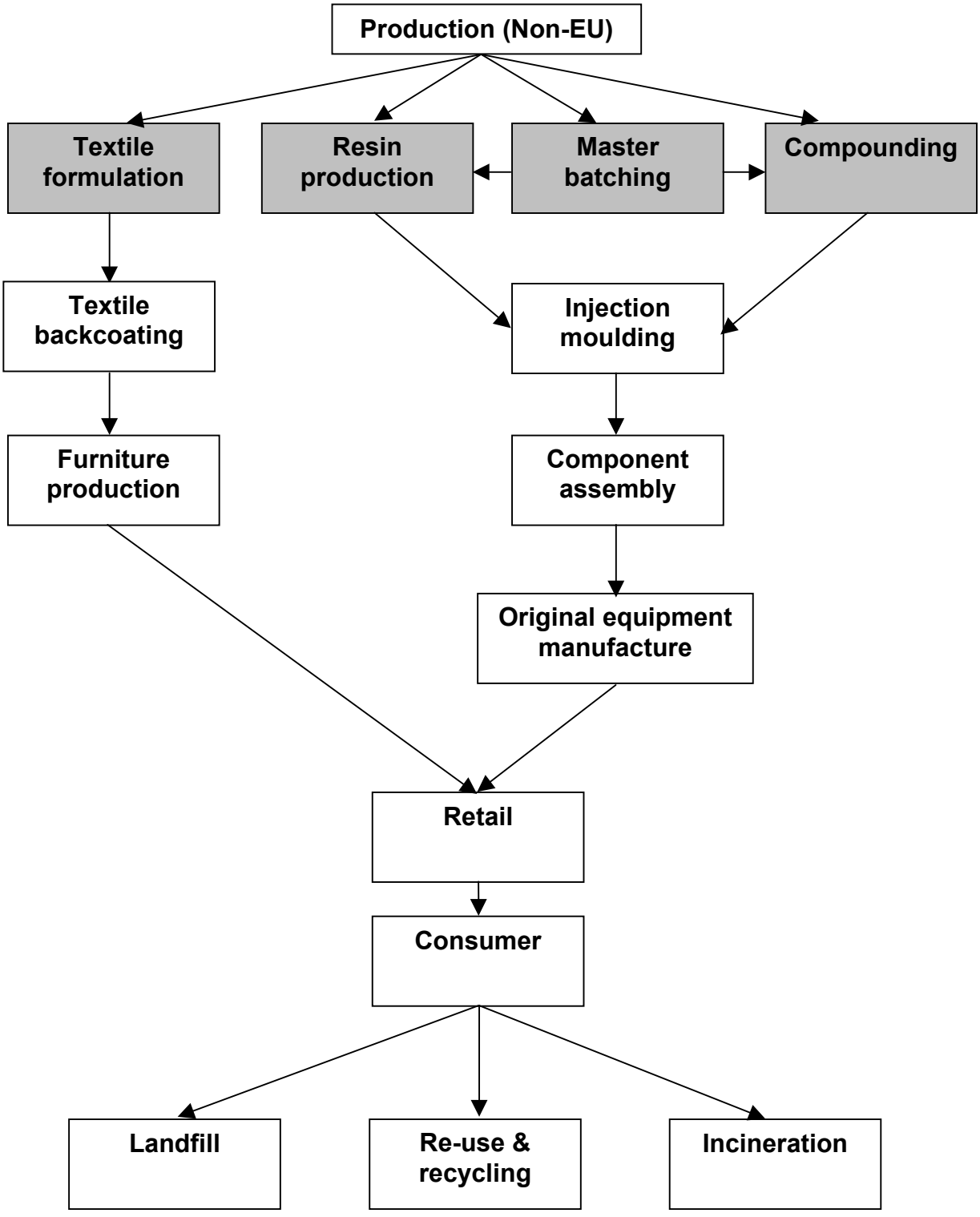

Figure 2.1 Flow chart of the principal life cycle stages of EBP in the EU

Boxes with grey shading indicate use of powder. This chart does not include every possible life cycle stage.

2.5 Regulatory initiatives

No substance-specific legislative controls currently exist. There have been a few reviews of the substance by other regulatory authorities, and there is some European legislation and an industry-led initiative that may have an indirect influence on the future use of EBP. These are summarised in the following sections.

2.5.1 European legislation

The European Directive 2002/96/EC[15] on Waste Electrical and Electronic Equipment (the 'WEEE' Directive) aims to minimise waste from obsolete electrical and electronic equipment and to reduce the disposal of such waste through reuse, recycling and other forms of recovery. The Directive seeks to improve the environmental performance of all operators in the life cycle of electrical and electronic equipment. These include producers, distributors, consumers, and in particular, those directly involved in the treatment of waste equipment.

The Directive encourages the electrical and electronic equipment manufacturers to design products that are easier to reuse and recycle. The producers must also instigate systems for the separate collection of waste electronic equipment, preferably using the best available treatment, recovery and recycling techniques. The Directive also requires plastics containing brominated flame retardants to be separated from other waste after collection.

The Integrated Pollution Control (IPC)[16] and Integrated Pollution Prevention and Control Regulations (IPPC, due to have totally replaced IPC by the end of 2007) might apply to some parts of the EBP life cycle[17]. Releases of EBP are restricted under the general principles of these regulations. In particular, all installations and mobile plant should be operated in such a way that:

- all the appropriate preventative measures are taken against pollution, in particular through application of the best available techniques;
- no significant pollution is caused.

In practice, if releases of EBP from a process falling under the IPPC regulations were sufficiently high to cause concern, then release limits would be imposed, or an improvement condition would be set requiring a reduction in releases over an agreed period of time.

2.5.2 Industry initiatives

The brominated flame retardant (BFR) industry has instigated several voluntary product stewardship initiatives. Both of the current European suppliers have added EBP to an initiative known as the Voluntary Emissions Control and Reduction Action Programme (VECAP™)[18]. This involves the issue of codes of good practice for the sustainable use of BFRs in the plastics and textile industries to encourage improved

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[15] O.J. No L 37, 13/02/2003, p. 0024-0038.

[16] Statutory Instrument 2000 No. 1973. The Pollution Prevention and Control (England and Wales) Regulations 2000 Part I (11).

[17] Plastics formulation is generally outside the scope of these Regulations, since no chemical reaction takes place. The use of certain materials (such as lead stabilisers) may bring this life cycle step within scope for some installations. Similarly, some textile formulation and processing sites might be within scope, although many are not.

[18] http://www.bsef.com/product_stew/vecap/index.php?/product_stew/vecap/vecap.php

control of emissions. The code for the plastics industry focuses on emissions during the plastics compounding stage, where handling of powders occurs. The code for the textiles industry focuses on the formulation and application of backcoatings, and identifies best industry practice for reducing and minimising emissions from these processes.

Since there are other potential suppliers of EBP, and VECAP^{TM} is a voluntary measure, it is feasible that some users of the substance might not have signed up to these codes (although there is no evidence to confirm this possibility).

2.5.3 Other regulatory activity

As of 10 November 2006 EBP does not appear on the High Production Volume Chemical lists of the International Council of Chemical Associations (ICCA), the US Environmental Protection Agency (EPA) or the Organisation for Economic Co-operation and Development (OECD). It does not appear on the OECD Exichem lists, nor was it identified in an Australian assessment of polybrominated flame retardants (NICNAS, 2001).

A recent German hazard review recommended that further studies should be performed before a conclusion could be reached on the level of risk posed by EBP (UBA, 2001). The review recommended the following studies:

- toxicokinetics;
- carcinogenic effects;
- survey of environmental contamination (e.g. in food chains, sewage sludge and also fish and sediment downstream from manufacturing and processing sites);
- analyses of residues in blood and fat tissue of workers.

Both Canada and the USA regulate EBP to control its release to the environment, and Albemarle Corporation has provided the following information (Albemarle, personal communication):

- EBP is a new chemical under the Canadian Environmental Protection Act (1999). Under this Act, controls may be placed on chemicals that are both used by new customers (e.g. those who notified after the Transitional Period) **and** suspected of being “toxic”. Environment Canada has informed Albemarle that there is a concern over potential degradation products, and the Canadian government has therefore placed controls on its environmental release by new customers. To date, only one new customer has notified Environment Canada of its use. This customer uses the product in wire and cable coatings for the telecommunications, electrical, power and automotive industries. Restrictions are consequently specified for releases and disposal, and these have been published in the Canada Gazette (2004) (the published restrictions are customer-specific). As other new customers notify Environment Canada, additional uses will be added.

- EBP is a new chemical under the US Toxic Substances Control Act (TSCA) (1976). Albemarle Corporation filed its Premanufacturing Notice (PMN) in 1989. In response to the PMN, the US EPA specified certain handling and environmental release requirements that applied to Albemarle and its customers. To extend these controls to cover all manufacture and use in the USA, the EPA issued a Significant New Use Rule (SNUR) in 1993. A copy of this was sent to the UK Government on 19 January 2001 as part of a notice of export under TSCA (US EPA, 2001). The SNUR does not indicate that the substance necessarily poses a risk, but rather that certain measures should be taken in the absence of sufficient information to make a

decision. The handling requirements include the New Chemicals Exposure Limit (NCELS) of 2 mg/m^3 (8 hour time-weighted average). The environmental controls call for no release to US waters.

3 Environmental exposure

This assessment has been prepared in accordance with the principles of Council Regulation (EEC) 793/93 (the Existing Substances Regulation or ESR)[19] and the methods laid down in Commission Regulation (EC) 1488/94[20], which is supported by a technical guidance document (TGD, 2003). The European Union System for the Evaluation of Substances (EUSES) computer program[21] (v2.0.3[22]) implements the TGD models. The EUSES output file for this assessment is confidential because of the information it contains on tonnage and use pattern.

The assessment is generic, representing a *realistic worst-case approach* for a hypothetical environment that broadly reflects average European conditions. Further details can be found in the TGD. The assessment is based on estimated sales figures for Europe. Since these figures are confidential, the calculations are presented in the confidential annex, but they are discussed qualitatively in the report as appropriate.

3.1 Environmental fate and distribution

3.1.1 Atmospheric degradation

No measured data are available. One of the main degradation processes in the troposphere is the gas-phase reaction of chemicals with the hydroxyl (OH) radical. Using EBP's chemical structure, the AOP program (v1.91) (US EPA, 2000) estimates the rate constant for this fate process as 2.4 x 10^{-12} cm^3/(molec.s). The estimated half-life for this reaction in the atmosphere is 53.6 hours (4.5 days), assuming 12 hours of daylight and 1.5 $\times$ 10^6 OH radicals/cm^3. The TGD recommends a lower hydroxyl radical concentration of 5 $\times$ 10^5 molecules/cm^3 (as a 24-hour average) than assumed in the AOP program. Using this concentration, the degradation half-life would be around 6.7 days. The reliability of these estimates for this type of chemical structure is unclear.

This reaction rate is very slow, but gas-phase reactions are unlikely to play a major role in atmospheric removal of EBP since its presence in the gas phase is likely to be low owing to its low vapour pressure and assumed high adsorption potential to particulates (see Section 3.1.5.1). The influence of particle adsorption on degradation processes is unknown for EBP, but it is likely to be protected from attack by hydroxyl radicals.

Photolysis experiments with decaBDE show that debromination may occur on exposure to UV radiation or sunlight under some conditions. This is considered further in Appendix 2.

[19] O.J. No L 084, 05/04/1993 p. 0001 – 0075.

[20] O.J. No L 161, 29/06/1994 p. 0003 – 0011.

[21] Available from the European Chemicals Bureau, http://ecb.jrc.it/.

[22] The use of the EUSES 2 model means that there are some differences in calculation compared to the original published ESR risk assessment of decabromodiphenyl ether (decaBDE). One of the main differences is that it is now assumed that 100% of the activities involving a substance take place in the region, unless there is a good reason to consider a more dispersed distribution. For one of the scenarios considered, there is insufficient information to assume a different distribution.

3.1.2 Aquatic degradation

Abiotic degradation

No data are available. The substance has no readily hydrolysable functional groups (although bromine atoms could theoretically be substituted with nucleophiles such as hydroxyl radicals in water). The water solubility is also very low (~0.72 µg/L), which would limit the amount of substance available for abiotic degradation in any case under normal environmental conditions. A hydrolysis rate constant cannot be estimated for this substance using the HYDROWIN v1.67 model (EPIWIN, 2000). Hydrolysis is therefore likely to be an insignificant removal process in the aquatic environment.

Detailed studies on decaBDE (EC, 2002; ECB, 2004) suggest that bromine atoms are quite readily removed by photolysis under certain conditions. This possibility is considered further in Appendix 2.

Biodegradation

Measured data

The biodegradability of EBP has been studied under aerobic conditions using an activated sludge inoculum in compliance with OECD test guideline 301C (modified MITI I test) and GLP (CITI, 1991a). A copy of the study report has been provided for this review. The purity of the EBP test sample was slightly lower than indicated in Section 1.2, at 96.3%. The sample (100 mg/L) was incubated with activated sludge (30 mg/L) from mixed sources from Japan at 25°C over 28 days. No emulsifier was used. No degradation was seen as measured by biological oxygen demand. The percentage biodegradation was 2% as measured by weighing. The reference substance (aniline) was degraded at the expected rate (no toxicity control check was made). The study is valid and EBP is therefore considered to be not readily biodegradable.

The MITI test is a stringent biodegradation test – a very high concentration of the test substance is exposed to a very low concentration of sludge. The low level of degradation observed in the study could therefore have been due to the poor availability of the substance to the microorganisms in the test medium (the measured solubility of EBP in pure water is only ~0.72 µg/L). There is no information about whether EBP might be inhibitory to the test organisms, although this is probably unlikely (see Section 4.1.6). These data alone are therefore insufficient to draw a firm conclusion about EBP's actual degradation potential under more environmentally realistic conditions.

Predicted data

Structure-activity relationships may also help to predict biodegradability. Inputting EBP's SMILES code (i.e. chemical structure) into the BIOWIN v4.01 model (US EPA, 2000) gives the following results:

- Probability of Rapid Biodegradation
  Linear Model: -0.7089
  Non-Linear Model: 0.0000

- Expert Survey Biodegradation Results
  Ultimate Survey Model: -0.4568
  Primary Survey Model: 0.7743

- Readily Biodegradable Probability (MITI Model)
  Linear Model: -0.6209
  Non-Linear Model: 0.0000

These results all imply that microbial degradation is most likely to be slow (metabolism rates in higher organisms are unknown). However, it is not known whether the models produce reliable predictions for this type of structure.

Summary

Overall, the data suggest that EBP is unlikely to biodegrade rapidly in the aquatic environment under aerobic conditions. This poor biodegradability may be linked to limited bioavailability to micro-organisms. Hydrolysis is also unlikely to be important as there are no hydrolysable groups and the substance has very low aqueous solubility.

No data is available on biodegradation under anaerobic conditions, as may be found in wastewater treatment plant (WWTP) or sediments. The possibility for reductive debromination is discussed further in Appendix 2.

3.1.3 Degradation in soil

No experimental data are available on degradation in soil. In one toxicity test with earthworms, however, unexplained losses in concentration were observed over 56 days (see Section 4.2.1.2 for further discussion).

3.1.4 Summary of environmental degradation data

EBP is unlikely to be rapidly degraded by reaction with OH radicals if released to the atmosphere. Abiotic degradation processes in water are likely to be negligible, and the substance is not readily biodegradable. The possibility of other degradation mechanisms cannot be excluded at the present time (see Appendix 2).

No information is available on degradation in the terrestrial environment.

For the purpose of EUSES modelling, EBP is considered not to be biodegradable. A rate constant of zero is therefore assumed for biodegradation in surface water and sewage treatment plant. The total rate constant for degradation in both bulk sediment and bulk soil is 6.9×10^{-8} d^{-1} at 12°C.

3.1.5 Environmental partitioning

Adsorption

The organic carbon/water partition coefficient (K_{oc}) is an important parameter because it is used to estimate other environmental partitioning coefficients. No measured values are available for EBP, but a substance with a water solubility as low as 0.72 µg/L is expected to adsorb to organic matter in sewage sludges, soils and sediments to a high degree (and Albemarle (2005) indicates that EBP's tendency to adsorb to surfaces can make chemical analysis difficult).

The K_{oc} can be predicted using quantitative structure-activity relationships (QSARs). The most commonly used models rely on the log K_{ow} as the input. Given the uncertainty in this value for EBP (see Section 1.3.7), alternative estimation techniques have been considered for this assessment:

- K_{oc} may be predicted using molecular connectivity indices, which are based on molecular structure only. For EBP, the predicted K_{oc} is 3.31×10^6 using the PCKOCWIN v1.66 model (US EPA, 2000) and SMILES input. The accuracy of the prediction is unknown.

- Although the measured water solubility value has some associated uncertainty (see Section 1.3.6), it is considered more reliable than the measured log K_{ow}. Boethling and Mackay (2000) cite several relationships between K_{oc} and water solubility. For example, Chiou *et al*. (1979) established the following equation for a group of fifteen halogenated hydrocarbons, including two polychlorobiphenyls and some low molecular weight bromoalkanes:

  $$\log K_{oc} = -0.557 \log S + 4.277$$ (where S is the solubility in µmol/L)

  Using a water solubility value of ~0.72 µg/L (equivalent to ~7.4×10^{-4} µmol/L based on a molecular weight of 971.23 g/mol) the K_{oc} is estimated as ~1×10^6 for EBP. This predicted value is just within the domain of the model (the lowest value for S for substances in the training set is 9.5×10^{-4} µmol/L). It should be noted that solubility-based equations tend to work best if the solubility is for the supercooled liquid rather than the solid.

Selected value

In the absence of a direct measurement, it is difficult to decide upon an appropriate value for the K_{oc}. The PCKOCWIN prediction and the estimate based on the equation of Chiou *et al*. (1979) are reasonably consistent despite the uncertainty in the water solubility value. The limit value recommended for the EUSES model is 1×10^6. In the absence of any further data, the environmental partitioning behaviour will be estimated on the basis of this limit as a default. This value is equivalent to a log K_{ow} of ~7.5.

Other partition coefficients have been calculated using EUSES as follows:

Solids/water partition coefficient for suspended matter	Kp_{susp}	1×10^5 L/kg
Solids/water partition coefficient for sediment	Kp_{sed}	5×10^4 L/kg
Solids/water partition coefficient for soil	Kp_{soil}	2×10^4 L/kg
Soil/water partitioning coefficient	$K_{soil\text{-}water}$	3×10^4
Suspended matter/water partitioning coefficient	$K_{susp\text{-}water}$	2.5×10^4
Sediment/water partitioning coefficient	$K_{sed\text{-}water}$	2.5×10^4

For comparison, a sediment/water partition coefficient (Kp_{sed}) of 7.9×10^4 L/kg was measured for decaBDE (EC, 2002), indicating a slightly higher level of adsorption. The impact of using a different K_{oc} value on the conclusions is considered in Appendix 1.

Volatilisation

The low vapour pressure for commercial EBP (assumed to be ~1×10^{-6} Pa at 25°C) indicates that it is unlikely to volatilise if spilt. Volatilisation from surface water is modelled by the Henry's Law constant (HLC).

A measured value is not available. The HLC can be estimated from the vapour pressure, molecular weight and water solubility of the substance using the equation provided in the TGD (2003). With an approximate vapour pressure of ~1×10^{-6} Pa, a molecular weight of 971.23 g/mol and a water solubility of ~0.72 µg/L, an HLC of ~1.35 $Pa.m^3$/mol can be estimated. Although there is some uncertainty in the input parameters, this value suggests that transfer from water to air (e.g. in a sewage treatment plant) should not be significant (since the value is below 10).

For comparison, the HLC can also be estimated using the HENRYWIN v3.10 model (US EPA, 2000) based on chemical structure alone. The values are 0.003 or 0.006 $Pa.m^3$/mol at 25°C (converted from the units of $atm.m^3$/mole used by the model), depending on whether the bond or group method is used. This would suggest a much lower volatility. The TGD (2003) notes that this program is useful for estimating the HLC of highly miscible or highly soluble compounds. The implication is that the program may not work well with poorly soluble compounds such as EBP.

A value of 1.35 $Pa.m^3$/mol is preferred for this assessment as a reasonable estimate of the HLC. The actual HLC value could be lower. In practice, both the very low water solubility and high adsorption to sediment and suspended particulate matter are likely to reduce the potential for volatilisation.

An air-water partitioning coefficient ($K_{air\text{-}water}$) may be derived from the HLC and is calculated as 5.69×10^{-4}. The $K_{air\text{-}water}$ and HLC suggest that volatilisation will not be a significant transfer mechanism for EBP from aquatic systems.

Precipitation

As discussed in Section 3.1.5.2, EBP is not volatile and so it is unlikely to enter the atmosphere in large amounts as vapour (the volatility during processing at elevated temperatures is unknown, but is probably relatively low in view of the high melting point). Once in the atmosphere, EBP is also likely to adsorb strongly onto particles. The wet and/or dry deposition of such particles is likely to govern the transport of the substance in the atmosphere.

Particles may be deposited near their source of origin or can potentially travel large distances from their point of emission, depending on weather conditions and other factors. Although some modelling studies have concluded that significant long-range atmospheric transport is unlikely for decaBDE (e.g. see ECB, 2004), particulates with diameters between 0.1 and 1 µm have an atmospheric half-life of around one week (approximate range: one day to one month) (personal communication from Professor R Harrison, University of Birmingham). This is long enough for the particulates to be transported many thousands of kilometres.

Distribution

Fugacity modelling indicates how a substance may be distributed in the environment following a release to a specific compartment (air, water, sediment or soil). The potential environmental distribution of EBP has been assessed using a generic level III, four compartment fugacity model (EQC v1.01, May 1997[23]) that is available for use within the OECD HPV programme. The model was run four times with a nominal release rate (entirely to air, water or soil, and equally to all three). The proportions of the released substance in each compartment at steady state are given in Table 3.1.

Table 3.1 Fugacity modelling results (per cent distribution at steady state)

Compartment	Release to			
	air	**water**	**soil**	**air:water:soil equally**
Air	0.005	<0.001	<0.001	<0.001
Water	0.004	0.86	0.003	0.006
Sediment	0.45	94.8	0.35	0.67
Soil	99.5	4.3	99.7	99.3

The modelling assumed that degradation in all compartments is negligible (the program assumes a half-life of 10^{11} hours). Using an atmospheric half-life of 53.6 hours produces virtually the same results (checked for the air emission only and equal emission scenarios). The reliability of these values is uncertain, however, due to the uncertainties in all of the values required for the input parameters (i.e. vapour pressure, water solubility and log K_{ow} (which in this case is taken to be ~7.5, back-calculated from the estimated K_{oc} of 1 x 10^6 L/kg)).

These results indicate that emissions to air are expected to partition to soil, that emissions to water are expected to partition to sediment, that emissions to soil are expected to remain in soil, and that emissions occurring to all three compartments are expected to partition to soil. In summary EBP would predominantly partition to solid phases when released to the environment; transport between compartments would be relatively insignificant.

[23] Model available from http://webdomino1.oecd.org/comnet/env/models.nsf

The SIMPLETREAT model used in EUSES estimates the fraction of a substance entering a standard WWTP that will be directed to air, water and sludge. For EBP the fractions are as follows:

To air	0.01%
To water	8.7%
To sludge	91.3%
Degradation	0%

These percentages are based on a lack of ready biodegradability, an estimated K_{oc} of 1 x 10^6 L/kg and HLC of 1.35 Pa.m^3/mol. The results imply that EBP is mostly removed by partitioning to sludge, with almost negligible volatilisation to air.

For comparison, the overall removal of decaBDE was estimated to be 91.7% (91.4% due to adsorption onto sewage sludge and 0.3% to air) (EC, 2002).

3.1.6 Aquatic bioaccumulation

Measured data

The Chemicals Inspection & Testing Institute (CITI, 1991b) has performed a bioaccumulation study on fish using a Japanese test method in accordance with the 1981 OECD test guideline 305D and GLP. A copy of the full study report was provided for this review.

A pilot study was conducted to establish an acute LC_{50} value for fish (see Section 4.1.1). The definitive bioaccumulation test was carried out with carp (*Cyprinus carpio*) at 25°C over eight weeks under a continuous flow-through system. Fish were fed pelleted food twice a day to correspond to about 2% of their total body weight. EBP was milled with a dispersant[24] to produce a stock test solution that was then dissolved in deionised water to obtain a 1,000 mg/L 'solution'. This stock solution was first diluted to an appropriate level with water in a 25-litre glass vessel, and then further diluted as part of the flow through system. Two exposure levels (I and II) were used (0.5 and 0.05 mg/L), together with a control that contained dispersant only. This study was performed prior to the water solubility study reported in Section 1.3.6. The purity of the test substance was recorded as 96.3%, which is slightly lower than the purity of more recent commercial material.

The concentration of EBP in water and fish (whole body homogenate) was measured analytically using chromatography[25] following solvent extraction with tetrahydrofuran and ethanol (twice per week for water and every two weeks for fish (two fish on each occasion), except for control fish). The nominal test concentrations were well maintained during the eight-week exposure period, as shown by analytical measurement. A peak was detected at the same position as that of the test substance for the control fish both at the start and end of the test (the mean level of this interfering peak equated to 2.33 µg/g EBP). This was subtracted from the test fish results.

At an exposure level of 0.5 mg/L, quantifiable levels of the substance were detected in only one fish sampled at the end of the exposure period (the concentration was 1.22 µg/g, just

[24] Crystal sugar and polyoxyethylene sorbitan monooleate (HCO-40), both at 20 times the test substance.

[25] The study report states that this was 'ion' chromatography, although this might be a translation error.

above the detection limit). Fish sampled at weeks 2, 4, and 6 had no quantifiable levels, and the concentration in the other fish was not measured at the end of the test.

At an exposure level of 0.05 mg/L, the substance could only be quantified in a single test fish sample, at the end of the second week (the concentration was 1.74 µg/g). Samples at 4, 6 and 8 weeks had no quantifiable levels.

The reported bioconcentration factor (BCF) was <2.5 L/kg at an exposure level of 0.5 mg/L and <25 L/kg at an exposure level of 0.05 mg/L. The single positive detection in week 2 for the lower exposure experiment gave a reported BCF of 34 L/kg.

A review of bioconcentration factors by Hardy (2004) briefly summarises the same results.

Discussion

The study is invalid because:

- The actual exposure concentrations are unknown – the use of dispersant meant that the test solutions greatly exceeded EBP's solubility in pure water (~0.72 µg/L; see Section 1.3.6), and the analytical measurements did not distinguish between dissolved and undissolved test substance.

- The number of fish was too small. OECD (1996) recommends a minimum of four fish per sampling point at each concentration, with more needed if greater statistical power is required.

- It is unlikely that the test fish achieved steady state. The substance was only quantifiable in one fish sample at each exposure concentration, so a steady state could not be established from the data. OECD (1996) provides an empirical K_{ow}–based relationship to assess the time needed to reach steady state. Although a reliable K_{ow} has not been established for EBP, for chemicals with log K_{ow} between 8 and 10 the expected time to reach 80% of steady-state concentration in fish is 110-750 days (i.e. more than the 8 week duration of the study).

- Fish tissue concentrations were not established with confidence. A substance-specific analytical technique was not used, and there was a significant interfering peak in the control fish analyses. The height of the interfering peak in the controls was in fact greater than the height of the test substance peak in most of the test fish samples. This may have been due to contamination during the analytical procedure (which is a common problem for the analogue substance decaBDE[26]), although the identity of the interfering substance was not established.

- Whole body homogenate was analysed, which means that the concentrations do not necessarily reflect internal tissue levels (since they would have included any substance adsorbed to the skin of the fish and to food in the gut).

Assuming that EBP was present in the water phase at around the water solubility limit (~0.72 µg/L), and that the measured fish concentrations represent tissue levels, then the BCF would be 1,600 L/kg. The BCF would be higher if the dissolved concentration were lower.

[26] By analogy with decaBDE, blank contamination and false positives are likely to be real problems when analysing EBP concentrations close to the detection limit. In order to carry out trace analyses reliably for this type of substance, it is usually necessary to include procedural blanks so that the contamination resulting from analytical artefacts can be properly assessed.

Conversely, if the fish concentrations relate mostly to the substance adsorbed to the skin or in the gut, the BCF might be lower.

Field studies

Law *et al*. (2006) studied the extent of bioaccumulation and trophic transfer of several brominated flame retardants, including EBP, in a food web from Lake Winnipeg, Canada.

Samples of six fish species, zooplankton, mussels, sediment and water were collected offshore of the town of Gimli on the south basin of the lake. Fish were stored whole on ice and transported back to the laboratory, where a skinless muscle tissue sample was removed from each fish and stored in WhirlPak bags at -20°C until analysis. Muscle tissue of the mussel was removed and used for analysis. Zooplankton and some smaller fish species were processed as composites due to the limited quantity of sample material. Surface sediment grab samples were collected from four sites in the south basin of Lake Winnipeg using a dredge sampler, and the top 2 cm of the sediment samples were removed and stored in WhirlPak bags at -30°C until analysis. Water was collected into stainless steel cans and then pulled through an in-line glass fibre filter onto the head of a Teflon column (34 cm) packed with 50 g of pre-cleaned XAD-2 adsorbent using a peristaltic pump. Each column was used to sample a total of 54 L of water (three 18 L cans).

Biota samples were homogenised and extracts taken, which were then reduced in volume and filtered. EBP was analysed by gas chromatography-mass spectrometry (GC-MS). An aliquot of the extract was used for gravimetrical lipid analysis. MS analysis was performed in the electron capture negative ionisation mode using methane as the buffer gas. EBP was detected under selected ion monitoring conditions (SIM) using bromide ions (*m/z* 79, 81). An external standard solution containing EBP was used to quantify the samples, and quality control procedures were followed to check for contamination. Unlike some of the substances in the study, EBP was not detectable in the procedural blanks.

Two criteria were used for confirmation of compounds on the GC. Firstly, the elution time of the compound had to be within ± 2 seconds in the sample and external standard. Secondly, the ratio of the *m/z* 79 and *m/z* 81 ions had to be within ± 15% of the theoretical value. To minimise degradation, a fast GC-temperature program and a short GC analytical column were used to reduce the residence time on the column. Despite this, a small amount of degradation was observed (estimated to be 8%), but no correction was applied as a result. The method detection limits are given in a supplement to the paper as 0.1 ng/g in biota and sediment, and 15 pg/L in water.

The structure of the Lake Winnipeg pelagic food web was elucidated using stable nitrogen isotopes. The trophic positions of the species sampled, based on ^{15}N:^{14}N ratios and assuming a constant enrichment factor, were as follows: mussel (*Lampsilis radiata*) → zooplankton, Whitefish (*Coregonus clupeaformis*) → Goldeye (*Hiodon alosoides*), White Sucker (*Catostomus commersoni*) → Burbot (*Lota lota*), Walleye (*Stizostedion vitreum*) (top predators).

EBP was not detected in water (i.e. concentration < 15 pg/L), nor sediment, zooplankton, mussels or Whitefish (i.e. concentration <0.1 ng/g). EBP was detected in some samples of the other fish species, and the results (blank and recovery corrected) are presented in Table 3.2.

Table 3.2 Range of concentrations of EBP in fish from Lake Winnipeg

Species	Number of samples[a]	□^{15}N (□ standard error)	% lipid	EBP concentration (ng/g lipid weight)	
				Range	Arithmetic mean
Walleye	5	17.8 (□0.3)	1.15	<DL-2.71	1.01
Whitefish	5	12.0 (□0.2)	8.78	<DL	-
Emerald Shiner	5	16.0 (□0.1)	3.18	<DL-1.51	0.30
Goldeye	3	16.1 (□0.2)	2.34	<DL-1.63	0.62
White Sucker	5	15.2 (□0.6)	2.27	<DL-0.24	0.08
Burbot	5	16.6 (□1.6)	0.33	<DL-3.30	0.66

a – the supplementary data sheet indicates that the some of the samples were composites from a larger group (composites were not used for either Whitefish or White Sucker). In the case of Emerald Shiner, each sample was a composite of >100 fish.
DL = detection limit of analytical method, 0.1 ng/g. For statistical purposes, a concentration of 0.05 ng/g was assumed in those instances where concentrations were below the DL.

The authors could not generate a meaningful relationship between EBP concentration and lipid content because it was detected in too few organisms. Fish wet weight concentrations are not reported in the paper (nor its data supplement). However, it is noted that the mean EBP concentration for Walleye was below the detection limit when expressed in terms of wet weight, but was the highest on average when expressed in terms of lipid weight (arithmetic mean of 1.0 ± 0.5 ng/g).

Trophic magnification factors (TMFs) were used to assess the food web magnification for the entire food web. TMFs are based on the relationship between trophic level and contaminant concentration and were calculated using the equations described in Tomy *et al.* (2004) and references therein. Biomagnification factors (BMFs) were calculated as the ratio of lipid corrected concentration in the predator divided by lipid corrected concentration in the prey. It should be noted that trophic interactions in this study were based on whole body concentrations for the invertebrate samples but muscle tissue only for the fish. Since muscle tissue concentrations may underestimate whole body concentrations, the BMF may also have been underestimated as a result.

A significant relationship (p-value <0.05) was found from the plot of natural log of EBP concentration (lipid weight) against trophic level (based on δ^{15}N-values) for the Lake Winnipeg food web. The authors state that the TMF of 2.7 (corrected from 8.6 by Law *et al.*, 2007) indicates that EBP is biomagnifying within this food web as a consequence. The highest estimated lipid-adjusted BMF was 9.2 for the Walleye/White Sucker feeding relationship, also suggesting biomagnification. Other BMFs above 1 were obtained for the Walleye/Emerald Shiner (*Notropis atherinoides*), Walleye/Goldeye and Burbot/Emerald Shiner feeding relationships.

Discussion

This study indicates that uptake of EBP occurs in wild fish, either directly from the dissolved phase or via food. However, the results and conclusions must be interpreted with caution for the following reasons:

- There is no information on the accuracy of the analytical method or the overall variability of the results (the actual number of non-detects and the standard error of the mean are not reported). It was assumed that the concentration in samples for

which the substance was not detected is half the detection limit. This introduces uncertainty, since the actual levels could have been higher or lower.

- EBP was only detected in a few samples of each fish species examined. The representivity of the samples is unclear, in terms of both sample numbers (very few samples were collected for some species) and time of collection (samples were not all collected at the same time – e.g. fish were collected from 2000 to 2002, mussels in 2002, sediment in 2003 and water in 2004). It is unknown whether the system was in steady state during this period.

- The estimation of trophic level from $\delta^{15}N$ concentrations integrates all potential feeding relationships in the food web. However, most of the BMFs have been estimated by assuming a predator consumes one prey species only, and as this is unlikely to be the case in reality, the resulting BMFs should be treated with caution. It is also possible that the organisms were exposed to other sources that were not examined in this study (e.g. sediment with higher levels of EBP than the collected samples).

- It could also be questioned how reliable the $\delta^{15}N$ approach is in determining the trophic level for this food chain. In particular, the Emerald Shiner (*Notropis atherinoides*) appears to be located at a higher trophic level than the Whitefish (*Coregonus clupeaformis*) based on the $\delta^{15}N$ data. However, this would not necessarily be expected based on their ecology and feeding habits. The Emerald Shiner is a relatively small fish (up to ~13 cm) that feeds mainly on microcrustaceans, midge larvae and algae, whereas the Whitefish is larger (up to ~100 cm) and similarly feeds on aquatic insects, molluscs and amphipods, but also other fish and fish eggs (information taken from www.fishbase.org).

- The concentrations measured in fish are very low (parts per billion), and relate only to muscle, whereas it is more relevant to consider whole fish concentrations. If it is assumed that the concentration of EBP is similar amongst all tissues in the fish when expressed on a lipid weight basis, the data obtained with muscle alone could be considered to be representative of the whole fish concentration. However, this may not necessarily be the case. The levels found in fish muscle were about three orders of magnitude lower than the concentrations in whole fish found in the *in vivo* BCF study (which were in the range 1-2 µg/g (parts per million)).

- The paper suggests that EBP (and decaBDE) biomagnified to a greater extent than hexabromocyclododecane isomers and lower molecular weight polybromodiphenyl ether congeners measured in the same samples. These latter substances are known to accumulate significantly in biota, so the conclusions do not appear to be consistent with what is known about these other substances.

Field studies that estimate TMFs and BMFs can provide a better indication of bioaccumulation and biomagnification potential than laboratory studies. However, in this case reliable conclusions cannot be drawn due to the low concentrations and detection frequency involved and uncertainties about the state of the system over the study period.

Predicted data

The BCF of an organic chemical can often be predicted using QSAR correlations with log K_{ow}, especially if the substance is not metabolised very readily. It is not considered helpful to provide predictions in the absence of a reliable K_{ow} value for EBP (see Section 1.3.7).

Other factors

There is no evidence of significant uptake in mammalian tests. EBP was poorly absorbed by the oral route in a single high dose (1,000 mg/kg/d) study with rats (see Section 4.4.1). However, absorption could be higher with lower doses and different solvents, by analogy with decaBDE (EC, 2002; ECB, 2004).

EBP has a two-carbon linkage between the aromatic rings, giving the molecule a good degree of flexibility. Flexibility tends to decrease absorption whereas rigidity assists passive diffusion through cell membranes (Dimitrov *et al*., 2002).

Comber *et al*. (2006) suggest several other chemical properties that limit the absorption and distribution of a chemical via passive transport. In summary, the fish BCF is unlikely to be above 2,000 if a substance has:

- an average maximum diameter greater than 17 Å (1.7 nm), plus a molecular weight greater than 1,100 g/mol;
- a maximum molecular length of greater than 43 Å (4.3 nm);
- a measured octanol solubility (in mg/L) below 0.002 times the molecular weight, as an indicator of lipid solubility (in the case of EBP, this would be 1.94 mg/L).

The molecular weight of EBP is high at 971.23 g/mole, but this fails the criterion.
There are many computational methods for estimating molecular size, which can also be expressed in several ways, and will vary with the conformation of the molecule (flexible molecules will have more conformations that rigid ones). The EBP molecule has sixteen possible conformers of different shapes. The molecule vibrates through these conformers and spends the most time in the lowest energy configurations. The most stable arrangement is the most probable size and shape for the EBP molecule, and this is more compact than would be expected based on a two-dimensional drawing of the molecule. The data in Table 3.3 were generated using three software programs (Chemsketch 8, OASIS Basic v1.02 (OASIS, 2004) and Spartan '04 (the latter estimate provided by Albemarle, personal communication)) with SMILES code input only.

Table 3.3 Molecular dimensions of EBP

Model	Width (nm)	Length (nm)
Chemsketch*	0.8	1.5
OASIS Basic	10.0	14.0
Spartan	0.9/0.9	1.1/1.6

* Chemsketch estimates a nucleus-to-nucleus distance. Therefore, 2 x half the Van der Waals radius of the selected atoms has to be added to estimate the Van der Waals length of the molecule (the radii were obtained from http://www.lenntech.com/Periodic-chart-elements/vanderwaals.htm).

These predictions tend to suggest that the substance's molecular size is too small to meet the size criteria given above. (The unit of measurement quoted by the OASIS software is nanometres, but the estimate would be in line with the other two if it were in fact angstrom (equal to 0.1 nanometre).)

The equilibrium solubility in octanol has not been measured and therefore it is unknown whether the third criterion is fulfilled. However, a concentration of 1.91 mg/L was measured in an n-octanol stock solution as part of the study to determine the octanol-water partition coefficient (see Section 1.3.7), which is close to the limit.

In addition, Kelly *et al*. (2004) concluded that the octanol-air partition coefficient (K_{oa}) was an important factor for assessing bioaccumulation potential in air-breathing organisms such as birds and mammals. Given the uncertainty over both the K_{ow} and vapour pressure values for EBP, it is not considered appropriate to estimate a K_{oa} at this time. However, this could change if further data were forthcoming.

Data from structural analogues

DecaBDE has similar physico-chemical properties to EBP (see Table 3.4) and molecular dimensions (ECB, 2004). The available data indicate that little or no uptake of decaBDE occurs in aquatic organisms exposed via the water phase (EC, 2002). The measured fish BCF was 4 L/kg, and the substance could not be detected in the fish. Some limited uptake was seen in experiments with fish exposed via food over periods up to 120 days, but the tissue concentrations were much lower than those present in the food.

Nevertheless, the bioaccumulation behaviour of this substance is complicated. For example, it is rapidly and extensively absorbed from food by Grey Seals (*Halichoerus grypus*) (see EC, 2002; ECB, 2004). Uptake from ingestion therefore seems to be important, and at least some food chains and species appear to accumulate the substance to a greater extent than expected from the laboratory fish data alone.

Summary of aquatic bioaccumulation

The actual numerical value for the fish BCF is unknown, since the measured limit value of 25 L/kg from the only available study is considered invalid. Given EBP's very low aqueous solubility and presumed high K_{ow}, accurate measurement of bioconcentration in the laboratory is very difficult.

Other information is available (including field data, structural considerations, mammalian test data and analogy with a related substance), but a conclusion cannot be drawn about the bioaccumulation potential of the substance. A BCF of 25 L/kg has been used in the subsequent calculations for this assessment for illustrative purposes. Calculations using a higher BCF of 1,600 L/kg are also presented in Appendix 1.

3.1.7 Terrestrial bioaccumulation

No measured data are available, so an earthworm BCF could be predicted using a QSAR based on the octanol-water partition coefficient (log K_{ow}) in accordance with the TGD. However, as for fish, given the uncertainty in the K_{ow} for EBP (see Section 1.3.7), it is not considered helpful to provide such a prediction.

Toxicity seen at high soil concentrations over 56 days indicates that EBP is bioavailable to earthworms and can accumulate to levels that cause effects (see Section 4.2.1.2). No toxicity (and therefore presumably limited uptake) was observed in tests with sediment worms, although the test duration was relatively short at 28 days (see Section 4.1.4.2).

Biota-soil accumulation factors of ~0.3 (range 0.1-0.7) have been measured for decaBDE from earthworm samples collected in the field (EA, 2007).

In summary, it is not possible to estimate a worm BCF for EBP based on the currently available information.

3.1.8 Summary of environmental fate and distribution

The available data indicate that EBP is involatile and poorly soluble in water. It is expected to adsorb strongly to organic matter in soils, sediments and sewage sludges. It is therefore likely to be relatively immobile in sediment and soil (unless particulates are transported in runoff or by wind, etc.). Degradation processes within these media are predicted to be very slow. If released directly to the atmosphere, EBP would most likely be associated with particulate matter. Some particles could be transported significant distances from any emission source, depending on weather conditions.

The potential for bioaccumulation in both aquatic and terrestrial organisms has not been quantified in the absence of reliable data for the substance itself. A relatively low fish BCF is assumed for the subsequent calculations, but a higher value is also considered in Appendix 1.

3.2 Environmental releases

3.2.1 General introduction

The estimates of releases in the following sections are based on the current supply volume that has been established through consultation with the main suppliers for the purposes of this report. However, since the substance is marketed as an alternative to decaBDE, an additional scenario is considered in Appendix 4 to investigate the impact of partial substitution leading to higher consumption volumes than at present. Given that there is currently no production of EBP in the UK or EU, releases from the manufacturing step are irrelevant and so have not been considered.

In the following discussion, the 'local' environment is considered to be an area close to a site of release (e.g. an industrial facility). The 'region' represents a highly industrialised area, 200 km × 200 km in area, with 20 million inhabitants. The continental environment is the size of the EU and is generally used to obtain "background" concentrations of the substance.

As described in Section 2.2, the industrial applications of EBP are virtually the same as those for decaBDE. A comparison of the properties of these two substances is given in Table 3.4.

Table 3.4 Comparison of physico-chemical properties of EBP and decaBDE

Property	EBP	DecaBDE
Physical state at n.t.p.	Solid (powder)	Solid (powder)
Particle size	5.6 µm (average)	typically <5 µm
Molecular weight, g/mole	971.23	959.2
Vapour pressure, Pa at ~20ºC	~1 x 10^{-6}	4.6 □10^{-6}
Water solubility, µg/L at 25°C	~0.72	<0.1
n-Octanol–water partition coefficient, log K_{ow}	~7-10 (use with caution)	□6.3
Henry's Law constant, $Pa.m^3/mol$	1.35 (estimated)	44.4 (estimated)

In the absence of any firm evidence to the contrary, the releases of EBP would be expected to be very similar to those for decaBDE from the same processes. **The release estimates in**

this report are therefore adapted from the various risk assessment reports for decaBDE (EC, 2002; ECB, 2004; EA, 2007). As the tonnage information is commercially confidential, full details of the calculations are provided only in the confidential annex. Additional comments from both plastics and textile industry user representatives have been taken into account for this report.

Although there is no information currently available about the levels of imports in finished or semi-finished goods, the following calculations take account of the possibility of release from finished articles over the lifetime of the products. Together with the scenario presented in Appendix 4, the assessment does therefore take some account of this source.

A minor additional use of EBP has been reported, but the supply volume associated with this application is low at the moment (details are provided in the confidential annex). An emission scenario has therefore not been established for this use, although this may need to be considered in future.

3.2.2 Polymer applications

Introduction

There are various stages in polymer processing such as compounding (blending of additives into the polymer) and conversion (production of the finished articles, for example by injection moulding). The different processes are not necessarily carried out on the same site – some companies specialise in compounding to produce master batches (plastic compounds that contain high concentrations of additives which are subsequently mixed by customers in their main polymer matrix). As a realistic worst case estimate of the emissions at a local scale it will be assumed that compounding and conversion are carried out at the same site, although it is recognised that this situation may not be typical for this industry sector in general terms.

An emission scenario document is available for plastic additives, which is largely based on UK industry data (OECD, 2004a). Release factors are provided for flame retardants for the various processes involved in the production of plastic. These are used in the following discussion for high impact polystyrene (HIPS), which is one of the major polymer types that is flame-retarded with EBP. The choice of polymer type for an emission scenario does, however, influence results. Different polymers are processed in different quantities at an individual site, so the consumption of EBP will be different depending on the polymer selected (some polymer types have higher usage on a site than polystyrene, but the loading rate may differ too).

Compounding and conversion

The compounding stage is susceptible to dust generation, mainly early in the mixing cycle, where localised containment may be used to recover the material for recycling. Particles would normally settle within the facility and so losses will ultimately be to solid waste or wastewater. In addition, volatilisation of the additive may occur. EBP has a low vapour pressure (assumed to be ~1×10^{-6} Pa at 25°C), placing the substance in the low volatility class for plastics additives (OECD, 2004a).

For particles of low volatility with diameters <40 µm, releases at the compounding stage are expected to be 0.051% to water and 0.001% to air, giving a total loss of 0.052% (OECD, 2004a).

Releases during conversion in closed systems are thought to be small. Some vapour might possibly be lost because of the processing temperatures used. A release of 0.001% to water and 0.001% to air can be assumed for substances with low volatility (OECD, 2004a). The total is therefore 0.002% for this stage.

The overall combined losses from these two stages are therefore 0.052% to water and 0.002% to air (0.054% overall).

The amount of additive used at a site is estimated from the amount of polymer processed at a site, and the fraction of the additive in the polymer. OECD (2004a) suggests that 623 tonnes of polystyrene may be used at a single site in a year as an initial assumption. OECD (2004a) indicates that brown goods (television sets, video recorders, etc.) may contain around 20% by weight of flame retardant. However, Section 2.2.2 indicates that the recommended loading of EBP required in HIPS to achieve the highest UL-94 rating is 12% (even less is required for HIPS to meet the lower UL-V2 rating). Consequently, the amount of EBP used at a single site is estimated to be 75 tonnes as a worst case.

Applying the release factors to this tonnage gives a local release of 39 kg/year to water and 1.5 kg/year to air. These figures will be used for the worst case assessment. Table B3.9 of Appendix 1 in Chapter 3 of the TGD suggests that a typical plant will operate over 300 days.

The number of users of EBP is currently unknown, but it is assumed that 10% of the total EU tonnage of EBP is consumed in a region given the amount involved and the wide distribution of the industry. For example, OECD (2004a) reports that around 50 companies specialise in plastics compounding in the UK, and that there are around 3,000 companies carrying out conversion activities. Many of these are small companies; indeed most industrial estates will have at least one company involved in plastics manufacturing. Releases at the regional and continental levels are confidential, since they are linked to the overall tonnage used in this application.

Discussion

One user representative has indicated agreement with these estimates (via Albemarle, personal communication). However, OECD (2004a) indicates that losses to wastewater may occur through raw materials handling as well as the compounding process. For EBP this would represent an additional loss of 0.8%. Nevertheless, ECB (2004) assumed that emissions of decaBDE from a polymer processing site could more realistically be 0.5 kg/year to waste water and 7 kg/year to air. This air emission is comparable to the default estimate of 1.5 kg/year derived above for EBP, but the water emission is substantially less. Losses from raw materials handling is therefore not considered further in this assessment.

Releases from polymer articles in service

Leaching losses

Given that plastic articles flame-retarded with EBP are mainly electrical goods used indoors, they are unlikely to be exposed to water and so leaching from the plastic is expected to be insignificant. OECD (2004a) suggests that an overall release to liquid waste will be 0.05% over the 10-20 year lifetime of a product used indoors.

Particulate losses

Particulates might be formed by abrasion over a product's lifetime. There is no actual information available to permit a reliable estimate of the significance of this source, but Section 3.2.4 considers this further. Articles like television cabinets would not be expected to produce particulates during their service life, although those with moving parts might.

Volatile losses

Since the substance is used as an additive flame retardant, it could potentially migrate through treated polymers and evaporate from the articles' surface (and adhere to settled dust), especially if the polymer gets hot. Measurements of volatile emissions of decaBDE during use of electrical and electronic equipment indicate that they are low, but not zero (ECB, 2004). OECD (2004a) suggests a release of 0.05% over the lifetime of the article, in both indoor and outdoor applications. One user representative has indicated agreement with these estimates (Albemarle, personal communication), although EBP blooms less than decaBDE so is less prone to volatile emissions from plastic articles.

Overall losses in service

The annual total release of EBP to air and water over the service life of products at steady state can be estimated from the overall tonnage used in this application and the emission factors given above (0.05% to air and to water). The figures are given in the confidential annex, and the reliability of the estimates is unknown.

3.2.3 Textile applications

Introduction

EBP is not used in textiles in the UK at present. The following sections therefore summarise the releases that might be expected from these processes if they were to take place. Full details are provided in the confidential annex.

Formulation and processing of textile backcoatings can sometimes occur at the same facility (known as self-compounding), but the two are kept separate for the purposes of this assessment. Only one supplier has provided information on the number and location of EBP users. Given that the level of use is much smaller – and the market more geographically restricted – than for polymer applications, this assessment assumes that all the tonnage is consumed in a single region as a screening level approach in the absence of more specific information.

The following estimates are based on industry information provided for decaBDE (see EC, 2002; ECB, 2004; EA, 2007).

Manufacture of flame retardant formulations

It is assumed that the whole tonnage is consumed at a single large site. Two sources of release to waste water from this process can be considered by analogy with decaBDE:

- Dust formation when the flame retardant powder is poured into the pre-mixer. Releases to air are likely to be very small (dust is normally removed from the air using fabric filters to limit human exposure to antimony compounds). Any loose dust is vacuumed up and the area is then washed down with water. The vast majority of the collected dust (>99%) is re-used.
- Washing out of the final formulation mixing tanks. Around 0.5% of the formulation is estimated to be lost in this way, and so 0.5% of the flame retardant consumed at the site will be released too[27]. Since the local release is the same as the regional release, the actual release figure is confidential.

As a worst case, all the release at the generic large site is assumed to be direct to a standard waste water treatment plant as defined in the TGD. The releases involve loss of the formulation itself, which is likely to be a viscous latex-based mixture. Environmental releases may therefore be overestimated for sites that use a solids extraction system.

Textile backcoating (processing)

Backcoating is a wet process, and so there is a potential for emission to waste water[28] during initial set-up and wash down of the coating equipment between batches. The waste is usually collected for suitable disposal but could be disposed down a drain. This process is generally carried out by small and medium-sized enterprises, which discharge predominantly to municipal sewage treatment plant without pre-treatment of their effluent (OECD, 2004b).

There were around 40 textile finishers of various sizes using flame retardant coatings across the EU in the mid-1990s, with about 10 in the UK (EC, 2002). Given that the market for EBP-treated textiles is currently more limited than for decaBDE, there will be far fewer finishers for EBP (and there are currently none in the UK).

Investigations of losses to waste water for decaBDE as part of a voluntary stewardship programme suggest that emission to sewer is typically below 3.6 kg/day per site (EA, 2007). In most cases emissions are much lower than this figure or close to zero (one exceptional site had higher emissions, but this has an unusual combination of operations).

A local release of 3.6 kg/day will therefore be assumed as a worst case (especially as both current suppliers have committed to include EBP under similar product stewardship programmes to decaBDE). Assuming 300 days operation, the local release to waste water will be 1,080 kg/year.

It will be assumed that there is one more finisher in the same region as the worst case site, emitting a smaller amount. ECB (2005) suggests that the emissions from such sites would be below 2 kg/day (information from Albemarle suggests they will be significantly lower). As a worst case, it will be assumed that the second site will emit 2 kg/day, giving a total release of 600 kg/year (assuming 300 working days).

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[27] The risk assessment of decabromodiphenyl ether (EC, 2002) appears to have made an incorrect assumption, in that the release is given as 0.1%, based on the level of the substance in a formulation of 0.2%. Consequently, the local release is higher in this document for the same scenario.

[28] Backcoating formulations are latex-based. Air emissions will therefore only be relevant during thermal treatments and drying operations, and are considered to be a minor (though not necessarily negligible) source compared to waste water (OECD, 2004b). Typical total air emissions from a very small number of textile sites were up to 320 g per site per year for decaBDE (ECB, 2004). Since EBP is less volatile, air releases are not considered further.

The overall regional release to waste water is therefore estimated to be 1,680 kg/year. Given that this is likely to be a significant overestimate (based on Albemarle information), it is assumed that there are no other continental emissions.

It should also be noted that these losses would vary depending on the application. For example, for automobile applications, the amount of fabric treated in a single batch tends to be quite large, and changes will be commensurately smaller than for other applications requiring smaller amounts of fabric to be treated (TFA, 2006).

Releases from treated textiles in service

Leaching losses

EBP is used to treat the same types of articles as decaBDE (i.e. mainly drapery and upholstery). Finished articles (window blinds, furniture, etc.) are expected to have a service life of 10 years or more (sunblinds, for example, are said to last 8-15 years). Treated fabrics are unlikely to be washed frequently, and in many cases are integral to the article itself (e.g. the fabric may be stapled to furniture frames).

OECD (2004b) provides little information on possible releases from articles in service, and there are no reliable data available with which to estimate the leaching loss rate of EBP from textiles. A possible leaching loss of 0.05% over the lifetime of the textile has been assumed for decaBDE, and in the absence of better information the same figure is used for EBP in this assessment (the derivation of this figure is discussed in ECB, 2004). This figure is only a crude estimate.

The current amount of EBP used in textile applications in the EU is confidential. Assuming that 2% of this is used in textiles subject to washing, and that the total loss of EBP during washing is 0.05% over the lifetime of the product, the total release of EBP can be estimated at steady state (the actual figure is confidential). This is a regional release, since all EBP-treated textiles are assumed to be used in a single region.

Particulate losses

The flame retardant backcoating may wear during the lifetime of the textile, leading to the loss of small particles as dust. The detection of decaBDE in samples of house dust at levels up to a couple of milligrams per kilogram show that backcoating deterioration is a real loss mechanism (EA, 2007). Indoors, dust will typically be collected in vacuum cleaners and disposed of in domestic refuse. Clearly this is not a completely efficient process; some dust may also be transported outdoors, either on clothing, or by ventilation. There is no information available with which to estimate such losses to the environment.

3.2.4 Disposal of treated articles

Currently around 88% of plastics containing brominated flame retardants (BFRs) ends up in landfill and 10% is incinerated (ECB, 2004). OECD (2004a) suggests that there will be no significant releases from plastic articles during landfill and incineration operations. The leaching potential of EBP from polymers is unknown, but is expected to be low in view of its very low water solubility and strong adsorption to organic carbon. Similarly, the low vapour pressure of EBP should limit its volatility. Emissions from landfill are therefore expected to be relatively small. Controlled incineration should destroy the substance.

OECD (2004b) does not provide much information on releases from textile disposal. There could be some losses, for example as particulates, during general handling of waste, especially if articles are broken up prior to disposal. The behaviour of EBP within the particulates is unknown.

It is considered premature to predict losses from this source at the present time due to the lack of reliable data with which to make an estimate (releases were estimated for decaBDE, but these were based on a number of highly uncertain assumptions).

Losses from plastics recycling

Currently less than 3% of plastic containing BFRs is recycled (ECB, 2004). Initiatives and legislation like the WEEE Directive are likely to increase recycling rates in the future (see Section 2.6.1). The suppliers of EBP specifically point out that plastics containing EBP can be recycled.

OECD (2004a) gives no suggestions about how to account for losses during recycling. Recycling thermoplastics involves melting and reshaping. These processes are similar to those involved in plastics production, so the emissions of EBP from this stage of the recycling process will in principle be similar to those during the polymer processing stage.

Emissions could also occur during the collection, separation and shredding/regrinding of plastics present in waste electrical and electronic equipment. These releases would occur as dust or polymer-associated particles. A number of relevant analyses on EBP have been published:

- Pettersson-Julander *et al*. (2004) analysed brominated flame retardants from the air of an electronic recycling facility in Sweden. One of the brominated substances detected was reported to be structurally similar to EBP although no definite identification was made.

- Julander *et al.* (2005) analysed twelve air samples from an electronic recycling facility in Örebro, Sweden. During the sampling, six dismantling stations were operative over two consecutive 8-hour shifts (total sampling time 16 hours). One station consisted of one worker dismantling television sets, computers and small electronic products using manual pneumatic tools. Four more workers were in the facility during the sampling period, working with incoming and outgoing goods. All sampling was done during January 2002. The samples represented three different dust fractions (respirable, total and inhalable dust; particle sizes in each fraction not described) and four samples were collected from each fraction.

  The filters were removed from the samplers without wipe out or rinsing. All solvent extraction and clean-up steps were performed in a dark room. Amber glassware was used except for the soxhlet glassware, which was covered with aluminium foil to avoid exposure of the samples to light. Extracts were analysed on a GC-MS in negative ionisation mode (NCI). No EBP standards were available at the time of analysis and so the substance was tentatively identified using full scan NCI spectrum monitoring for specific ions. Levels were semi-quantitatively calculated using the relative response factor of the closest eluting polybromodiphenyl ether.

  EBP was tentatively identified in five of the 12 samples at levels above the method detection limit. The concentration range was 0.06–0.8 ng/m^3, with the highest concentration in the inhalable fraction. The second highest concentration (0.4 ng/m^3) was detected in one of the respirable dust fraction samples. These levels are around

two to three orders of magnitude lower than the concentrations of some of the polybromodiphenyl ethers that were detected in the same study.

- Kierkegaard *et al*. (2004) also collected an air sample from an electronics dismantling facility in Sweden, using a personal air sampling pump. The sampling time was 6 hours, representing approximately 1 m^3 of air. Both the glass fibre filter and the adsorbent were analysed. A peak matching EBP was detected in the filter sample extract, and its concentration in the air sample was subsequently determined to be 0.7 ng/m^3. The concentration was below the detection limit in the procedural blank, and no EBP was detected in the sampler adsorbent. This is an indication that the substance is associated mainly with particles in the air. The analytical methods are mentioned in Section 3.3.1.2.1. The concentration ratio of the substance and decaBDE was 0.06.

More detailed data are available on emissions of polybrominated diphenyl ethers (assumed to be mainly decaBDE) from plastic recycling plant (see ECB (2004) for further discussion). Estimated emission factors were 1.9 mg/kg for a plant without incineration and up to 0.024 mg/kg for a plant with incineration. Assuming that a) the quantity of treated articles disposed of or recycled each year is equal to the quantity of new treated articles produced or imported each year, and b) the recycling rate is around 65% (one of the targets of the WEEE Directive), then the tonnage of EBP present in articles that could be subject to recycling each year in the near future can be estimated (the actual figure is confidential).

The emission is mainly to air, of which 10% is assumed to occur in a region. The resulting figures are provided in the confidential annex, but are given as an illustration only, in view of the large number of assumptions used in their derivation. The emissions are likely to be in the form of particulates, which could settle as dust in the facility and subsequently be washed into the wastewater stream. It is not currently possible to estimate the significance of this source for environmental exposure any further.

3.2.5 Summary of releases

The release estimates from the sections above are summarised in the confidential annex due to the commercial sensitivity of the tonnage information on which they are based. No substance-specific measured release data are available for comparison.

The local polymer manufacturing scenario relates to a site that both adds EBP to the polymer and processes it into articles as a worst case. This combination of operations may not be typical for the industry in general, and the estimated releases will be lower for sites that only carry out one of these processes. Most of the losses are likely to occur at the compounding stage. The scenario is based on an emission scenario document for plastic additives, which was developed using detailed information on the UK plastics industry. The key assumptions to obtain the release estimates are that EBP is of ‘low’ volatility and that 75 tonnes of EBP are used at the site annually as a worst case. There is no information on the number of sites involved, but releases estimated for the regional model are taken as 10% of the total release in the EU. There is some evidence to suggest that aqueous releases from polymer processing sites in particular might be overestimated.

The local textile processing scenario is based on information from industry provided for decaBDE. The key assumption is that all of the use takes place in a single region, with formulation at a single site. Air releases are assumed to be low and have not been quantified. The releases to wastewater are likely to be conservative. In particular, they will be overestimated for sites that use a solids extraction system prior to discharge to a sewage treatment plant.

Both the polymer and textile scenarios could be refined with information on the quantities used and released at a typical worst-case site, as well as the number of sites involved. Although the quantity of EBP used in textiles is substantially lower than for polymer applications, textile applications give rise to relatively higher emissions at the local scale. This is not surprising given that textile processes are wet, whereas polymer manufacture is generally dry.

Diffuse emissions at the regional level will occur due to losses of the substance from flame-retarded products in use. These emissions are extremely difficult to quantify. A number of assumptions have been made, but the reliability of the estimates is unknown. Release during disposal, including plastics recycling, is a possibility that has not been addressed quantitatively.

Finally, it should be noted that there is at least one minor use of EBP for which release estimates have not been developed at all.

3.3 Environmental concentrations

3.3.1 Aquatic compartment (surface water, sediment and wastewater treatment plant)

Estimated aquatic environmental concentrations

The predicted environmental concentrations for water local to the point of release (PEC_{local}) are calculated using the environmental releases detailed in Section 3.2 and the equations set out in Chapter 3 of the TGD (2003). Essentially, concentrations are estimated in sewage effluent from a 'standard' WWTP for each life cycle step, and the concentration in the receiving water is calculated by assuming a default dilution factor of 10. The PEC_{local} is made up of:

- a local water concentration (C_{local}) resulting from the relevant process emission followed by re-distribution in a WWTP and dilution of the effluent in a river by a factor of 10;
- a background concentration that results from emissions in the regional environment ($PEC_{regional}$). This regional PEC is itself a result of direct emissions from industrial processes using the substance, and diffuse emissions as a consequence of the use of end products.

The PEC for sediment can be derived from the PEC_{local} for surface water using the suspended matter–water partitioning coefficient, assuming equilibrium partitioning.

PECs for WWTP are based on influent concentrations arising from direct releases.

The results are presented in Table 3.5 (rounded to two significant figures).

Table 3.5 Aquatic PECs

Life cycle stage	PEC for surface water (mg/L)	PEC for sediment (mg/kg wwt)	PEC for WWTP organisms (mg/L)
Polymer processing (combined compounding and conversion site)	2.3×10^{-4}	5	5.6×10^{-3}
Textile backcoating formulation	9.8×10^{-3}	210	0.24
Textile backcoating application	6.2×10^{-3}	140	0.16
Regional	confidential	Confidential	-

It should be noted that the local surface water PECs for the two textile scenarios are greater than the solubility measured in pure water (7.2×10^{-4} mg/L). No adjustments have been made to the EUSES calculations, since these could affect the amount directed to sediment. This does, however, suggest that these PECs are overestimated, and this is taken into account in the risk characterisation (Section 5.1.1).

Measured aquatic environmental concentrations

Albemarle (2005) indicates that the substance's low water solubility, vapour pressure and tendency to adsorb to surfaces present an analytical challenge. EBP is difficult to vaporise in a gas chromatograph, and laboratory and glassware contamination is a significant issue that must be controlled and eliminated, especially when evaluating trace levels. Quality control and appropriate blank analyses are therefore very important. Similar issues have been raised for decaBDE (see EC, 2002 and ECB, 2004 for more details).

Freshwaters, wastewater treatment and industrial effluents

There has been no specific monitoring programme for EBP in European freshwaters. Detection of the substance in surface water would be infrequent, due to its low water solubility and potential for adsorption to sediment.

Sewage sludge samples were collected as part of a Swedish survey of 50 sewage treatment plants (STP) in 2000 (Kierkegaard *et al.*, 2004). The samples consisted of pooled subsamples collected over a period of about a month. The STPs were chosen to be representative for Sweden with respect to size and geographic distribution. STPs serving industries that were believed to use brominated flame retardants were also included. The plants were divided into three classes depending on size in person equivalents (PE): there were eight large (>75,000 PE), six medium (20,000-75,000 PE), and 36 small (<20,000 PE) STPs.

All sludges were dewatered, 24 were anaerobically digested, and seven others were aerobically stabilised. They were stored at -20°C until analysis. In this study, EBP was positively identified by high-resolution mass spectrometry and quantified by low-resolution mass spectrometry with electron capture negative ionization in sewage sludge.

An unknown substance was detected in 25 out of the 50 samples screened, and its retention time corresponded to that of an EBP standard solution. Two sludges were chosen for identification and quantification (both from the group of small STPs, one anaerobically digested, and the other aerobically stabilized). EBP was positively verified in both samples, and the concentrations were estimated to be 52 and 32 ng/g (µg/kg) dry weight respectively.

The authors indicated that the method was not optimised for this compound, and recovery studies had not been performed. The substance was also detected in the procedural blank, but the amount present was less than 2% of the amount detected in the sample.

The levels in the remaining 23 sewage sludge samples were roughly estimated using a relative response factor between EBP and decaBDE from the two quantified samples, the peak areas of the two compounds in the screened samples, and the previously quantified decaBDE concentrations. The estimated levels in most samples were below those in the two quantified samples. The highest estimated level was about 100 ng/g dry weight. Some of the samples in which EBP was not detected could, however, potentially have EBP concentrations in this range because the final volume of the extracts was adjusted to the amount of decaBDE present in the samples. The authors recommended a more detailed study to confirm these results.

The authors noted that EBP was imported to Sweden in quantities below 15 tonnes in 2000. No correlation between EBP and STP size was observed. However, the substance was detected more frequently in sludge from STPs located in industrial and/or highly populated regions. All samples contained decaBDE in higher concentrations (EBP/decaBDE ratios ranging from 0.02 to 0.7).

Sediment

Kierkegaard *et al.* (2004) have performed the only monitoring study currently available. A concentration of 24 ng/g (µg/kg) dry weight was detected in a single sediment sample collected in 2001 from the Western Scheldt estuary (Nauw van Bath) in The Netherlands. The sample was dried, ground, sieved to <125 µm, and stored in amber glass jars until analysis. The analytical methods are mentioned in Section 3.3.1.2.1.

The Western Scheldt estuary is historically contaminated with decaBDE; the decaBDE concentration in the same sample was 1,280 ng/g dry weight, giving a substance/decaBDE ratio of 0.02.

Comparison of measured and estimated aquatic concentrations

Due to the limited amount of data, it is not possible to compare the estimated PECs with measured concentrations. Consequently, the modelled PECs (based on a large number of assumptions) are used for risk characterisation. It is recognised that they are likely to be conservative, and this is considered further in the risk characterisation (Section 5.1).

3.3.2 Terrestrial compartment

Estimated soil concentrations

The TGD method takes into account direct releases to soil, application of sewage sludge containing the chemical and atmospheric deposition. No direct releases to soil are expected in this case, and atmospheric deposition is likely to make a relatively small contribution in view of the low releases to air. The major contribution to soil PECs is therefore from the spreading of sewage sludge.

Different soil PECs are calculated depending on the protection goal. These vary in terms of the depth of soil considered, and the duration and/or route of exposure. Sludge application is assumed to occur once a year for 10 years. The concentration in soil is then calculated at

either 30 or 180 days after the last application of sludge (the 30-day average is used in the risk characterisation for soil organisms; the 180-day average is used to estimate exposure of animals and humans through the food chain).

At the regional level the soil concentration in unpolluted or ‘natural’ soil must be used as the background concentration, to avoid double counting of application through sludge. The PECs for the terrestrial compartment are given in Table 3.6.

Table 3.6 Terrestrial PECs

Life cycle stage	PEC_{soil} (mg/kg wwt)			$PEC_{porewater}$ (mg/L)
	30-d average	Agricultural	Grassland	(agricultural soil)
Polymer processing (combined compounding and conversion site)	2.2	2.2	0.89	1.2×10^{-4}
Textile backcoating formulation	96	96	38	5.4×10^{-3} a
Textile backcoating application	61	61	24	3.5×10^{-3} a
Regional	confidential			

a – higher than the measured water solubility.

The regional concentration is not given in the table, but makes only a small contribution to the PECs reported here.

The concentration in dry sewage sludge is estimated to be 150 mg/kg for the polymer processing scenario, and ~6,500 mg/kg for the two textile scenarios. The proposed EU standard for adsorbable organohalogens (AOX) in sewage sludge is 500 mg/kg dry matter (EC, 2000). AOX is defined as “the binding of halogen-containing chemical to activated carbon” which includes chlorinated and brominated organics. The two textile scenarios therefore lead to sewage sludge concentrations that are thirteen times higher than the proposed maximum allowable for agricultural use. If the sludge standard (500 mg/kg dry matter) is taken as a limit value, the 30-d average PEC would be 7.4 mg/kg wwt for the worst textile scenario.

Measured soil environmental concentrations

Due to the absence of data for soils, it is not possible to compare the estimated PECs with measured concentrations.

3.3.3 Atmospheric compartment

PECs for the air compartment have been estimated for each use pattern using EUSES, and are all significantly less than 1 $\mu g/m^3$.

There are no reported measurements of atmospheric concentrations from Europe (Venier *et al*. (2006) detected EBP in some air samples collected at five sites in the Great Lakes region of North America). EBP was detected at a level of 0.023 ng/m^3 in one of five air samples taken from Swedish households (Karlsson *et al*., 2007). It was also detected in household dust samples in the same study. EBP has also been detected in dust collected from the air of electronics recycling facilities (see Section 3.2.4.1). However, none of these data can be compared to the levels estimated using EUSES.

3.3.4 Food chain exposure

Estimated environmental concentrations

If a substance accumulates in the food chain, it might reach a concentration in food that could cause toxic effects in a predator that eats that food. This is referred to as secondary poisoning.
PECs for fish-eating predators have been calculated with EUSES using a BCF value of 25 L/kg, a default biomagnification factor of 1 (in accordance with the TGD recommendation for

a substance with a BCF below 2,000 L/kg) and the estimated PECs for surface water. Half of the dietary intake is assumed to come from local and half from regional sources, to take account of the fact that some species forage for food over a wide area. The PECs are shown in Table 3.7.

Table 3.7 PECs for secondary poisoning

Life cycle stage	PEC for fish eaten by predators (mg/kg wwt)
Polymer processing (combined compounding and conversion site)	2.4×10^{-3}
Textile backcoating formulation	0.10
Textile backcoating application	0.06

The PECs should be considered as an illustration only, since the fish BCF is not reliable (see Section 3.1.6); the uncertainty in the fish BCF is considered further in Appendix 1. The PECs for both of the textile scenarios are derived from aqueous concentrations that are in excess of the water solubility, which casts further doubt on their reliability.

PECs for the terrestrial food chain can not be estimated in the absence of information on earthworm bioconcentration.

Measured environmental concentrations in biota

Law *et al*. (2006) measured EBP in a pelagic food web of the south basin of Lake Winnipeg, Canada (see Section 3.1.6.3 for a summary of that paper and discussion of the results). EBP was detected in a few samples of all but one of the fish species examined at low ng/g (parts per billion, or µg/kg) levels. Since the source of exposure of these fish is unknown, the data cannot be compared with the calculated PECs.

Zhu & Hites (2006) detected EBP in tree bark samples collected in Arkansas, USA, linked to the two manufacturing facilities.

3.4 Human exposure via the environment

Only exposure via the environment is considered for the purposes of this assessment. A wider assessment of human exposure should also consider occupational exposures in the plastics and textiles industries (including recycling) and consumer exposure to flame-retarded articles (including exposure via dust).

3.4.1 Estimated daily intake

No data are available on measured levels in human diets in Europe. The exposure to humans via environmental routes has therefore been estimated using EUSES, and the results for the worst case scenario (textile backcoating formulation) are given in Table 3.8. The regional concentrations are substantially smaller. To be consistent with the degree of partitioning assumed for other compartments, a log K_{ow} of 7.5 has been assumed for the model, although it is recognised that this value could be higher (this is considered further in Appendix 1).

Table 3.8 Estimated worst case daily human intake values

Route	Predicted concentration	Estimated daily dose (mg/kg bw/day)
Wet fish	0.2 mg/kg	3.3×10^{-4}
Root tissue of plants	1,000 mg/kg	5.7
Leaves of plants	7×10^{-3} mg/kg	1.2×10^{-4}
Drinking water	5.4 µg/L	1.6×10^{-4}
Meat	1.5 mg/kg	6.3×10^{-3}
Milk	0.46 mg/kg	3.7×10^{-3}
Air	3.5×10^{-7} mg/m^3	9.9×10^{-8}
Total local daily dose	**-**	**5.7**

Around 99% of the predicted dose arises from consumption of root crops. However, the values should be considered with caution because:

- The model tends to overestimate root concentrations for highly hydrophobic substances like EBP.
- The drinking water concentration is around an order of magnitude higher than the solubility in pure water. This is based on the soil pore water concentration, which is directly used to estimate levels in root crops. If the soil pore water concentration is limited to the water solubility of the substance, the root crop concentration reduces to 140 mg/kg (see Section 4.2.1.3), leading to an estimated overall daily dose of ~0.8 mg/kg/d.

4 Effects assessment

The following sections provide a summary of the toxicity of the substance towards organisms. The information is taken directly from study reports provided by Albemarle unless otherwise indicated.

4.1 Aquatic compartment (including sediment)

4.1.1 Toxicity to fish

Acute toxicity

Freshwater species

A 96-hour acute toxicity test has been performed with the rainbow trout *Oncorhynchus mykiss* in accordance with OECD test guideline 203 and GLP (Blankinship & Krueger, 2003a). Test solutions were prepared as water accommodated fractions (WAFs) using various loading rates, by stirring EBP in water for approximately 48 hours, then siphoning off an appropriate volume following settling for one and a half hours. No effects on mortality were evident at any concentration including the highest loading rate of 110 mg/L. No analytical measurements were made to determine actual exposure concentrations.

The study implies that the substance is not acutely toxic to fish at levels of water saturation. Given the excess of test substance used to make the WAF, it could be assumed that the water solubility limit – ~0.72 µg/L at 25°C – was reached. Nevertheless, Albemarle (2005) suggests that the substance is highly adsorptive to glassware, as might be expected for such a poorly soluble substance. Aquatic toxicity tests should therefore be designed to minimise potential losses, for example by using suitable test vessels and flow-through exposure regimes. Analytical verification of actual exposure concentrations is also important for results to be considered fully valid.

The stainless steel test vessels used in this study should have reduced adsorption compared to glassware. However, the study used a static test design, and the actual EBP concentrations in solution were not confirmed. The results should therefore be treated with a degree of caution. Albemarle has commented that the study used the WAF methodology because stable and measurable water concentrations could not be generated with EBP, despite significant efforts (Albemarle, personal communication).

A second study (performed prior to the analytical determination of the water solubility) is reported by the Chemicals Inspection & Testing Institute (CITI, 1991), as part of preparatory work for a bioaccumulation study (see Section 3.2.6). The test was performed with the orange-red killifish *Oryzias latipes* (now more generally known as the Japanese medaka) over 48 hours with semi-static renewal every 8-16 hours according to Japanese Industrial Standard JIS K 0102-1986-71. The test solution was prepared by milling EBP with a dispersant[29] and then dissolving mix in deionised water to obtain a 1000 mg/L stock solution. No mortalities were recorded over the 48 hour period (at a stated test concentration of 50

[29] Crystal sugar and polyoxyethylene sorbitan monooleate (HCO-40), both at 20 times the test substance.

mg/L – the report does not indicate how this was made from the stock solution, although it was presumably by dilution). This – presumed nominal – concentration is over four orders of magnitude higher than the solubility in pure water of around 0.72 µg/L (the study report records a water solubility of <10 mg/L by visual inspection). These results suggest that EBP was not truly in solution. Despite the method of test solution preparation, which is now no longer preferred for this type of test (see OECD, 2000), the results support the former study.

Saltwater species

No data are available.

Chronic toxicity

No long-term fish toxicity data are currently available for either fresh or salt water species. However, some information is available from an eight-week bioaccumulation study with carp (*Cyprinus carpio*) under continuous flow-through conditions (CITI, 1991). Two exposure concentrations were used (0.5 and 0.05 mg/L), which were achieved using dispersant. These concentrations are at least two orders of magnitude higher than the measured solubility in pure water (see Section 3.2.6 for further discussion of this test). No abnormalities in behaviour or appearance were observed during this study, although the fish were not necessarily at a sensitive life stage (the fish were 24.6 g in weight and 9.8 cm long on average at the start of the test – a length of 3.0±1.0 cm is recommended for this species in OECD guideline 203 for acute toxicity).

4.1.2 Toxicity to aquatic invertebrates

Acute toxicity

Freshwater species

A 48-hour acute toxicity test has been performed with the cladoceran (commonly known as the water flea) *Daphnia magna* in accordance with OECD test guideline 202 and GLP (Blankinship & Krueger, 2003b). Test solutions were prepared as water accommodated fractions as for the fish study. No effects were evident at any concentration including the highest loading rate of 110 mg/L. No analytical measurements were made to determine actual exposure concentrations.

The study implies that the substance is not acutely toxic to *D. magna* at saturated concentrations (assumed to be up to the water solubility limit). A static test design was used, and the actual concentrations in solution remain unconfirmed – adsorption to the glass test vessels cannot be ruled out. As for the fish test, interpretation of the result may therefore need a degree of caution.

Saltwater species

No data are available.

Chronic toxicity

No long-term invertebrate toxicity data are currently available in either fresh or salt water species.

4.1.3 Toxicity to aquatic primary producers

Freshwater species

A 96-hour toxicity test has been performed with the alga *Selenastrum capricornutum*[30] in accordance with OECD test guideline 201 and GLP (Desjardins & Krueger, 2003). Test solutions were prepared as water accommodated fractions using algal culture medium in a similar way as for the fish study. No effects for any growth parameter (biomass or growth rate) were evident at any concentration including the highest loading rate of 110 mg/L. No analytical measurements were made to determine actual exposure concentrations.

The study implies that the substance is not acutely toxic to algae at saturated concentrations (assumed to be up to the water solubility limit). A static test design was used (which is typical for tests with algae), and the actual concentrations in solution remain unconfirmed – adsorption to the polycarbonate test vessels cannot be ruled out. As for the other aquatic tests, the result may therefore need to be treated with a degree of caution.

Saltwater species

No data are available.

4.1.4 Sediment-dwelling organisms

Insects

A prolonged sediment toxicity test using spiked sediment has been carried out with the midge *Chironomus riparius* (Krueger *et al*., 2003a). The test protocol was based on the OECD draft test guideline 218 (February 2001) and was performed to GLP. Artificial sediment was used, with alpha-cellulose as the source of organic matter. The test sediment was described as a loamy sand, with an organic matter content of 3.1% (and an organic carbon content of 1.8%). EBP was added directly to dry sediment for each exposure concentration, and mixed for 44 hours (the study report mentions a solvent control in one paragraph, but this is presumably a typographical error since solvent was not used in the test). Water was then added, and the test system allowed to equilibrate for 48 hours before the midge larvae were introduced.

Groups of midge larvae were exposed to a geometric series of five nominal test concentrations (313, 625, 1,250, 2,500 and 5,000 mg/kg dry weight) and a control for 28 days at 20±2°C using a static system. The larvae were fed with ground rabbit pellets throughout the test.

Analysis of the concentration of EBP in sediment, pore water and overlying water was carried out for the control and both the lowest and highest test concentrations at days 0, 7 and 28,

[30] This species has now been renamed *Pseudokirchneriella subcapitata*.

using HPLC. The limit of quantitation of the analytical method was 100 mg/kg for sediment samples, and 1 mg/L for the water samples. All measured water concentrations were below the quantitation limit (which is significantly higher than the solubility of the substance in pure water). The measured concentrations were ≥ 87% of nominal in all sediments analysed. The results are therefore presented in terms of nominal concentrations.

A small number of emerged adults in three treatment groups showed signs of both lethargy and a loss of equilibrium, and there were a few deaths of both larvae and adults too. All of these findings were considered incidental to treatment because of their low occurrence, inconsistency across replicates within a treatment group and lack of a concentration-dependent pattern. The report concludes that there were no treatment-related effects on mortality, development time, emergence rates or development rates. This study therefore suggests an unbounded NOEC of 5,000 mg/kg dry weight.

Oligochaetes

A prolonged sediment toxicity test using spiked sediment has been carried out with the oligochaete *Lumbriculus variegatus* (Krueger *et al*., 2003b). The test protocol was based on the ASTM E 1706-95b Guideline and USEPA Series 850 Ecological Effects Test Guidelines (OPPTS No. 850.1735) and was performed to GLP. The sediment and test system was essentially the same as in the *Chironomus* test, except that a flow-through renewal regime was used (approximately two volume additions of water per day).

Groups of adult oligochaetes were exposed to a geometric series of five nominal test concentrations (313, 625, 1,250, 2,500 and 5,000 mg/kg dry weight) and a control for 28 days at 23±2°C. The organisms were fed with salmon starter every three days throughout the test. Analysis of the concentration of EBP in sediment, pore water and overlying water was carried out in the same way as the *Chironomus* test. The measured concentration in the water samples was below the limit of quantitation by the analytical method. As the measured concentrations were ≥ 89% of nominal in all sediments analysed, the results are reported based on the nominal concentrations.

The endpoints determined in the study were survival/reproduction and growth. There was a statistically significant ($p<0.05$) reduction in the number of oligochaetes in the 2,500 mg/kg treatment group (11.1) compared to the control (15.5), but this decrease was considered incidental because no statistically significant effect was seen at the highest concentration of 5,000 mg/kg. There were no treatment-related effects on growth. This study therefore suggests an unbounded NOEC of 5,000 mg/kg dry weight.

Since EBP was added to the sediment at the start of the test, and was not present in the influent water, the flow-through test system has the potential to cause loss of test substance during the exposure period. However, the water solubility of EBP is very low and the monitoring data from the sediment itself indicated that the concentrations were well maintained throughout the test. The actual loss in the flow-through water was therefore probably very small and unlikely to affect the results of the test.

Observations on sediment toxicity studies

Both the *Chironomus* and oligochaete tests used sediment with an organic carbon content of 1.8%. The aim is to maximise the availability of the substance in the pore-water phase. Since EBP is expected to be highly adsorptive, and has low water solubility, the majority of the substance would still be found mainly on the solid phase (as indicated by the analytical measurements). The substance could therefore still contribute to toxicity if direct ingestion of

sediment-bound substance is an important route. The sediment choice appears to have maximised the potential for exposure through both pore water and direct ingestion.

However, the TGD recommends that sediment toxicity test methods should try to ensure that exposure via food cannot be avoided for highly adsorptive substances. In these two studies, fresh food was provided throughout (in accordance with the guidelines). Since EBP was not present in the food, it is possible that the results of the tests could underestimate the actual toxicity because the organisms' exposure to the substance could potentially have been reduced during the course of the test. For example, in the case of *Lumbriculus*, the provision of fresh food might make the organisms less likely to burrow. In fact, there was a general trend to have greater numbers of oligochaetes on the surface of the sediment and screens in the treatment groups compared to the controls. The significance of this route of exposure for EBP therefore remains unknown.

In addition, there was no check as to whether the equilibration time was sufficiently long to achieve a homogenous dispersion of the substance throughout the sediment in either study.

Despite these criticisms, the lack of any substantial effects at the highest test concentrations suggests that EBP is not significantly toxic to either midge larvae or oligochaetes. It is not known whether a longer exposure period might alter this conclusion.

4.1.5 Wastewater treatment plant micro-organisms

No toxicity tests have been performed, and no information can be derived from the ready biodegradation test (see Section 3.2.2.2). This is a data gap, although the substance does not appear to cause toxic effects to other aquatic organisms over short exposures, and the same is likely to be true of micro-organisms.

4.1.6 Other sources of toxicity information

Quantitative structure–activity relationships

In view of the absence of long-term toxicity data for fish and invertebrates, toxicity could also be predicted using quantitative structure-activity relationships (QSARs). Many QSAR models are available, but they are generally based on relationships between toxicity and log K_{ow}. Given the problems with identifying a reliable value for this parameter (see Section 1.3.7) it is considered unhelpful to predict toxicity this way.

Read across from structural analogues

As for other end points in this assessment, it may be relevant to consider the available toxicity data for decaBDE (EC, 2002), although small differences in physico-chemical properties and molecular structure (e.g. the ethane bridge versus an ether linkage) may affect bioavailability and metabolism.

A lack of long-term aquatic effects up to the water solubility limit was inferred from aquatic tests on related polybromodiphenyl ethers. DecaBDE was tested with *Lumbriculus variegatus* in two different sediments over 28 days; no effects were seen and the lowest NOEC was 3,841 mg/kg dry weight. DecaBDE did not inhibit the respiration of WWTP micro-organisms up to a concentration of 15 mg/L (EC, 2002).

4.1.7 Predicted no-effect concentrations (PNECs) for the aquatic compartment

Calculation of a PNEC for surface water

Acute toxicity results are available for fish, invertebrates and algae (see Sections 4.1.1-4.1.3). Although there are a number of drawbacks with these studies (e.g. the use of static exposures), no toxic effects were observed in any of the tests, so it is not possible to derive a meaningful PNEC for surface water (fresh or marine) based on these data.

The TGD suggests that the PNEC can be set at 1/100th of the water solubility value as a worst case. For EBP, this would produce a PNEC of ~7 ng/L. However, this value is likely to be unrealistically low. For example, there is no evidence of significant long-term toxicity in either the algal test[31] or the bioconcentration test with fish. A further measure of long-term toxicity is provided by two tests with freshwater sediment-dwelling invertebrates. No statistically significant effects were observed at concentrations up to 5,000 mg/kg dry weight (equivalent to 1,086 mg/kg wet weight using EUSES). This can be converted to a pore water NOEC if equilibrium partitioning were assumed using the following equation (TGD, 2003):

$$NOEC_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \cdot NOEC_{water} \cdot 1000$$

where $NOEC_{sed}$ is the No Observed Effect Concentration in sediment (mg/kg wwt)
$NOEC_{water}$ is the No Observed Effect Concentration in water (mg/L)
RHO_{susp} is the bulk density of wet suspended matter (1,150 kg/m^3)
$K_{susp\ water}$ is the suspended matter-water partition coefficient (2.5 x 10^4 - although there is some uncertainty associated with this value (see Section 3.1.5.1.1))

In this case, the pore water NOEC would be 50 µg/L, which is significantly greater than the water solubility of ~0.72 µg/L. In other words, no effects are apparent up to the water solubility limit. This provides some additional evidence that long-term toxicity to pelagic species is unlikely.

It is therefore not considered useful to derive a PNEC for surface water.

Calculation of PNEC for sediment

Two long-term toxicity tests have been performed with freshwater sediment-dwelling organisms. No statistically significant effects were observed with either *Chironomus* or *Lumbriculus* at the highest concentrations tested (5,000 mg/kg dry weight in both cases). The $PNEC_{sediment}$ is therefore ≥ 100 mg/kg dry weight, based on this unbounded NOEC and an assessment factor of 50 (in accordance with the TGD).

Since the sediment PECs are calculated in terms of wet weight, a dry to wet weight conversion is necessary. EUSES 2.0 does this automatically, and the equivalent values are a NOEC of ≥ 1,090 mg/kg wet weight, and a $PNEC_{sediment}$ of ≥ 21 mg/kg wet weight.

[31] The TGD recommends that 72-hour (or longer) EC_{50} values for algal growth are considered equivalent to a short-term result, and that a 72-hour (or longer) NOEC is considered as a long-term result.

The sediment PECs are also estimated assuming a standard sediment organic carbon content of 5%. This is higher than the actual organic carbon content of the test sediments (1.8%), and so normalisation can be performed (this is recommended in some circumstances for soil data, but no guidance is given for sediment). The corrected $PNEC_{sediment(standard)}$ would be ≥ 60 mg/kg wet weight, and this value is used in the risk characterisation.

A PNEC for marine sediments can also be estimated from this value, using an additional factor of 10 to account for increased species diversity. The marine $PNEC_{sediment(standard)}$ is therefore ≥ 6 mg/kg wet weight.

Calculation of PNEC for WWTP micro-organisms

No toxicity test data are available and so a $PNEC_{WWTP}$ cannot be derived.

4.2 Terrestrial compartment

4.2.1 Terrestrial toxicity data

Plants

A prolonged toxicity test has been carried out with six species of plants (Porch & Krueger, 2005). The test protocol was based on the US EPA OPPTS Guideline 850.4100 and 850.4225, and OECD test guideline 208 (proposed revision of 2000), and was performed to GLP. Artificial soil was made by mixing kaolinite clay, industrial quartz sand and peat. Crushed limestone and a slow-release fertiliser were also added. The particle size distribution of the soil was 50% sand, 28% silt and 22% clay. The soil had a pH of 6.5 and an organic matter content of 2.7% (the organic carbon content is not provided, but can be estimated as about 1.6%). The commercial EBP used in the tests was of slightly lower purity than that indicated in Section 1.2, at 97.5%. The substance was mixed with sand before addition to the bulk soil and mixing for between 15 and 20 minutes. Soil moisture was between 10 and 11.6%. After mixing, three subsamples of the soil were collected for analysis to confirm the initial concentration of the test substance within the treated soil, and also to determine its homogeneity. The samples were frozen after collection until they were analysed.

The following six plant species were tested:

- Monocotyledons: corn (*Zea mays*), onion (*Allium cepa*) and rye grass (*Lolium perenne*);
- Dicotyledons: cucumber (*Cucumis sativa*), soybean (*Glycine max*) and tomato (*Lycopersicon esculentum*).

The initial test for onion and tomato had to be repeated due to inadequate control emergence.

Each species was exposed to a series of five nominal test concentrations (391, 781, 1,563, 3,125 and 6,250 mg/kg dry weight) and a control for 21 days. Water lost by transpiration and evaporation was replaced by sub-irrigation (to minimise leaching). Weekly observations of emergence (number of emerged seedlings per pot) were made. At the termination of the test, the growth of the emerged seedlings was evaluated in terms of the mean shoot height and the mean shoot dry weight. A qualitative assessment of the condition of each seedling was also made (i.e. presence or absence of signs of phytotoxicity such as colour changes, necrosis, leaf wrinkling, chlorosis, plant lodging or plant stunting).

Analysis of the concentration of EBP in soil was carried out using HPLC. The limit of quantitation of the analytical method was 100 mg/kg. Analysis indicated that the mean measured concentrations at day 0 were generally at least 93% of the nominal value (one soil in each of the two repeat tests had a lower recovery, of 86 and 75% nominal). The results are therefore presented in terms of nominal concentrations.

No adverse effects on any endpoint were reported for corn, rye grass or soybean up to the highest concentration tested (6,250 mg/kg dry soil). Some reduction in mean height and weight were observed relative to the controls, but these showed no dose-response relationship and so were considered incidental to treatment.

Slight effects were reported for the other three species as follows:

- *Cucumber:* The group mean survival was reduced by 18% at the highest test concentration of 6,250 mg/kg dry soil, and this was significantly different ($p<0.05$) from the control mean.
- *Onion:* Reductions in mean height relative to controls of 22 and 24% were observed at the two highest concentrations (3,125 and 6,250 mg/kg respectively). Although the dose-response was not monotonic across all the treatment groups, these height reductions were statistically significant ($p<0.05$), and were accompanied by weight reductions of 32 and 30% respectively.
- *Tomato:* Effects on height and dry weight were observed at the highest concentration of 6,250 mg/kg dry soil, with reductions of 37 and 40% respectively compared to controls, and these were statistically significant ($p<0.05$).

Consequently, the most sensitive species was onion, with a NOEC of 1,563 mg/kg dry soil. Based on the dose-response, an EC_{25} of 2,440 mg/kg dry weight was calculated.

Earthworms

A prolonged toxicity test has been carried out with the earthworm *Eisenia fetida* (Aufderheide, 2003). The test protocol was based on the US EPA OPPTS Guideline 850.620, OECD test guideline 207 and the proposed OECD guideline for earthworm reproduction (2000), and was performed to GLP. Artificial soil was made by mixing 70% silica sand, 20% kaolin clay and 10% sphagnum peat. No information is provided on organic matter or carbon content (a similar experiment was conducted with decaBDE, with soil prepared in a similar way; in that study, the soil organic matter content was reported to be 4.7%, equivalent to about 2.7% organic carbon (EC, 2002)). The pH of the artificial soil was adjusted to 6.0±0.5. The water holding capacity of the soil was determined to be 61 mL/100 g dry soil and the percentage water at 60% of the water holding capacity was calculated to be 23% on a soil dry weight basis. EBP was added directly to air-dried soil for each exposure concentration, and mixed for at least 24 hours before hydration to ~60% of the water holding capacity with an appropriate volume of deionised water.

Groups of adult worms were exposed to a series of five nominal test concentrations (313, 625, 1,250, 2,500 and 5,000 mg/kg dry weight) and a control for 56 days at 20±2°C. The worms were fed with 3-4 mL of invertebrate diet slurry at least weekly during the first 28 days of exposure, which was deposited 1-2 cm below the soil surface. A reduced quantity of food was added during the final 28 days (1-3 mL per week).

After 28 days, the content of each test chamber was removed to determine the number and weight of surviving worms and to observe any behavioural or pathological abnormalities. Following these observations, the test soil was returned to the chambers and worms replaced on the soil surface in order to observe burrowing behaviour. At the end of the test, the number of juvenile worms was determined.

Analysis of the concentration of EBP in soil was carried out for each treatment on days 0, 28 and 56, using HPLC after extraction with dibromoethane. Samples were also collected just prior to test initiation to check the homogeneity of the substance in the soils. The limit of quantitation of the analytical method was 227 mg/kg dry soil. The results show that the soils were adequately mixed prior to test initiation. The overall mean measured concentrations ranged from 61 to 76% of nominal, and there was an apparent decline during the course of the test in almost all treatments (see Table 4.1). The results are therefore presented in terms of mean measured concentrations.

Table 4.1 Measured EBP soil concentrations in the earthworm test (units are mg/kg dry weight)

Nominal	Day 0		Day 28		Day 56		Mean	
	Measured	% nominal	Measured	% nominal	Measured	% nominal	Measured	% nominal
313	289	*92*	227	*73*	178	*57*	231	***74***
625	546	*87*	448	*72*	326	*52*	440	***70***
1,250	1,020	*82*	516[a]	*41*	746	*60*	761	***61***
2,500	2,210	*88*	1,760	*70*	1,750	*70*	1,910	***76***
5,000	4,280	*86*	3,330	*67*	3,560	*71*	3,720	***74***

a - This low value is a mean and was confirmed by duplicate re-analysis.

The control treatment response was within the expected range for each parameter. Animal survival and weight gain was not adversely affected at any treatment level. The NOEC for survival was therefore ≥3,720 mg/kg dry weight (mean measured concentration).

There was, however, a statistically significant ($p<0.05$) reduction in reproductive output at the highest test concentration (18 juveniles per replicate) compared to the control (44 juveniles per replicate). The 56-day reproduction NOEC was therefore 1,970 mg/kg dry weight based on mean measured concentrations. The corresponding LOEC was 3,720 mg/kg dry weight.

Observations on soil toxicity studies

Both of the soil tests produced some evidence of toxicity, when none was observed in any of the aquatic tests. The plant test presumably involves exposure via the pore water only, and these data would suggest that the substance is bioavailable and can exert effects under such conditions. Although effects were only seen at high soil concentrations, the influence of dissolution kinetics is not known – i.e. it is possible that at lower concentrations insufficient time was allowed for the substance to reach a saturated pore water concentration.

These results are unexpected given the findings from the aquatic tests and the very low water solubility of the substance. No measurements of plant uptake were made. However, the concentration in plant roots can be estimated by assuming that the uptake from water can be estimated from the K_{ow} (which is itself an uncertain value in this case) using the following equation (TGD, 2003):

$$Croot_{plant} = \frac{K_{plant-water} \times C_{porewater}}{RHO_{plant}}$$

where $Croot_{plant}$ = concentration in root tissue
$K_{plant\text{-}water}$ = partition coefficient between plant tissue and water
$C_{porewater}$ = concentration in soil pore water
RHO_{plant} = bulk density of plant tissue = 700 kg/m^3 (default)

If it were assumed that the soil pore water were saturated with EBP, and that the concentration is ~0.72 µg/L (or ~0.72 mg/m^3, i.e. the solubility in pure water), then the resulting concentration in plant roots would be ~140 mg/kg ($K_{plant\text{-}water}$ based on a log K_{ow} of ~7.5, to be consistent with the assumed K_{oc} value).

Other explanations for the observed effects in plants are that:

- the substance somehow interferes with nutrient uptake (e.g., due to some sort of physical effect);
- a degradation product or metabolite is involved.

Given that this is speculation, and that three out of six species were affected, the results will be assumed to be due to a toxicological response in the absence of further information.

EBP is not readily biodegradable or volatile, and so the decline in soil concentration from ≥82% down to 52-71% of nominal over 56 days in the earthworm test is also surprising. One test concentration dipped to 41% of nominal midway through the test, before rising to 60% at the end. There are several possible explanations for this observation including:

- Binding to soil particulates or the container walls could mean that less EBP was available for extraction as time went on. This has been observed with some pesticides for example, although the substance would not be expected to bind ionically or covalently with the soil matrix. The lack of experimental K_{oc} data for the substance itself makes it difficult to know if this is relevant, but there could be important implications for the soil PEC estimates if it were (since the substance would become less bioavailable with time).
- The extraction technique and analytical method might not have been completely reliable.
- The distribution of the test substance in the soil might not have been as homogeneous as was thought.
- The substance could have degraded. The data provider has reported that there was no evidence of formation of substances with shorter retention times than the test substance on the HPLC chromatograms (Albemarle, personal communication). The chromatograms are not presented in the study report, and the raw data have not been requested by the Environment Agency to confirm this.

Without further work, it is not possible to conclude which (if any) of these factors was involved. It should also be noted that the plant test was half of the duration of the earthworm test, and so losses would have been lower.

Data from structural analogues

Toxicity data for decaBDE are available for plants and earthworms (EC, 2002). No effects were seen with the same six species of plants over 21 days at concentrations up to 5,349 mg/kg dry weight. The 56-day NOEC from the earthworm reproduction study was ≥4,910 mg/kg dry weight.

4.2.2 Predicted no-effect concentration (PNEC) for the soil compartment

Toxicity data are available for plants and earthworms. Some toxic effects were observed at relatively high concentrations for three out of six plant species, as well as for earthworms. The most sensitive plant species was onion, with a NOEC of 1,563 mg/kg dry weight; the earthworm NOEC for reproduction is 1,970 mg/kg dry weight.

The TGD suggests that soil organism NOECs should be normalised to the standard organic matter content of soil of 3.4% as used in the TGD when it can be assumed that:

- Simple partitioning with organic matter drives the binding behaviour (rather than a chemical reaction). This would be expected for EBP due to a lack of ionic or reactive functional groups.
- Organisms are exposed predominantly via pore water. The situation with earthworms is unknown, but they would have been exposed to significant levels adsorbed to soil particles. It is presumed that the toxic effects on plants involved pore water exposure.

The soil organic carbon contents were not measured, but have been estimated for this assessment. In addition, the NOECs also have to be converted to wet weight for comparison with the soil PECs.

A $PNEC_{soil(standard)}$ of 26 mg/kg wet weight is calculated by EUSES from these data using an assessment factor of 50.

4.3 Atmospheric compartment

There are no data on the effects of EBP through aerial exposure of non-mammalian organisms. There is no indication from similar substances of effects on terrestrial plants via atmospheric exposure. Abiotic effects (e.g. global warming, ozone depletion/formation, etc.) are unlikely to occur given the very low vapour pressure and low reactivity of the substance. A PNEC has therefore not been derived.

4.4 Mammalian toxicity

4.4.1 Toxicokinetics

Studies in animals

Oral

The absorption and excretion of EBP have been investigated in the rat following a single exposure by the oral route (MRI, 2004).

Groups of six Sprague-Dawley rats were to be given a single dose of 100 mg/kg/d or 1,000 mg/kg/d EBP (50 µCi/kg) by intravenous administration and oral gavage respectively. However, during the validation phase of the study, ^{14}C-EBP was found to be insoluble in any solvent compatible with intravenous administration. Also, it was observed that its physico-chemical properties prevented its complete oxidation in faeces and tissue samples, thereby limiting the ability to measure $^{14}CO_2$-related activity in these samples. Therefore, the intravenous administration portion of the study could not be performed and radioactivity was measured in samples (i.e. plasma, urine, bile) that could be counted directly via liquid scintillation only.

Three groups of six animals were administered a single dose of 1,000 mg/kg (50 µCi/kg) ^{14}C-EBP suspended in corn oil by gavage. At various intervals for up to 168 hours post-dosing, urine and faeces were collected from the group 1 animals (conventional), blood samples from the group 2 animals (jugular vein-cannulated) and bile and blood samples from the group 3 rats (jugular vein- and bile duct-cannulated). Radioactivity was then measured by liquid scintillation counting in the different samples of urine, plasma, cage rinse and bile. Tissue samples (brain, liver, fat, gastrointestinal tract, kidney and spleen) and residual

carcasses were removed and together with the faeces were stored for future reference in case a suitable method of radioanalysis is developed.

No radioactivity was detected in any of the samples collected at any time interval. The absence of measurable activity suggests that in this study, EBP was poorly absorbed by the oral route.

Inhalation

No studies are available.

Studies in humans

There are no data available.

Summary of toxicokinetics

No information is available on the toxicokinetics of EBP in humans.

In animals, EBP was poorly absorbed via the oral route. No radioactivity was detected in the analysable samples (plasma, bile, and urine) following a single dose of EBP suspended in corn oil, although this may have been influenced by the particle size of the test material in suspension. No data are available on distribution, metabolism and excretion following oral absorption; however, based on the poor absorption, general systemic distribution of EBP (and/or its metabolite(s)) following oral exposure is likely to be low. There are no data available for the inhalation and dermal routes of exposure. However, it can be predicted from the physico-chemical properties that absorption following inhalation or dermal exposure is likely to be very low. For risk characterisation purposes, a worst-case estimate of 10% is assumed for all three routes of exposure.

4.4.2 Acute toxicity

Studies in animals

Inhalation

There are no studies available.

Oral

In a limit test compliant with GLP standards and OECD guidelines, 10 Sprague-Dawley rats (five males and five females) were administered a single dose of 5,000 mg/kg EBP suspended in 0.25% methylcellulose by oral gavage and were observed for fourteen days (Mallory, 1988a). Clinical signs of toxicity, mortality and central nervous system (CNS) effects in the animals were monitored daily and the bodyweights recorded at study initiation and at seven day intervals thereafter.

All animals survived until scheduled sacrifice on day 14. No signs of toxicity were observed and no visible lesions/effects on any tissue/organ were seen on gross examination at necropsy.

Based upon the results of this study, EBP is considered to be of low acute oral toxicity. The oral LD_{50} in the rat was determined to be greater than 5,000 mg/kg.

The safety data sheet for the substance manufactured by Chemtura Corporation also gives an oral LD_{50} in the rat of >5,000 mg/kg (Great Lakes, 2003).

Dermal

A well-conducted study performed to GLP and OECD test guidelines in rabbits is available. EBP (2,000 mg/kg) moistened with saline was applied directly on shaved intact skin of 10 New Zealand White rabbits (five males and five females) under occlusive conditions for 24 hours (Mallory, 1988b). Following exposure, the wrappings were removed and the residual test article washed off the skin using water. Clinical signs, mortality and bodyweights were monitored and recorded till scheduled sacrifice on day 14.

There were no effects on bodyweights and none of the animals died during the study. The only clinical sign seen was diarrhoea in one animal. At necropsy, no lesions were found in any tissue/organ on gross examination.

The results of this study indicate that EBP is of low acute dermal toxicity. The dermal LD_{50} in the rabbit was estimated to be above 2,000 mg/kg.

The safety data sheet for the substance manufactured by Chemtura Corporation also gives a dermal LD_{50} in the rat of >2,000 mg/kg (Great Lakes, 2003). No test report has been reviewed.

Studies in humans

No data are available.

Summary of acute toxicity

No information is available on the effects of single exposure in humans.

In animals, EBP is of low acute toxicity via the oral and dermal routes of exposure with no deaths and no signs of systemic toxicity resulting from exposure of rats and rabbits at the limit doses specified in the OECD testing guidelines (i.e. 5,000 mg/kg and 2,000 mg/kg respectively). With regards to exposure via inhalation, there are no studies available. However, given that EBP bioavailability following inhalation exposure is likely to be low, EBP is predicted to be of low acute inhalation toxicity.

4.4.3 Irritation

Studies in animals

Skin

A study in rabbits performed to GLP and OECD test guidelines is available. A dose of 500 mg of EBP moistened with saline was applied to the shaved skin of six New Zealand White rabbits (three males and three females) under occlusive conditions for four hours (Mallory,

1988c). Following exposure, the application site was rinsed off with water and observed for signs of irritation (erythema and oedema) with scores recorded at 1, 24, 48, and 72 hours post-treatment. No signs of skin irritation were observed; the mean 24-72 hour score for erythema and oedema was 0.

The results of this study indicate that EBP is not a skin irritant in rabbits.

Eye

The potential of EBP to cause eye irritation was investigated in a study performed to GLP and OECD test guidelines in the rabbit (Mallory, 1988d). EBP (100 mg) was instilled into the conjunctival sac of one eye of each of six albino New Zealand rabbits (three males and three females) and the eyes were examined at 1, 24, 48 and 72 hours post-application.

No iridial or corneal effects were noted at any of the time points. Conjunctival redness (score 1) was noted in all of the animals at 1 hour. This persisted until 48 hours in one male only. No effects were seen in any of the animals at 72 hours.

Overall, EBP was not considered to be an eye irritant in this study.

Respiratory Tract

The safety data sheet for the substance manufactured by Chemtura Corporation states that it may cause irritation to the respiratory system (Great Lakes, 2003). This may be because the substance is a powder, but no further information is currently available.

However, given the particle size, the generally unreactive nature of the substance and the absence of skin and eye irritation potential, it is reasonable to conclude that EBP is not a respiratory tract irritant.

Studies in humans

There are no data available.

Summary of irritation

There are no data available regarding EBP potential to cause skin, eye or respiratory tract irritation in humans. However, based upon two standard animal studies, EBP has been shown not to cause skin or eye irritation. There are no specific data on respiratory tract irritation, but the particle size, absence of skin or eye irritation and the generally unreactive nature of EBP suggest that it would not irritate the respiratory tract.

4.4.4 Corrosivity

From the data presented in Section 4.4.3 it is evident that EBP is not a corrosive chemical.

4.4.5 Sensitisation

Studies in animals

The sensitisation potential of EBP has been investigated in a guinea pig maximisation test (Newton, 2003). Forty guinea pigs were divided into three groups: a treatment group of 20 animals (10 male, 10 female) and negative and positive control groups of 10 animals each (five male and 5 female in each group). For the induction phase, the test animals were injected intradermally with 5% EBP and 50% Freund's Complete Adjuvant (FCA). The control animals were given the vehicle intradermally (0.5% methylcellulose) and 50% FCA, and the positive control animals were injected with 5% hexylcinnamic aldehyde (HCA) and 50% FCA. The test concentration level was selected based on an initial irritation screening test. A week after the injection, patches of the vehicle, positive control (100% HCA) or EBP (100%) were applied topically to the shaved test sites under occlusive wrappings for 48 hours.

Fourteen days post-induction, animals were challenged by applying topical patches of EBP (1% suspended in 0.5% methylcellulose) occlusively to the shaved left flank, and of the vehicle (0.5% methylcellulose) to the right flank of the control and treated groups. For the positive control group, HCA (50% in mineral oil) was applied occlusively to the left flank and mineral oil to the right flank. The patches were removed after 24 hours and the challenge sites scored for dermal irritation at 24 and 48 hours thereafter.

A positive response (mild erythema) was observed at 24 hours in 90% of the animals in all of the groups. At the 48-hour observation, the percentage of animals with a positive response in the negative control and test groups was reduced to 20% (2/10-control, 4/20-treated) whilst 50% of the positive control animals showed a reaction. At 24 hours the results in the negative control animals were comparable to those of the positive control animals, and given that EBP is not a skin irritant, these findings cannot be interpreted. However, it is predicted that EBP would have low potential to cause skin sensitisation given that it is generally unreactive.

Studies in humans

Skin

There are no data available.

Respiratory Tract

There are no data available.

Summary of sensitisation

No data are available on the skin or respiratory sensitisation potential of EBP in humans. In animals, a guinea-pig maximisation test has produced inconclusive results. Overall, however, the generally unreactive nature of EBP would suggest a very low skin or respiratory sensitisation potential.

4.4.6 Repeated dose toxicity

Studies in animals

Inhalation

No studies are available.

Oral

Two studies in the rat are available, which have investigated the repeated dose toxicity of EBP over periods of 28 and 90 days. The results of the 90-day study have been published (Hardy *et al*., 2002).

28 day study
In a study conducted to GLP standards and OECD guidelines, groups of six male and six female Sprague-Dawley (SD) rats were dosed with 0, 125, 400 and 1,250 mg/kg/d EBP (purity 96.3%) suspended in corn oil by gavage 7 days/week for 28 days (Margitich, 1991). No rationale was provided in the study report for how the dose levels were selected. An additional six animals per sex were included in the control and high-dose groups for a recovery analysis. Clinical signs were monitored daily and body weights and food consumption were analysed weekly. Clinical chemistry, haematology, urinalysis, opthamological examinations, gross and histopathological investigations were also conducted.

No treatment-related deaths or clinical signs were observed and there were no adverse effects on terminal bodyweights, bodyweight gain or food consumption. At the end of the 28-day treatment period, all animals were necropsied except for 12 animals (six males and six females) randomly selected from the control and the high-dose groups respectively, which were left on the study, untreated, for an additional period of 14 days. No treatment-induced gross findings were seen at necropsy with the exception of a dose-dependent increase in the relative (to bodyweight) liver weight of the treated females (by 4%, 4% and 10% at the low-, mid-, and high-dose respectively) that was statistically significant in the high-dose group. In the absence of any associated histopathology, this relatively mild increase in liver weight, which reversed after 14 days of no treatment, is considered to be an adaptive response to the increased metabolic demand arising from xenobiotic metabolism rather than an adverse effect of EBP. Also, no treatment-related ocular lesions or significant differences in urinalysis parameters were observed. Statistically significant differences were seen in some clinical chemistry and haematology values but these were within historical control ranges and did not follow any pattern.

Tissue samples from the control and high dose groups were examined for histopathology. There were no treatment-related findings. Early stages of chronic progressive nephropathy of the kidney and multifocal nonsupparative hepatitis occurred to a similar extent in both control and treated animals, and are therefore considered to be not treatment-related. No compound-related findings were observed in the recovery groups. Overall, there were no adverse effects observed in this 28-day study in SD rats at exposure levels up to 1,250 mg/kg/d EBP.

90 day study
Ten SD rats/sex/group were dosed with 0, 100, 320, 1,000 mg/kg/d EBP (purity 96.3%) suspended in corn oil by gavage once daily 7 days/week for 90 days in a GLP- and OECD-compliant study (Hardy *et al*., 2002 and Margitich, 1992). The dose levels were

selected based on the findings of the 28-day study summarised above. Also incorporated in the study were an additional 10 rats per sex in the control and high dose groups to investigate recovery after 28 days of no treatment. Daily clinical observation was done throughout the study duration and the bodyweights and food consumption were analysed weekly. Blood was collected on day 30 and at sacrifice for clinical chemistry and haematological analysis. Urine was collected shortly before sacrifice for urinalysis. Opthamological examination was conducted at study initiation and prior to necropsy. All animals were sacrificed after 90 days, except the randomly selected 20 animals (10 males and 10 females) in the control and high dose groups respectively, which were left untreated for a further period of 28 days. Gross examinations were performed on all animals, and histopathology tests were performed on approximately 40 tissues including the liver, kidney, lungs, heart, gonads, accessory genital organs, thymus, adrenal glands and spleen.

There were no clinical signs of toxicity or deaths observed in the animals. Food consumption, bodyweights and bodyweight gain were generally comparable between the control and the treated animals except in a few instances. No differences were observed in urinalysis parameters and no treatment-related ocular lesions were found. Statistically significant differences were observed in some haematological parameters (increased red blood cell count, haematocrit, haemoglobin, white blood cell and lymphocytes values) between the control and the mid- and high-dose males and the high-dose females. However, these were not considered to be toxicologically relevant because the values were either within historical control ranges, not consistent at the different time points (30 and 90 days) or occurred in a non-dose related manner.

Furthermore, in contrast to these increased values, statistically significant reductions in some of these haematological parameters (red blood cell, haematocrit, and haemoglobin) were observed in the high-dose recovery males. Dose-dependent decreases in serum aspartate aminotransferase values were noted in the treated males (by 7%, 20% and 31% for the low-, mid-, and high-dose respectively; statistically significant at mid- and high-dose only) on day 30 but not at study termination. In females, both alanine and aspartate aminotransferases were reduced (by approximately 20-40% at the mid- and high-dose levels) on day 30 only, but not in a dose-related manner. However, all clinical chemistry parameters in both sexes were either comparable to controls or within historical control values at study termination and after the recovery period. Decreases in the serum concentrations of these enzymes are not considered to be toxicologically significant.

No treatment-related gross findings were noted in any dose groups either at the 90-day sacrifice or following recovery for 28 days. A statistically significant increase in the relative and absolute liver weight of the high-dose females (by 13%) and in the relative, but not the absolute liver weight of the high-dose males (by 8%) was observed at the 90-day sacrifice, but not following recovery for 28 days. Minor treatment-related histopathological change was seen in the high- and mid-dose males. This was characterised as minimal centrilobular hepatocyte hypertrophy (0/10, 0/10 and 8/10 animals in the 0, 320 and 1,000 mg/kg/d cohorts respectively). Other minor changes observed included centrilobular/parenchymal inflammatory cells with or without hepatocyte degeneration, and hepatocyte vacuolation. The incidences of these findings were generally low, isolated or not significantly different from controls. Consequently, the changes are not regarded as toxicologically relevant. No treatment-related changes were found in the livers of female rats. Centrilobular hepatocyte hypertrophy has been reported as a common adaptive response in rodent liver to xenobiotic exposure.

Generally, minimal hepatocyte hypertrophy in the absence of any other significant findings is not considered to be biologically adverse, but rather regarded as a physiological response to increase metabolic demand. There is no information on liver enzyme induction

by EBP. Nevertheless, given that the increase in liver weight (8%) in the affected sex (i.e. males) was within the acceptable range for an adaptive response and the liver change (centrilobular hepatocyte hypertrophy) was not evident in the high dose recovery animals, thus suggesting that the effect is reversible on removal of exposure; the finding is considered as toxicologically insignificant. The absence of any treatment-related histopathological findings in females suggests that the increase in liver weight of the high-dose group relative to controls is an adaptive, rather than a toxic, response to EBP exposure (even though it is greater than 10%).

Overall, a NOAEL of 1,000 mg/kg/d is identified from this study.

Dermal

No studies are available.

Studies in humans

There are no data available.

Summary of repeated dose toxicity

There are no data on the effects of EBP repeated exposure in humans.

In animals, no data are available for the potential repeated dose effects of EBP via the inhalation or dermal routes of exposure. For the oral route of exposure, a 28-day and a 90-day study in the rat are available. In both of these studies, with the exception of some effects on the liver, the systemic toxicity of EBP appeared to be very low. Increased liver weight (up to 10%) was observed at the top dose of 1,250 mg/kg/d in the 28-day study and at the top dose of 1,000 mg/kg/d in the 90-day study. This was accompanied in the 90-day study by minor histopathological change (centrilobular hepatocyte hypertrophy) regarded as a physiological response to repeated administration of EBP and its liver metabolism. No such changes were evident in the recovery animals, suggesting that the effect is therefore adaptive and reversible on removal of exposure. A NOAEL of 1,000 mg/kg/d identified from the 90-day study will be taken forward to the risk characterisation.

4.4.7 Mutagenicity

In vitro *studies*

Bacterial studies

EBP was examined for mutagenic activity in *Escherichia coli* WP2 uvrA and in five strains of *Salmonella typhimurium* (TA 98, TA100, TA1535, TA1537, TA1538) both in the presence and absence of metabolic activation (San and Wagner, 1991). EBP suspended in dimethylsulfoxide (DMSO) was tested at concentrations of 333, 667, 1,000, 3,333 or 5,000 μg/plate. Arochlor-induced rat liver S9 was used as the metabolic activation system. The assay was conducted in triplicate and appropriate positive and negative (vehicle) controls were used.

Precipitation was observed at all concentrations, although no cytotoxicity was seen up to the highest concentration. Appropriate responses were observed with the negative and positive

controls. EBP gave a negative mutagenic response in *E. coli* with or without metabolic activation. In *S. typhimurium*, a slight, non-statistically significant increase in the number of revertant colonies was observed at the highest concentration (5,000 μg/plate) in the absence of metabolic activation in the TA 98 strain only.

A second independent experiment was performed to validate the results. No increases in the number of revertant colonies were seen in either the *E. coli* or *S. typhimurium* assays. As the positive response observed in TA98 at the top concentration in the first experiment was not confirmed in this second test, it is considered to represent an incidental finding.

EBP was considered non-mutagenic in this bacterial study up to the limit concentration of 5,000 μg/plate. Dosing of EBP in suspension might have limited the value of this test. However, it cannot be completely ruled out that the bacteria absorbed some material via phagocytosis.

Mammalian cell studies

EBP has been tested for clastogenic potential in a well-conducted GLP- and OECD-compliant *in vitro* mammalian chromosome aberration test using Chinese hamster lung (CHL) cells (Putman and Morris, 1991). The assay was conducted in duplicate in both the presence and absence of an Arochlor-induced S9 activation system and appropriate positive and negative (vehicle) controls were used.

A preliminary toxicity test was conducted in order to establish the concentrations to be used in the main assay. The main assay was performed by exposing duplicate cultures of CHL cells to EBP suspended in DMSO at concentrations of 78.5, 157, 313 and 625 μg/ml. The selection of the highest concentration was limited by excessive precipitation of the test article rather than by cytoxicity. Cells were exposed for six hours in both the presence and absence of S9, and for 24 and 48 hours without S9 activation. A minimum of 200 metaphase spreads (100 per duplicate treatment condition) were examined and scored for chromatid and chromosome type aberrations.

Toxicity (measured by mitotic inhibition) was observed at the highest concentration tested. In the cultures without S9, the mitotic index was reduced by 13% and 52% at the 6-h and 24/48-h treatments respectively, whilst in the cultures with S9 (a six-hour treatment only) there was a 33% inhibition. Appropriate responses were observed with the negative and positive controls. EBP did not induce any significant increase in the percentage of cells with structural or numerical aberrations with or without metabolic activation.

An independent repeat assay was conducted with EBP suspended in carboxymethylcellulose (selected to reduce precipitation) at concentrations of 625, 1,250, 2,500 and 5,000 μg/ml in the presence and absence of S9. The exposure times were the same as those used in the first assay. In order to facilitate the analysis of the metaphases and to reduce the interference of precipitation, the test article was washed off prior to Colcemid treatment.

The highest concentration induced 60-79% reduction in the mitotic index. No significant increase in the percentage of cells with structural or numerical aberrations was observed with EBP in both the presence and absence of S9.

Based on the results of this study, EBP was considered non-clastogenic in CHL cells up to concentrations causing cytotoxicity or resulting in precipitation.

In vivo studies

No data are available.

Studies in humans

No data are available.

Summary of mutagenicity

EBP has been investigated for mutagenicity in two well-conducted *in vitro* studies. In an Ames test, EBP was negative with and without metabolic activation. Similarly, no clastogenic activity was evident in a chromosome aberration assay in Chinese hamster lung cells.

No *in vivo* data are available.

Overall, in view of the clearly negative *in vitro* studies and the absence of structural alerts, it is concluded that there are no concerns for *in vivo* mutagenicity with EBP.

4.4.8 Carcinogenicity

Studies in animals

No data are available.

Studies in humans

No data are available.

Summary of carcinogenicity

There are no data on the carcinogenic potential of EBP in humans or animals. However, the absence of indications for carcinogenicity from repeated exposure studies (for example, proliferative changes) and the lack of genotoxic activity in the available *in vitro* mutagenicity data would suggest that EBP is unlikely to be carcinogenic.

4.4.9 Toxicity for Reproduction

Effects on fertility

Studies in animals

No reproductive studies have been performed on EBP. However, no effects on reproductive organs were observed in the 90-day study at doses up to 1,000 mg/kg/d, thus suggesting that EBP has no potential effect on fertility.

Studies in humans

There are no data available.

Developmental toxicity

Studies in animals

Two well-conducted GLP- and OECD-compliant studies (OECD test guideline 414 adopted in 1981) have evaluated the teratogenic effects of EBP in the rat and the rabbit.

Rats
Groups of 25 mated female SD rats were given 0, 125, 400 or 1,250 mg/kg/d EBP suspended in corn oil by oral gavage on gestational days 6-15 and sacrificed on day 20 (Mercieca, 1992a). The rationale for the dose selection was not stated in the report. Clinical signs of toxicity were monitored daily and body weight and food consumption was measured at 3-4 day intervals. Litters were delivered by caesarean section; the numbers and location of viable and non-viable foetuses, resorption sites, and total number of implantations and ovarian corpora lutea were determined. All foetuses were examined for external abnormalities, individually weighed and sexed. One half of the foetuses from each litter were then examined for visceral abnormalities and the other half for skeletal abnormalities.

There were no indications of toxicity among the dams during gestation except for whitish coloured faeces (probably due to the large quantity of the test material in the faeces) observed in about half of the highest dose dams. All the animals survived until scheduled necropsy and the body weights and food consumption of the treated animals were comparable to those of the controls.

There were no treatment-related effects on foetal weight, sex ratio and early or late resorption. There were no external or visceral abnormalities. Regarding skeletal abnormalities, a statistically significant increase in the number of litters with unossified hyoid and reduced ossification of the skull was noted at 400 mg/kg/d. This observation was considered to be incidental, as a similar increase was not seen at the top dose. A number of variations occurred to a similar extent in the control and treated animals.

In this study, no developmental toxicity was observed in the rat up to the very high dose level of 1,250 mg/kg/d.
Rabbits
Groups of 20 previously artificially inseminated female New Zealand White rabbits were administered 0, 125, 400 or 1,250 mg/kg/d EBP suspended in 0.5% methylcellulose by oral gavage on gestation day 6-18 (Mercieca, 1992b). The rationale for the dose selection was not stated in the report. Observations of the dams included clinical signs, body weights and food consumption. All surviving dams were sacrificed on day 29 of gestation and subjected to caesarean section to deliver the litters. The total number of corpora lutea, uterine implantations, early and late resorptions, viable and non-viable foetuses, and the sex and individual weights of foetuses were recorded. All the foetuses were examined for external, visceral and skeletal abnormalities.

No treatment-related mortality or clinical signs of toxicity were seen in the dams. Abortion occurred in one animal each of the 125 and 400 mg/kg/d groups and in two animals of the 1,250 mg/kg/d group. However, in view of the low incidence of this observation and given

that rabbits are known to have a high spontaneous abortion rate, this finding is considered to be incidental.

There were no treatment-related effects on foetal weight, sex ratio, and early or late resorption. No abnormalities related to treatment with EBP were seen. The only statistically significant difference was an increased number of litters with the 27th presacral vertebra at 1,250 mg/kg/d (9 litters compared to 4 in controls). However, given that this increase (by 56.3%) was within the laboratory historical control range (12.5-93.8%), it was not considered adverse. A low incidence of vascular abnormalities was observed in the mid- and high-dose groups. Enlarged aortic valve, bulbous aortic arch and poorly developed right ventricle were observed in one foetus from the 400 mg/kg/d group. Malformation of the aortic arch and undeveloped right ventricle were seen in two foetuses from a single litter of the 1,250 mg/kg/d group. Based on these low incidences, the reported malformations were considered not to be indicative of a treatment-related effect.

Overall, no maternal toxicity was observed in this study up to the top dose. There were no adverse developmental effects in rabbits given EBP up to the very high dose of 1,250 mg/kg/d EBP.

Studies in humans

There are no data available.

Summary of toxicity for reproduction

There are no data on the effects of EBP on fertility. However, there were no adverse effects on the reproductive organs in a rat 90-day study at doses up to 1,000 mg/kg/d.

In relation to developmental effects, there are no data available in humans. In animal studies, EBP was shown not to be a developmental toxicant. No adverse effects on the foetus were observed in rats or rabbits in two conventional pre-natal developmental toxicity studies at doses up to 1,250 mg/kg/d.

4.4.10 Other sources of toxicity information

As for other endpoints in this assessment, it is relevant to consider the available toxicity data for decaBDE (EC, 2002) where none exist for EBP (i.e. carcinogenicity and fertility).

As well as possessing similar molecular structures, decaBDE and EBP have broadly similar physico-chemical properties (see Table 3.4); both have low water solubility and are expected to have a relatively high K_{ow} value. These data suggest that both substances might have poor systemic bioavailability. However, recent kinetic information on decaBDE indicates that oral absorption could be as high as 26%. Once absorbed, a number of different metabolites (protein or lipid-bound metabolites, mono-hydroxylated metabolites, including nona- and octabromodiphenyl ethers, phenolic metabolites with 5 to 7 bromine atoms possessing a guaiacol-structure and traces of nonabrominated diphenyl ethers) can be generated. No reliable kinetic data are available for EBP for comparison.

For the toxicological endpoints (where such data exist), there is at least a qualitative similarity in toxicological profiles. Both substances are of low acute toxicity, non-irritating, non-sensitising and non-mutagenic. However, whilst the liver seems to be the target organ of toxicity for both decaBDE and EBP, the dose levels at which the effect is seen differs greatly. The liver changes were observed at and above 1,000 mg/kg/d in a 90-day rat study with EBP, whereas the effect was only seen with decaBDE after 24 months exposure at around

2,000 mg/kg/d (no effect was seen in a 90-day study with doses as high as 3,000 mg/kg/d). Furthermore, while decaBDE affects the spleen and lymph nodes in rats at around 2,000 mg/kg/d following chronic exposure, no such effects are seen with EBP at doses up to 1,000 mg/kg/d.

In relation to the carcinogenicity and fertility endpoints, liver tumours observed with decaBDE were judged not significant enough to warrant classification; the only available one-generation study was considered inconclusive because of the relatively low dose levels tested.

In conclusion, there are no significant data on decaBDE to provide information on the toxicological profile of EBP, and in any case there are too many uncertainties over the scientific validity of any toxicological “read-across” for human health endpoints. A similar conclusion was drawn for ecotoxicological effects in Section 4.1.6.2.

4.4.11 Summary of mammalian toxicity

Although there are data gaps, the available information is adequate to make a robust hazard evaluation of EBP without the need for further testing.

There is no information on the toxicokinetics of EBP in humans and the only data available in animals is a single oral exposure study investigating absorption in the rat. This study showed that EBP is poorly absorbed via the oral route. Regarding the inhalation and dermal routes of exposure, the physico-chemical properties of EBP suggest that absorption via these routes is also likely to be very low. A worst-case estimate of 10% will be taken forward to the risk characterisation for all of these three routes. In relation to systemic distribution, metabolism and excretion, no data are available. However, given that absorption is poor, general systemic distribution of EBP (and/or its metabolite(s)) is also likely to be low.

No toxicological information is available on the effects of single exposure to EBP in humans. In animals, EBP is of low acute toxicity via the oral and dermal routes of exposure. Acute toxicity following inhalation exposure is also expected to be low.

There are no data available in humans relating to skin or eye irritation. However, EBP caused no skin or eye irritation in standard animal studies. Due to its unreactive nature and given the absence of skin or eye irritation, EBP is unlikely to cause respiratory tract irritation.

No data are available on the skin or respiratory sensitisation potential of EBP in humans. In animals, there a guinea-pig maximisation test has produced only inconclusive results. Overall, however, the generally unreactive nature of EBP would suggest a very low skin or respiratory sensitisation potential.

No information is available on the effects of repeated exposure in humans. In animals the only available data relate to the oral route of exposure. Two studies (exposure over 28 and 90 days) are available, both showing that EBP elicited very low systemic toxicity. Increased liver weight was seen at the top dose in both studies (1,250 and 1,000 mg/kg/d respectively); this enlargement was accompanied in the 90-day study only by minor histopathological change (centrilobular hepatocyte hypertrophy), although these changes were considered not to be toxicologically significant. No such changes were seen in the recovery animals, thereby suggesting that the effect is reversible upon removal of exposure. Overall, the NOAEL of 1,000 mg/kg/d identified from the 90-day study is taken forward to the risk characterisation.

EBP has been investigated for mutagenicity in two well-conducted *in vitro* studies. In an Ames test, EBP was negative with and without metabolic activation. Similarly, no clastogenic

activity was evident in a chromosome aberration assay in Chinese hamster lung cells. No *in vivo* data are available, but, in view of the clearly negative *in vitro* studies and the absence of structural alerts, it is concluded that there are no concerns for *in vivo* mutagenicity with EBP.

There are no data on the carcinogenic potential of EBP in humans or animals. However, the absence of signs for carcinogenicity from repeated exposure studies (for example, proliferative changes) and the lack of genotoxic activity in the available *in vitro* mutagenicity data would suggest that EBP is unlikely to be carcinogenic.

There are no data on the effects of EBP on fertility. However, there were no adverse effects on the reproductive organs in a rat 90-day study at doses up to 1,000 mg/kg/d. In relation to developmental effects, there are no data available in humans. However, in animals, EBP produced no adverse effects on foetuses of exposed pregnant animals (rats and rabbits) in two conventional studies at doses up to 1,250 mg/kg/d.

4.4.12 Derivation of $PNEC_{oral}$ for secondary poisoning

Secondary poisoning refers to the potential risks to predators that might be exposed to the substance via their food. The most appropriate data for estimating a $PNEC_{oral}$ are those from chronic dietary studies. No such study exists, but liver effects were observed at the high dose in male rats exposed to the substance suspended in corn oil by gavage over 90 days (although the severity was quite minimal). The NOAEL taken from this study for risk characterisation was 1,000 mg/kg/d. The rats were 46 days (>6 weeks) old at the start of the study, so an unbounded NOEC of 20,000 mg/kg in food can be derived using a conversion factor of 20. Applying an assessment factor of 90 to this NOEC in accordance with the TGD gives a $PNEC_{oral}$ of ≥ 220 mg/kg in food.

4.5 Hazard classification

EBP is not currently classified for either environmental or human health hazards on Annex 1 of Directive 67/548/EEC (according to both the ESIS database and the N-Class database[32]). Since there is no agreed harmonised classification, suppliers hold the responsibility to self-classify. The two suppliers identified in Section 2 do not classify the substance for either environmental or human health hazards.

No toxicity has been observed in three standard acute aquatic tests. EBP is not readily biodegradable. There are no reliable K_{ow} or fish BCF data. The suppliers' classification is correct based on the data that are currently available, but a case could be made for R53 until better data are available.

There is no need to classify EBP for human health hazards based on the available data.

4.6 PBT Assessment

Substances that are persistent (P), bioaccumulative (B) and toxic (T) pose a special risk to remote environments (such as the open ocean), because of their potential for long-range transport and accumulation in food chains. PEC/PNEC comparisons are not appropriate because of the unacceptably high uncertainty in predicting reliable exposure and/or effect concentrations, and the consequences in terms of the difficulty in reversing any adverse effects should they occur.

32 http://apps.kemi.se/nclass/default.asp

EBP is a potential source of other substances that meet the screening PBT criteria based on predicted properties only. This does not mean that these substances are in fact PBT chemicals, or that EBP actually degrades to them. However, it is important to highlight concern so that EBP degradation and the degradation products can be screened for PBT characteristics. These hypothetical degradation products are considered in detail in Appendix 2.

4.6.1 Persistence (P) assessment

Degradation is discussed in Section 3.1. No marine or freshwater standard simulation test data are available and only one biodegradation test has been performed. The data indicate that EBP is not readily biodegradable. The substance is therefore potentially persistent (i.e. half-life >60 days in marine water or >40 days in freshwater, or >180 days in marine sediment or >120 days in freshwater sediment). Further work could be done to establish a half-life if necessary.

4.6.2 Bioaccumulation (B) assessment

Bioaccumulation data are discussed in Section 3.1.6. Although both a measured log K_{ow} and an *in vivo* fish BCF test are available, the numerical results are considered to be invalid for the purposes of this report. In the absence of more reliable data, it is difficult to reach a firm view on the substance's bioaccumulation potential. The log K_{ow} value in particular is expected to be significantly higher than 3.5, and would probably meet the screening criterion for a very bioaccumulative substance (>5). Uptake in fish under both laboratory and field conditions has been shown to occur. A low level of accumulation would be expected in fish by analogy with the analogue substance decaBDE, although the bioaccumulation behaviour of that substance is complicated. A worst case interpretation of the fish data would give an upper limit to the BCF of 1,600 L/kg, assuming that the fish were exposed at the apparent water solubility limit, and that the concentrations in fish relate to internal tissues (rather than skin and gut contents). There is some uncertainty about the actual water solubility value, and if lower, the worst case BCF would be higher (the 'bioaccumulative' (B) criterion is a BCF >2,000; the Chemicals Stakeholder Forum's criterion of concern is a BCF >500). A BCF above 2,000 cannot be ruled out based on structural and physico-chemical considerations.

Further information is needed to draw a satisfactory conclusion. This is discussed in the risk characterisation section.

4.6.3 Toxicity (T) assessment

Toxicity is discussed in detail in the preceding parts of Section 4. No appropriate long-term marine organism toxicity data are available. No acute aquatic toxicity has been observed in tests that are likely to have exposed freshwater organisms at the water solubility limit of ~0.72 µg/L (although the actual exposure levels were unconfirmed). Chronic aquatic toxicity is not expected. The substance does not meet the T criterion (i.e. chronic NOEC <0.01 mg/L). The available mammalian toxicity data do not trigger the T criterion either.

4.6.4 Summary

EBP is considered to be potentially persistent according to the TGD definitions, based on screening information only. The lack of reliable data means a firm conclusion on bioaccumulation potential cannot be drawn yet. It does not meet the toxicity criterion.

5 Risk characterisation

The following sections characterise risks for the aquatic, terrestrial and atmospheric compartments and the risk of secondary poisoning of predators in the food chain. The risk characterisation is performed by comparing the PECs with the PNECs to derive a risk characterisation ratio (RCR). An RCR <1 implies that any risk resulting from that level of exposure is acceptable. An RCR >1 implies a potential risk, and all such values are highlighted in bold in the following tables. It should be noted that the available assessment methodology might not be applicable to this substance in view of its poor solubility and expected high adsorption potential.

5.1 Aquatic compartment

5.1.1 Surface water and sediment

Risk characterisation ratios

EBP enters the aquatic compartment directly due to industrial applications of the substance itself, and indirectly due to diffuse releases from treated products in use.

It is not possible to derive a meaningful PNEC for surface water, and risks are likely to be low. Sediment is the more important aquatic compartment to protect, given the assumption that EBP has the potential for significant adsorption to organic matter. The RCRs for the sediment compartment are shown in *Table 5.1*.

Table 5.1 Risk characterisation for the aquatic compartment

Life cycle stage	PEC for surface water (mg/L)	RCR for surface water	PEC for sediment (mg/kg wwt)	RCR for sediment
Polymer processing (combined compounding and conversion site)	2.3×10^{-4}	-	5.0	0.2
Textile backcoating formulation	9.8×10^{-3}	-	210	**3.5**
Textile backcoating application	6.2×10^{-3}	-	140	**2.2**

Water solubility is 7.2×10^{-4} mg/l. $PNEC_{sediment}$ is ≥ 60 mg/kg wet weight

The background concentration does not make a significant contribution to the local PECs.

No risks are identified for freshwater sediment for the polymer processing scenario (the RCR for regional sediment is also substantially below 1). A freshwater sediment risk cannot be excluded for the formulation and application of textile backcoatings.

Uncertainties and possible refinements

Emissions

The exposure assessment relies on estimated values for environmental releases based on a mixture of information, none of which is specific for the substance. The surface water PECs for the textile scenarios are above the solubility limit in pure water, which suggests that they are overestimated. PECs are also expected to be lower for sites that use a solids extraction system prior to discharge to a sewage treatment plant. There is therefore scope to refine the PECs, for example by providing:

- the annual and daily consumption of EBP at a reasonable worst case site for each life cycle step;
- substance-specific process data (e.g. release rates, number of sites, etc.), and related emission control methods.

It should be noted that air releases are assumed to be relatively small, although this could be confirmed by industry.

Diffuse emissions at the regional level will occur due to losses of the substance from flame-retarded products in use and at disposal. These emissions will undoubtedly occur, but they are difficult to quantify. It will be difficult to produce an estimate without a comprehensive monitoring campaign in sewage sludge or sediments close to known sources of release, and sites that represent regional levels.

Release during plastics recycling is a possibility that has not been addressed quantitatively.

Other factors relevant to exposure

The model algorithms used in the exposure assessment were not developed for highly hydrophobic substances, and so there is some uncertainty in the calculation of the PECs (as shown by the fact that sediment levels are based on predicted water concentrations that exceed the actual water solubility of EBP).

The sediment PECs are also based on an *assumed* K_{oc} value. Whilst the selected value is in keeping with information for the related substance decaBDE, measurement of either a reliable K_{oc} or K_{ow} value would provide some reassurance about the selected value. Measurement of the latter might be more straightforward.

A more accurate vapour pressure measurement could be performed, although its impact on the conclusions is likely to be low (see Appendix 1).

Any further test of degradation potential (see Appendix 2) might also have an impact on the PECs (e.g. by increasing the level of removal in a WWTP). However, environmental half-life (unless very short) has little effect on the local concentrations for water and sediment. Indeed, if EBP is persistent in sediment, then sediment concentrations might build up over time at the local scale (this is not modelled with EUSES).

Effects

Surface water
No chronic toxicity data are available for pelagic organisms. A long-term study to confirm the expected lack of toxicity might be helpful, although it would present practical challenges as follows:

- The maintenance of test concentrations at or below the water solubility limit over a prolonged period would be problematic (due to adsorption to test vessels and food). A flow-through test design would be required, and tests conducted over relatively short periods (e.g. using a rapidly reproducing species such as *Daphnia pulex*) with suitable non-adsorbing vessels might be preferable.
- The limit of detection of the analytical method used in the water solubility test is very close to the water solubility limit itself. Analytical verification of such low concentrations requires further method development.

Given the physico-chemical properties of the substance, sediment should be the more important aquatic compartment to protect.

Sediment
The $PNEC_{sediment}$ is a limit value based on two tests that failed to show any toxic effects at doses up to 5,000 mg/kg sediment. An additional prolonged sediment organism toxicity test (e.g. with *Hyalella*) could be performed, which would lead to a five-fold reduction of the assessment factor (and hence the PNEC, assuming that the additional species was not more sensitive than those already tested). This would remove the concern for both of the textile scenarios. Another experiment with one of the tested species at higher concentrations may be another option to refine the $PNEC_{sediment}$ value.

Summary

Several actions can be taken to refine the current assessment. Improved estimates of emissions from textile applications would be the most beneficial; they would need to include the quantity of EBP used at sites and information on emission control methods. Targeted monitoring to support this data may be useful. A more reliable K_{oc} or K_{ow} value could also be obtained.

5.1.2 Marine waters and sediment

Risk characterisation ratios

A marine risk assessment has been carried out (see Appendix 3). The main difference from the freshwater assessment is that direct discharge is assumed (i.e. there is no removal in a WWTP).

As for freshwater, no risks are expected for marine organisms for the polymer processing scenario, and a tentative risk is identified for marine sediment organisms from the formulation and application of textile backcoatings (the maximum RCR is ≤ 40). However, both current suppliers have stated that none of their textile customers are close to the coast or a river estuary, and so these risks are hypothetical.

PBT assessment

EBP is not a PBT substance, since it is not toxic, but there is no reliable information on its bioaccumulation potential and this needs to be addressed (see Section 4.6). The substance is also a potential source of other substances that meet the *screening* PBT criteria based on predicted properties (see Section 5.6 and Appendix 2). These other substances are not necessarily PBT chemicals, nor does EBP necessarily have the potential to degrade to them, but it is important to highlight this possibility when considering further data needs.

Uncertainties and possible refinements

More reliable data are needed to establish EBP's bioaccumulation potential. Ideally this would be done with a fish feeding study over a suitable duration and with a suitable analytical method. A prerequisite would be a better estimate of the K_{ow} value. By analogy with decaBDE, it is possible that a fish BCF might not be a reliable indicator of bioaccumulation potential for such a highly hydrophobic substance, and further investigations might be needed depending on the outcome of the test.

In terms of the conclusions for sediment, the same uncertainties apply as for the freshwater compartment – the PEC assessment relies on the same emission estimates and fate parameters, and the PNECs are derived from the freshwater toxicity data set. Therefore, the areas for refinement are essentially identical to those for the freshwater compartment, if textile users were found to be located at the coast in future.

5.1.3 Wastewater treatment plant micro-organisms

Risk characterisation ratios

Since no toxicity data are available for WWTP micro-organisms, RCRs cannot be derived. The PECs are shown in Table 5.2.

Table 5.2 PECs and RCRs for WWTP

Life cycle stage	PEC for WWTP (mg/L)	RCR for WWTP
Polymer processing (combined compounding and conversion site)	5.6×10^{-3}	-
Textile backcoating formulation	0.24	-
Textile backcoating application	0.16	-

Based on these PECs a limit test using, for example, OECD guideline 209 (activated sludge respiration inhibition test) could potentially be performed at 5 mg/L. Assuming that no effects were observed, this would give a $PNEC_{WWTP}$ of 0.5 mg/L and hence no risks (this concentration limit would need to be reviewed if the PECs were to change with the provision of better data on releases).
As EBP does not cause toxic effects to other aquatic organisms over short exposures, the same is likely to be true of micro-organisms. It may also be noted that the related substance decaBDE did not inhibit the respiration of WWTP micro-organisms up to a concentration of 15 mg/L (the PNECWWTP was ≥1.5 mg/L) (EC, 2002). A toxicity test is therefore considered to be a low priority for this substance.

5.2 Terrestrial compartment

5.2.1 Risk characterisation ratios

Direct releases of EBP to the terrestrial compartment are unlikely to occur given its use pattern. However, exposure may occur because of the application of sewage sludge from processes that use the substance and discharge aqueous effluent to water. The RCRs for the terrestrial compartment are shown in *Table 5.3*.

Table 5.3 PECs and RCRs for the terrestrial compartment

Life cycle stage	PEC for soil (mg/kg wwt)	RCR for soil
Polymer processing (combined compounding and conversion site)	2.2	0.08
Textile backcoating formulation	96	**3.7**
Textile backcoating application	61	**2.4**

$PNEC_{soil(standard)}$ is 26 mg/kg wet weight

Both the formulation and application of textile backcoatings give rise to a risk, although the RCRs are only just above 1. The regional soil concentration gives an RCR that is substantially lower than 1.

5.2.2 Uncertainties and possible refinements

The predicted environmental concentrations are based on the same release estimates and fate parameters as for the aquatic compartment, which are themselves uncertain (see Section 5.1.1.2). There are no data from environmental monitoring to confirm the predicted levels. More specific information on the releases to waste water and sludge disposal practice from textile applications would have an impact on the soil concentration. Measurements of concentrations in sludge would also be useful. One supplier has stated that none of their textile customers produce sewage sludge that is spread to land (the sludge is either incinerated or disposed of at a controlled landfill), and so there will be no terrestrial risk in those cases.

As noted in Section 3.3.2.1, the PECs for the two textile scenarios are based on concentrations in sewage sludge that exceed the proposed maximum allowable AOX limit for agricultural use. If the proposed sludge standard (500 mg/kg dry matter) is taken as a limit value, the RCR would be ~0.3. In other words, provided that such a standard were complied with, there would be no risks to soil from this substance.

The PEC values for soil are calculated following 10 years of sludge application, and so the persistence of the substance in soil is a factor in the calculations. The exposure estimates could therefore possibly be refined through the determination of degradation half-lives in soil, or a further test of aquatic degradability (although significant degradation would need to be seen to have any substantial impact – see Appendix 1). In relation to this, some further work could be done to investigate the reasons for the decline in soil concentration observed in the earthworm test. If the bioavailability of the substance is reduced by interaction with the soil matrix over time, this might have implications for the soil PEC estimates.

Finally, a long-term soil micro-organism toxicity study (e.g. OECD guideline 216 or 217) would allow a lower assessment factor of 10 to be used in the PNEC derivation. Provided

that toxicity was not seen at lower concentrations than in the existing studies, this would remove the concern for this compartment.

5.3 Atmospheric compartment

The fate of the substance in the atmosphere is expected to be governed by its strong adsorption to particulate matter. There is some potential for it to be transported long distances from its source of release on particles, which could lead to contamination of the Arctic. It needs to be recognised that this is an area of developing science, so no specific conclusions have been drawn on this issue.

No effect data are available for non-mammalian species that can be used to derive a PNEC. Abiotic effects are not expected. Although the lack of toxicity data for suitable species cannot be taken as implying no concern, there is unlikely to be a risk for this compartment because air concentrations are already predicted to be relatively low, and are likely to be even lower if the vapour pressure is significantly less than the value assumed in this assessment.

5.4 Food chain risks (secondary poisoning)

5.4.1 Risk characterisation ratios

Predators may be exposed to EBP in their diet. The RCRs for the aquatic food chain are shown in Table 5.4. It is not possible to estimate risks for the terrestrial food chain, due to the lack of an earthworm BCF or a reliable K_{ow} value that could be used for a prediction.

Table 5.4 PECs and RCRs for secondary poisoning

Life cycle stage	Aquatic food chain	
	PEC for fish (mg/kg wwt)	**RCR for fish eating predators**
Polymer processing (combined compounding and conversion site)	2.4×10^{-3}	<0.01
Textile backcoating formulation	0.10	<0.01
Textile backcoating application	0.05	<0.01

$PNEC_{oral,\ predator}$ is ≥ 220 mg/kg in food

No risks are identified. Similarly, no risks are predicted for marine predators (see Appendix 3).

5.4.2 Uncertainties and possible refinements

The PECs for fish are estimated using water concentrations that are higher than the solubility in pure water, and so are conservative. The measured fish BCF of 25 L/kg has been used in this assessment is invalid and has only been used as an illustration. A worst case interpretation of the data suggests that the BCF could be around 1,600 L/kg or higher. However, if it were assumed that the surface water concentrations are the same order of magnitude as the solubility in pure water, a fish BCF of around 1,600 L/kg would not lead to any concern for secondary poisoning in either the freshwater or marine food chains (see Appendix 1).

Further investigation of the fish BCF is considered necessary for the PBT assessment, so this information would be useful here. The fish BCF would have to be in the region of 10,000 for there to be a risk of secondary poisoning.

Further measurement of K_{ow} would provide data to enable an estimate of an earthworm BCF to be made.

5.5 HUMAN HEALTH RISKS

Overall, no hazards have been identified in relation to acute toxicity, irritation, mutagenicity, carcinogenicity or reproductive toxicity. No definitive conclusions can be drawn in relation to skin sensitisation due to limitations in the database, and the only key health effect identified concerns repeated dose toxicity. The NOAEL of 1,000 mg/kg/d identified in a rat 90-day study will be used in the risk characterisation.

5.5.1 Local Exposure

Repeated Exposure

The maximum continuous human exposure from local environmental sources predicted by EUSES is 5.7 mg/kg/d in the vicinity of textile backcoating formulation plant. As noted in Section 3.4.1.1, this is likely to be an overestimate. The margin of safety (MOS) between this exposure and the NOAEL for repeated exposure is ~175. This MOS value is high, so there is no concern for local exposures in relation to repeated-dose effects.

5.5.2 Regional Exposure

As detailed in Section 3.4.1, the data for regional exposure cannot be made publicly available because of confidentiality issues. However, the continuous total daily intake is significantly lower than the worst case local exposure; there is no concern, therefore, for regional exposures in relation to repeated-dose effects.

5.5.3 Uncertainties and possible refinements

Apart from uncertainties in the release estimates for the aquatic and terrestrial environments as mentioned in preceding sections, the main area of uncertainty for the human food chain concerns EBP's partitioning behaviour and the validity of the models for this type of substance.

The major contribution to the overall daily dose is predicted to be from root crops. However, this concentration is derived from an overestimated soil pore water concentration. If this is limited to the water solubility of the substance, the root crop concentration reduces, leading to an estimated daily dose of ~0.8 mg/kg/d.

In any case, there is uncertainty in the K_{ow} and fish BCF values that have been used for the modelling. Appendix 1 presents a brief analysis of the effect of changing these values, but more reliable values are already considered necessary for other end points.

5.6 Potential degradation products

As a source of bromine, EBP can contribute to the formation of brominated dibenzo-*p*-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (e.g. recycling). However, the available evidence suggests that EBP will not be a significant source of such substances during these processes (see Appendix 2). In addition, emission controls are required on incinerators by law, which should mean that the majority of emissions are at acceptable levels.

EBP is a potential source (via degradation processes) of other substances that flag up as a concern at a screening level. The significance of these degradation products is unknown at the moment, and further work is required to clarify this issue (see Appendix 2). In the absence of such information, the possibility that hazardous substances might be formed as a result of metabolism in organisms or degradation in soils, sludges and sediments cannot be excluded. The significance of this possible phenomenon is unknown.

6 Conclusions

EBP is used to flame retard polymer articles in the UK, and this use does not appear to pose any direct environmental risks (including risks to humans exposed via the environment) based on present knowledge.

EBP is also used to flame retard textiles in continental Europe. No risks are identified for surface water, WWTP, the atmosphere, predators or humans following environmental exposure. The formulation and application of textile backcoatings might lead to a possible risk for sediment and soil organisms. The following information would be needed to clarify whether there are genuine risks if UK supply for textile use were to occur in future:

- Improved estimates of emissions from textile sites (with information on control methods – including sludge disposal practice – and the amounts used at sites). Targeted monitoring to support this may be useful.
- The number of user sites and their geographical spread could also be established.
- Further toxicity tests could also be performed to refine the sediment and soil PNECs, although it should be noted that the substance is not highly toxic.

The conclusions are the same if an increased level of supply is assumed (see Appendix 4), although additional work that might be useful if EBP becomes more widely used could include a survey of EBP concentrations in municipal sewage sludges and a substance flow analysis for EBP in the waste stream.

As a source of bromine, EBP can contribute to the formation of brominated dibenzo-*p*-dioxins and dibenzofurans during combustion of treated articles or other high temperature processes (e.g. recycling). The available evidence suggests that EBP will not be a significant source of such substances during these processes. In addition, emission controls are required on incinerators by law, which should mean that the majority of emissions are at acceptable levels.

There are, however, important qualitative concerns. The key information requirements are:

- *Data to provide more reliable information about bioaccumulation potential.* In the first instance a more reliable indication of the log K_{ow} would be preferred. This would permit an estimate of both fish and earthworm bioconcentration to be made using QSARs (and would also validate the assumed partitioning behaviour in the environment). It is recognised that there could be some practical challenges since the water solubility is so low. Measurement of the n-octanol solubility would be the simplest way of indicating the approximate magnitude of the K_{ow}. A test using the HPLC method could also quickly confirm whether the K_{ow} is significantly higher than the current measured value, although this method suffers from a lack of reliable reference substances with a high log K_{ow}, and there are issues related to the type of eluent used for highly hydrophobic substances (Hayward *et al*, 2006). OECD test guideline 123 (slow-stirring method) would therefore be preferred for a definitive measurement. In addition, further refinement of the analytical method might be needed to improve method sensitivity and reliability.

  Given the lack of reliable data for such a highly hydrophobic substance, bioaccumulation should also subsequently be measured in a fish dietary test using a substance-specific analytical technique and sufficient test duration. A definitive fish BCF would allow the PBT/vPvB assessment to be completed.

Depending on the results of these tests, further work on uptake and accumulation in wildlife might be needed. For example, a bioaccumulation test with earthworms may be useful, provided it takes place over a suitable timescale (an OECD guideline is currently under development).

- *Data to provide information on actual products of degradation and metabolism and their rate of formation.* A number of studies can be envisaged, as summarised in Appendix 2. The results of an enhanced inherent biodegradability test (with identification of any biotransformation products) could be used to guide more detailed long-term simulation tests in sediment (e.g. OECD test guideline 308) and/or sewage sludge (e.g. proposed OECD test guideline 311).

  In addition, recent studies that have been carried out for decaBDE under environmentally relevant conditions could provide useful model test systems for comparison, for example *in vitro* measurements of metabolic potential in fish liver tissue, degradation experiments with natural reductants, dusts, etc.

  Such studies can be costly and time consuming and so proper experimental design and stakeholder endorsement is very important.

  Depending on the results of such tests, the need for further information on specific properties of the metabolites and/or monitoring could also be considered.

Both current European suppliers have made product stewardship commitments to reduce point source releases of EBP from downstream users. Since EBP is expected to be highly persistent, ongoing diffuse releases (e.g. from treated articles) could still lead to widespread distribution in the environment – whilst the actual levels are difficult to determine, they are likely to be relatively low based on current knowledge.

One supplier (Albemarle Europe SPRL) has responded to the conclusions of this assessment by committing to perform an enhanced inherent degradation test, a soil micro-organism toxicity test (OECD 216, Nitrogen Transformation Test), and a rat pharmacokinetic study (using a lower dose level than the original test). Depending on the results, a fish dietary bioaccumulation study might also be considered.

References

Albemarle, undated-a. *Flame Retarding Polyamides with SAYTEX 8010.* Albemarle Corporation.

Albemarle, undated-b. *Flame Retarding High Impact Polystyrene.* Albemarle Corporation. http://www.albemarle.com/saytextechpaperf.htm accessed October 2005.

Albemarle, 2001. *SAYTEX® 8010 Flame Retardant*. Albemarle Corporation. http://www.albemarle.com/acrofiles/bc1005f_SAYTEX_8010_datasheet.pdf accessed October 2005.

Albemarle, 2005. IUCLID data set, updated 30 June 2005. Albemarle Corporation.

Aufderheide J, 2003. *Effects of Saytex 8010 on the survival and reproduction of the earthworm,* Eisenia fetida. ABC Laboratories, Inc. ABC Study No. 47634 submitted to Albemarle Corporation.

Blankinship A S & Krueger H O, 2003a. *S8010: A 96-hour static acute toxicity test with the rainbow trout (*Oncorhynchus mykiss*).* Wildlife International Ltd. Project number: 471A-107 submitted to Albemarle Corporation.

Blankinship A S & Krueger H O, 2003b. *S8010: A 48-hour static acute toxicity test with the cladoceran (*Daphnia magna*).* Wildlife International Ltd. Project number: 471A-106 submitted to Albemarle Corporation.

Boethling R S & Mackay D, 2000. *Handbook of Property Estimation Methods for Chemicals*. CRC Press LLC.

Canada Gazette, 2004. *Canada Gazette* Part I, Vol. 138, No. 40, 2644-2646. Ottawa, October 2, 2004.

Chemtura, 2006. *Great Lakes FF-680 Material Safety Data Sheet*. Effective date 02/02/2006. Chemtura Corporation. http://www.e1.greatlakes.com/common/msdspdf/00018.pdf accessed October 2005.

Chiou C T, Peters L J & Freed V H, 1979. A physical concept of soil-water equilibria for nonionic organic compounds. *Science*, 206(4420), 831-832.

[CITI] Chemicals Inspection & Testing Institute, 1991a. *Test of biodegradability of Saytex-402 by microorganisms*. Kurume Research Laboratories, Chemical Biotesting Center. Test number 11893 submitted to Ethyl Corporation.

[CITI] Chemicals Inspection & Testing Institute, 1991b. *Test of bioaccumulation of Saytex-402 in carp*. Kurume Research Laboratories, Chemical Biotesting Center. Test number 41894 submitted to Ethyl Corporation.

Comber M, Robertson S & Sijm D, 2006. *Discussion paper for the Technical Committee for New and Existing Substances' subgroup on PBTs*.

Desjardins D & Krueger H O, 2003. *S8010: A 96-hour toxicity test with the freshwater alga (*Selenastrum capricornutum*).* Wildlife International Ltd. Project number: 471A-108A submitted to Albemarle Corporation.

Dimitrov S D, Dimitrova N C, Walker J D, Veith G D and Mekenyan O G, 2002. Predicting bioconcentration factors of highly hydrophobic chemicals. Effects of molecular size. *Pure and Applied Chemistry*, 74, 1823-1830.

[EA] Environment Agency, 2003. *Prioritisation of flame retardants for environmental risk assessment*. Bristol. frreportfinal_578692.pdf. Available at http://www.environment-agency.gov.uk/

[EA] Environment Agency, 2005. *Environmental Risk Assessment Report for Tetrabromobisphenol-A*. Draft of August 2005.

[EA] Environment Agency, 2007. *Addendum to the May 2004 Environmental Risk Assessment Report for Decabromodiphenyl Ether (CAS no. 1163-19-5)*. Draft of January 2007.

[EC] European Commission, 2000. *Working Document on Sludge*, 3rd Draft. April 2000. Available at http://europa.eu.int/comm/environment/waste/sludge/sludge_en.pdf.

[EC] European Commission, 2002. *European Union Risk Assessment Report: Bis(pentabromodiphenyl ether). 1st Priority List, Volume 17*. EUR 20402 EN. European Chemicals Bureau, Institute of Health and Consumer Protection. Available at http://ecb.jrc.it/existing-chemicals/.

[ECB] European Chemicals Bureau, 2004. *Update of the Risk Assessment of Bis(pentabromodiphenyl ether). R013_0405_env - Final Environmental Draft of May 2004*. Available at http://ecb.jrc.it/existing-chemicals/.

EURAS, 2006. Review of the environmental risk evaluation report on 1,2-bis(pentabromophenyl)ethane (EBP) by Frederik Verdonck and Marnix Vangheluwe, 31 March 2006.

Great Lakes, undated. *Technical Information: Firemaster® 2100. Product Data Sheet. Great Lakes Polymer Additives*. http://www.e1.greatlakes.com/freb/common/pdf/Firemaster_2100_ds.pdf accessed October 2005.

Great Lakes, 2002. *Flame retardants*. Great Lakes Polymer Additives. 3rd Edition 2002.

Great Lakes, 2003. *Safety Data Sheet: Firemaster® 2100. Great Lakes Chemical Corporation*. Revision date 18 November 2003. http://www.e1.greatlakes.com/common/msdspdf/04410504.pdf accessed October 2005.

Hardy M L, Margitich D, Ackerman L & Smith R L, 2002. *The subchronic oral toxicity of ethane, 1,2-bis(pentabromophenyl) (Saytex 8010) in rats*. International Journal of Toxicology, 21(3), 165-170.

Hardy M L, 2004. A comparison of the fish bioconcentration factors for brominated flame retardants with their nonbrominated analogues. *Environmental Toxicology and Chemistry*, 23(3), 656-661.

Hayward S J, Lei Y D & Wania F, 2006. Comparative evaluation of three high-performance liquid chromatography–based K_{ow} estimation methods for highly hydrophobic organic compounds: polybrominated diphenyl ethers and hexabromocyclododecane. *Environmental Toxicology and Chemistry*, 25(8), 2018-2027.

Julander A, Westberg H, Engwall M & van Bavel B, 2005. Distribution of brominated flame retardants in different dust fractions in air from an electronics recycling facility. *Science of the Total Environment*, 350(1-3), 151-160.

Karlsson M, Julander A, Van Bavel B & Hardell L, 2007. Levels of brominated flame retardants in blood in relation to levels in household air and dust. *Environment International*, 33, 62-69.

Kelly B C, Gobas F A P C & McLachlan M S, 2004. Intestinal absorption and biomagnification of organic contaminants in fish, wildlife and humans. *Environmental Toxicology and Chemistry*, 23, 2324-2336.

KemI, 2001. *Risk assessment of bis(2-ethylhexyl) phthalate. Consolidated Final Report: September 2001. Chapters 0-3*. National Chemicals Inspectorate, Sweden. Available at http://ecb.ei.jrc.it/existing-chemicals/.

KemI, 2005. *Risk assessment of hexabromocyclododecane. Draft of February 2005.* National Chemicals Inspectorate, Sweden.

Kierkegaard A, Björklund J & Fridén U, 2004. Identification of the flame retardant decabromodiphenyl ethane in the environment. *Environmental Science and Technology*, 38(12), 3247-3253.

Kishino T and Kobayashi K, 1995. Relation between toxicity and accumulation of chlorophenols at various pH, and their absorption mechanism in fish. *Water Research*, 29, 431-442.

Krueger H O, Thomas S & Kendall T Z, 2003a. *S8010: A prolonged sediment toxicity test with* Chironomus riparius *using spiked sediment*. Wildlife International Ltd. Project number: 471A-110 submitted to Albemarle Corporation.

Krueger H O, Thomas S & Kendall T Z, 2003b. *S8010: A prolonged sediment toxicity test with* Lumbriculus variegatus *using spiked sediment with 2% total organic carbon*. Wildlife International Ltd. Project number: 471A-109 submitted to Albemarle Corporation.

Law K, Halldorson T, Danell R, Stern G, Gewurtz S, Alaee M, Marvin C, Whittle M and Tomy G, 2006. Bioaccumulation and trophic transfer of some brominated flame retardants in a Lake Winnipeg (Canada) food web. *Environmental Toxicology and Chemistry*, 25(8), 2177-2186.

Law K, Halldorson T, Danell R, Stern G, Gewurtz S, Alaee M, Marvin C, Whittle M and Tomy G, 2007. Erratum. *Environmental Toxicology and Chemistry*, 26(1), 190.
Mackay D, Shiu WY, Ma KC and Lee SC, 2006. *Handbook of Physical-chemical Properties and Environmental Fate for Organic Chemicals*, 2nd Edition. CRC Press/Taylor & Francis.

Mallory V, 1988a. *Acute exposure oral toxicity. PH 402-ET-001-88. Decabromodiphenylethane, Lot #SH-6427-49.* Pharmakon Research International, Inc Waverly, PA.

Mallory V, 1988b. *Acute exposure dermal toxicity. PH 422-ET-001-88. Decabromodiphenylethane, Lot #SH-6427-49.* Pharmakon Research International, Inc Waverly, PA.

Mallory V, 1988c. *Primary dermal irritation study in rabbits. PH 420-ET-001-88. Decabromodiphenylethane, Lot #SH-6427-49.* Pharmakon Research International, Inc, Waverly, PA.

Mallory V, 1988d. *Primary eye irritation study in rabbits. PH 421-ET-001-88. Decabromodiphenylethane, Lot #SH-6427-49.* Pharmakon Research International, Inc, Waverly, PA.

Margitich D L, 1991. *28 day toxicity study in rats. PH 436-ET-002-90. Saytex 402, Lot #23-014-2A.* Pharmakon Research International, Inc, Waverly, PA.

Margitich D L, 1992. *Subchronic 90 day oral toxicity study in rats. PH 470-ET-001-91. Saytex 402, Lot #23-014-2A.* Pharmakon Research International, Inc, Waverly, PA.

Mercieca M D, 1992a. *Developmental toxicity (teratology) study in rats with Saytex 402. SLS Study No. 3196.24.* Springborn Laboratories, Inc, Spencerville, OH.

Mercieca M D, 1992b. *Developmental toxicity (teratology) study in rabbits with Saytex 402. SLS Study No. 3196.26.* Springborn Laboratories, Inc, Spencerville, OH.

[MRI] Midwest Research Institute, 2004. *^{14}C-Saytex 8010: Absorption, distribution, metabolism, excretion and pharmacokinetics following a single intravenous or oral administration to rats. MRI Project No. 310388.1.001.* Midwest Research Institute, Kansas City, Missouri.

Newton P E, 2003. *A sensitization study (maximization method) of Saytex 8010 in guinea pigs. Study No. 972-001.* MPI Research, Inc, Mattawan, Michigan.

[NICNAS] National Industrial Chemicals Notification and Assessment Scheme, 2001. *Polybrominated Flame Retardants (PBFRs). Priority Existing Chemical Assessment Report No. 20.* Sydney. June 2001.

OASIS, 2004. OASIS Basic v1.02 estimation software, developed by the Laboratory of Mathematical Chemistry, Bourgas 'Prof. As Zlatarov' University, Bulgaria.

[OECD] Organisation for Economic Co-operation and Development, 1996. *Bioaccumulation: Flow-through Fish Test*. Organisation for Economic Cooperation and Development (OECD), OECD Guideline for the Testing of Chemicals No. 305, Paris, France.

[OECD] Organisation for Economic Co-operation and Development, 2000. *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures*. OECD Series on Testing and Assessment Number 23. ENV/JM/MONO(2000)6. June 2000. Available at http://www.oecd.org/ehs/.

[OECD] Organisation for Economic Co-operation and Development, 2004a. *Emission Scenario Document on Plastic Additives*. OECD Series on Emission Scenario Documents Number 3. ENV/JM/MONO(2004)8. 24 June 2004. Available at http://www.oecd.org/ehs/.

[OECD] Organisation for Economic Co-operation and Development, 2004b. *Emission Scenario Document on Textile Finishing Industry*. OECD Series on Emission Scenario Documents Number 7. ENV/JM/MONO(2004)12. 24 June 2004. Available at http://www.oecd.org/ehs/.

Pettersson-Julander A, van Bavel B, Engwall M & and Westberg H, 2004. Personal air sampling and analysis of polybrominated diphenyl ethers and other bromine containing compounds at an electronic recycling facility in Sweden. *Journal of Environmental Monitoring*, 6 (11), 874-880.

Porch J R and Krueger H O, 2005. S8010: *A toxicity test to determine the effects of the test substance on seedling emergence of six species of plants*. Wildlife International Ltd. Project number: 471-101A submitted to Albemarle Corporation.

Putman D L and Morris M J, 1992. *Chromosome aberrations in Chinese hamster lung (CHL) cells. T9499.227025 Saytex 402.* Microbiological Associates, Inc, Rockville, MD.

Ranken P F, Choudhury P and Hardy M L, 1994. *SAYTEX® 8010 and the German Ordinance.* Technical paper for Albemarle Corporation. Dated 9/22/94.

Ranken P F and Hardy M L, 1994. *SAYTEX® 8010 Flame retardant: Laboratory simulation of municipal waste incineration.* Technical paper for Albemarle Corporation. Revised 5/4/94.

Saarikoski J, Lindstrom M, Tyynila M and Viluksela M, 1986. Factors affecting the absorption of phenolics and carboxylic acids in the guppy (*Poecilia reticulata*). *Ecotoxicology and Environment Safety*, 11, 158-173.

San R H and Wagner V O, 1991. Salmonella*/Mammalian-microsome plate incorporation mutagenicity assay (Ames test) and* Escherichia coli *WP2 uvrA reverse mutation assay. Saytex 402.* Microbiological Associates, Inc, Rockville, MD.

Stehly G R and Hayton W L, 1990. Effect of pH on the accumulation kinetics of pentachlorophenol in goldfish. *Archives of Environment Contamination and Toxicology*, 19, 464-470.

[TFA] Textile Finishers' Association, 2006. A report based upon consultation by Peter Wragg of TEXCONSUL Ltd with members of the Textile Finishers Association, Bradford. Prepared for John Lambert (Secretary), Textile Finishers' Association. April 2006.

TGD, 2003. *Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment of existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market*. European Commission, Joint Research Centre, EUR 20418 EN, 2003.

Tomy G T, Budakowski W R, Halldorson T H J, Whittle D M, Keir M J, Marvin C, MacInnis G and Alaee M, 2004. Biomagnification of a- and g-hexabromocyclododecane isomers in a Lake Ontario food web. *Environmental Science and Technology*, 38, 2298-2303.

[UBA] Umweltbundesamt, 2001. *Erarbeitung von Bewertungsgrundlagen zur Substitution umweltrelevanter Flammschutzmittel*. Germany, March 2001. An English translation of Part 1 of this report [Substituting Environmentally Relevant Flame Retardants: Assessment Fundamentals (results and summary overview)] is available at http://www.umweltbundesamt.org/fpdf-l/1988.pdf (accessed October 2005).

[US EPA] United States Environmental Protection Agency, 2000. EPI Suite™. Estimations Programs Interface for Windows (EPIWIN) v3.11. Developed by Syracuse Research Corporation for the United States Environmental Protection Agency, Washington, DC. Available at http://www.epa.gov/opptintr/exposure/.

[US EPA] United States Environmental Protection Agency, 2001. Letter from the Office of Prevention, Pesticides and Toxic Substances to the Health & Safety Executive, dated 19 January 2001.

Van Hoven R L, McGregor J A & Nixon W B, 1999a. *Saytex 8010: Determination of water solubility by the generator column method.* Wildlife International Ltd. Project number: 471C-101 submitted to Albemarle Corporation.

Van Hoven R L, McGregor J A & Nixon W B, 1999b. *Saytex 8010: Determination of the n-octanol/water partition coefficient by the generator column method.* Wildlife International Ltd. Project number: 471C-103 submitted to Albemarle Corporation.

Van Hoven R L, Glassbrook N & Nixon W B, 2002. *Determination of the vapor pressure of Saytex 8010 using the spinning rotor gauge method.* Wildlife International Ltd. Project number: 471C-102 submitted to Albemarle Corporation.

Venier M, Hoh E & Hites R A, 2006. Brominated flame retardants in the Integrated Atmospheric Deposition Network (IADN) sites. *Annual Conference on Great Lakes Research*, Vol. 49, no pages given.

[WHO] World Health Organisation, 2005. *Concise International Chemical Assessment Document 66: 2,4,6-Tribromophenol and Other Simple Brominated Phenols*. World Health Organisation, Geneva.
http://www.who.int/ipcs/publications/cicad/cicad_66_web_version.pdf

Zhu L Y, Hites R A, 2006. Brominated flame retardants in tree bark from North America. *Environmental Science and Technology*, 40, 3711-3716.

The following references do not contain any significant additional information and so are not cited in the main report:

Andersson P L, Örn U, Öberg K and Tysklind M (2004). Chemical characterisation and strategic selection of BFRs for PBT assessment. Conference abstract for 'Brominated Flame Retardants 2004', 249-252.
http://www.bfr2004.com/Individual%20Papers/BFR2004%20Abstract%20056%20Andersson.pdf accessed October 2005.
Proposal to include the substance in QSAR analyses in relation to PBT assessment.

Betts K (2004). Another brominated flame retardant in the environment.
Environmental Science & Technology, 38(12), 214A-215A.
News report of the Kierkegaard et al. *(2004) study.*

Konstantinov A, Chittim B, McAlees A, MacPherson K, McCrindle R, Potter D, Reiner E, Tashiro C and Yeo B (2004). Synthesis and Characterization of Native and Mass Labeled [$^{13}C_{14}$]-Decabromodiphenylethane. Conference abstract for 'Brominated Flame Retardants 2004', 367-370.
http://www.bfr2004.com/Individual%20Papers/BFR2004%20Abstract%20083%20Konstantinov.pdf accessed October 2005.
Information on synthesis and characterisation.

McPherson A, Thorpe B and Blake A (2004). Brominated flame retardants in dust on computers: the case for safer chemicals and better computer design. Clean Production Action. June 2004.
http://www.computertakeback.com/docUploads/bfr_report_hires.pdf?CFID=10007238&CFTOKEN=76408271 accessed October 2005.
Refers to the need for more information on the substance as part of a general discussion.

Örn U and Bergman Å (2004). An attempt to assess the present commercial production of brominated flame retardants. Conference abstract for 'Brominated Flame Retardants 2004', 467-472.
www.bfr2004.com/Individual%20Papers/BFR2004%20Abstract%20108%20Orn.pdf accessed October 2005.
Provides an estimated annual global consumption, but the basis of the estimate is unclear and it is not relevant to this assessment.

Glossary

Bioconcentration factor (BCF)	A measure of chemical uptake, being the ratio between the concentration in an organism and the concentration in an environmental compartment (usually water)
CAS number (no.)	An identifying code number assigned to chemicals by the Chemical Abstract Services. The CAS number is a generally recognised identification reference for a chemical; it is possible that a substance can have more than one such number
Lowest observed effect concentration	The lowest concentration in a toxicity test that gives rise to adverse effects (relative to a control)
Median effective concentration (EC_{50})	The concentration in a toxicity test at which a particular effect is observed in half of the organisms exposed for a specified time
Median lethal concentration/dose (LC/D_{50})	The concentration in a toxicity test that can be expected to cause death in half of the organisms exposed for a specified time
No observed effect concentration (NOEC)	The highest concentration in a toxicity test that does not give rise to adverse effects (relative to a control)
Octanol-water partition coefficient (K_{ow})	This parameter gives an indication of the partitioning behaviour of a substance between water and lipid-containing materials such as cell membranes or organic matter in soils and sediments
Organic carbon-water partition coefficient (K_{oc})	This parameter gives an indication of the partitioning behaviour of a substance between water and organic matter in soils, sediments and sewage sludge
Readily biodegradable	Rapid environmental degradation to carbon dioxide and water, etc., as measured by laboratory screening tests involving micro-organisms

Abbreviations

~	Approximately
AF	Assessment factor
ASTM	American Society for Testing and Materials
BCF	Bioconcentration factor
bw	Body weight/*Bw*, *b.w.*
CAS	Chemical Abstract Services
CHL	Chinese hamster lung
d	day
DecaBDE	Decabromodiphenyl ether
DMSO	Dimethylsulfoxide
dwt	Dry weight
EBP	The substance that is the subject of this report
EC	European Communities
EC_{50}	Median effect concentration
EC_x	As EC_{50}, but for x% effect; x usually being 0, 10, or 100
ECB	European Chemicals Bureau
EEC	European Economic Communities
EINECS	European Inventory of Existing Commercial Chemical Substances – this lists all chemical substances that were supplied to the market prior to 18th September 1981
EPA	Environmental Protection Agency (USA)
ESD	Emission Scenario Document
ESIS	European chemical Substances Information System
ESR	The Existing Substances Regulation – Council Regulation (EEC) 793/93 on the evaluation and control of the risks of 'existing' substances
EU	European Union
EUSES	European Union System for the Evaluation of Substances (software tool in support of the TGD on risk assessment)
GLP	Good laboratory practice
h	hour
HLC	Henry's Law constant
HPLC	High pressure liquid chromatography
HPV	High Production Volume (supply >1000 tonnes/year)
HPVC	High production volume chemical (supply >1000 tonnes/year)
ICCA	International Council of Chemical Associations
IPC	Integrated pollution control
IPPC	Integrated Pollution Prevention and Control (EC Directive 96/61/EEC)
IUCLID	International Uniform Chemical Information Database: contains data collected under the Existing Substances Regulation (ESR)
IUPAC	International Union for Pure and Applied Chemistry – the IUPAC name is the formal chemical name
km	Kilometre
K_{oc}	Organic carbon normalised distribution coefficient
K_{ow}	Octanol–water partition coefficient
Kp	Solids–water partition coefficient
$L(E)C_{50}$	Median lethal (effect) concentration
LD_{50}	Median lethal dose
LOEC	Lowest observed effect concentration
log K_{ow}	Log of the octanol-water partition coefficient (K_{ow})
LPV	Low production volume (supply 10-1,000 tonnes/year)
LPVC	Low production volume chemical (supply 10-1,000 tonnes/year)

mg/kg/d	Milligrams per kilogram per day
MITI	Ministry of International Trade and Industry, Japan
mmHg	Millimetres of mercury, a measure of pressure.
ng	Nanogram (10^{-9} gram)
nm	Nanometre (10^{-9} metre)
NO(A)EL	No observed (adverse) effect level
NOEC	No observed effect concentration
n.t.p.	Normal temperature and pressure (20°C and 101.3 kPa)
OECD	Organisation for Economic Cooperation and Development
O.J.	Official Journal of the European Communities
OPPTS	Office of Prevention, Pesticides and Toxic Substances (part of the US EPA)
OSPAR	Oslo and Paris Convention for the protection of the marine environment of the Northeast Atlantic, http://www.ospar.org
P	Persistent
PBDD	Polybrominated dibenzo-p-dioxin
PBDE	Polybromodiphenyl ether
PBDF	Polybrominated dibenzofuran
PBT	Persistent, bioaccumulative and toxic
PEC	Predicted environmental concentration
pg	Picogram (10^{-12} gram)
pH	Logarithm (to the base 10) of the hydrogen ion concentration [H^+]
pKa	Logarithm (to the base 10) of the acid dissociation constant
PNEC	Predicted no effect concentration
ppb	Parts per billion
(Q)SAR	(Quantitative) Structure-Activity Relationship
RCR	Risk characterisation ratio
SEPA	Scottish Environmental Protection Agency
SMILES	Simplified Molecular Input Line Entry System – the SMILES code is a chemical notation system used to represent a molecular structure by a linear string of symbols; it is a simple way of entering chemical structural information into a computer programme
SRC	Syracuse Research Corporation
TGD	Technical Guidance Document
TSCA	Toxic Substances Control Act (USA)
TWA	Time-weighted average
UBA	Umweltbundesamt (Federal Environment Protection Agency in Austria and Germany)
US EPA	Environmental Protection Agency, USA
UV	Ultraviolet region of the electromagnetic spectrum
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative
w/w	Weight per weight ratio
WAF	water accommodated fraction
wt	Weight
wwt	Wet weight
WWTP	Wastewater treatment plant

Appendix 1: Sensitivity analysis

The exposure assessment is based on a number of assumptions, and certain parameters have an important influence on the predicted exposure concentrations (PECs). As discussed in Section 3 of the main report, there is some uncertainty associated with each of the key fate properties, specifically the:

- vapour pressure;
- octanol-water partition coefficient, and consequently the organic carbon-water partition coefficient;
- fish bioconcentration factor,
- degradation rate in water and soil.

Single values have been selected based on the available data. However, the uncertainty in some of these values is high, and so it is useful to consider whether a change to any one value makes a difference to the PECs and the conclusions. Because of the complexity of assessing the various combinations that are possible, this Appendix generally only considers the influence of varying each parameter in turn using EUSES. In addition, since the release estimates might change with the provision of more data, the discussion is qualitative.

A1.1 Vapour pressure

The vapour pressure has two main impacts on this assessment. It determines the magnitude of the Henry's Law constant (HLC), and it is used to assign the substance to a particular volatility class for the assessment of releases from polymer processing.

Only a limit value is currently available from a test (<1 x 10^{-4} Pa at 20°C). The value chosen for this assessment is two orders of magnitude lower than this value. If it were higher, predicted air concentrations might be higher (due to both increased partitioning to air in a WWTP, and assignment to a different volatility class for polymer processing[33]). It seems unlikely that the substance would be significantly more volatile than decaBDE given its melting point, so this is not considered further. A lower vapour pressure is also possible. This might lead to a different distribution in a WWTP, but this would not make a large difference to the overall conclusions.

A1.2 Organic carbon-water partition coefficient (K_{oc})

The K_{oc} is an important parameter for this assessment. It is used to estimate distribution in the WWTP as well as partitioning between water, sediments and soils.

The measured log K_{ow} suggests that the K_{oc} value could be as low as 945. The implication is that the substance would not partition strongly to sludge, with a consequent higher release to the WWTP effluent. This is not in keeping with the expectations for this substance by analogy with similar substances (e.g. decaBDE) and analytical chemistry experience reported by Albemarle (2005). The K_{oc} used in the assessment (1 x 10^{6}) already leads to surface water concentrations above the water solubility for some scenarios; a lower value would therefore exacerbate this problem.

[33] For comparison, the well-studied plasticiser diethylhexyl phthalate (DEHP, CAS no. 117-81-7) has a vapour pressure of around 3.4 x 10^{-5} Pa at 20°C (KemI, 2001). This substance is considered to be of 'medium' volatility in OECD, 2004a.

A separate sensitivity analysis has been performed in a little more detail (EURAS, 2006). The K_{oc} was varied between 1,000 and 1,000,000,000 L/kg (the level III fugacity model predicted K_{oc} is 1.79 x 10^{13} L/kg), and the analysis is presented graphically in *Figure A1.1*.

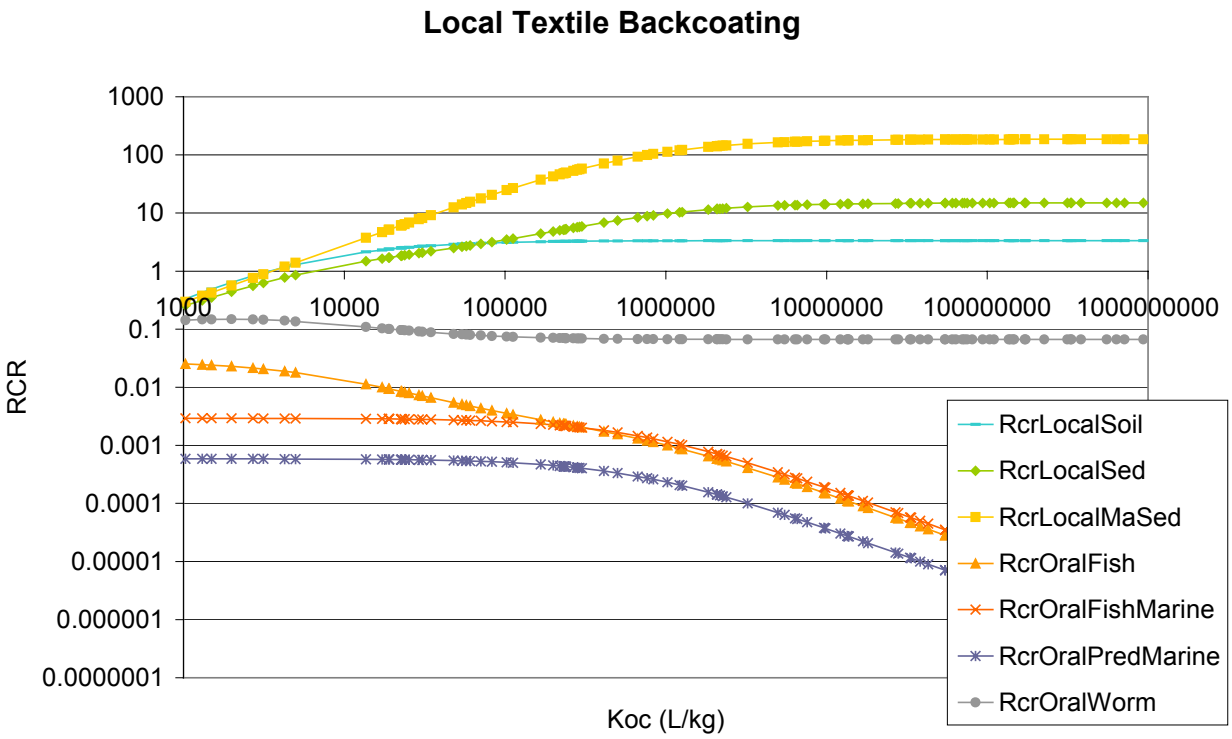

Figure A1.1 Sensitivity of local RCRs for the textile backcoating application scenario towards K_{oc}

The slope of the curves in the figure represents the sensitivity of the local RCRs to the K_{oc}. The figures show that the K_{oc} may change the RCR over several orders of magnitude, although once above 1,000,000 L/kg there is little change for soil and sediments. The sensitivity is high for soil, sediment and marine sediment when the K_{oc} is below 1,000,000 L/kg and also for secondary poisoning when the K_{oc} is above 100,000 L/kg.

Since a K_{oc} of 1,000,000 L/kg is assumed in the main report, a higher K_{oc} is unlikely to make significant difference to the overall conclusions. However, a lower K_{oc} may lead to very different conclusions, so some further reassurance over the choice of value would be helpful.

A1.3 Octanol-water partition coefficient (K_{ow})

The K_{ow} is only used in the main assessment to estimate partitioning between media in the human food chain. As discussed in the main report, it is likely that the measured K_{ow} value is an underestimate, and so a log K_{ow} of ~7.5 is used.

If the measured K_{ow} is used, the estimated daily dose reduces by a factor of around 3,000, due mainly to a lower predicted concentration in plant tissue. Given that the validity of the models is already uncertain for substances with a log K_{ow} of ~7.5, the impact of using a higher value is not considered further.

A1.4 Fish bioconcentration factor

The fish BCF is relevant to the secondary poisoning assessment for marine and fresh waters, as well as the estimation of human exposure via the environment. The measured BCF of 25 L/kg is used in the main assessment. However, there are a number of uncertainties related to the study that gave this value, and a worst case interpretation of the data suggests that the BCF could be in the region of 1,600 L/kg or possibly higher.

The scenarios in the main assessment lead to surface water concentrations that are higher than the measured solubility in pure water (0.72 µg/L). It is therefore unrealistic to apply the higher BCF value to these. If it were assumed that the surface water concentrations are the same order of magnitude as the solubility in pure water, the local fish concentration would be in the region of 1.2 mg/kg wet weight, based on the higher BCF. This concentration is higher than the highest predicted fish concentration for the human food chain of 0.2 mg/kg. However, since the $PNEC_{oral,\ predator}$ is ≥ 220 mg/kg in food, this concentration would not lead to any concern for secondary poisoning in either the freshwater or marine food chains.

Given experience with decaBDE, it is possible that the fish BCF is not a good model of bioaccumulation potential for this type of substance, and that the true level of bioaccumulation might be higher. The fish BCF would have to be in the region of 10,000 for there to be a risk of secondary poisoning (based on the PECs that are above water solubility).

A1.5 Degradation

The only experimental data available indicate that EBP is not readily biodegradable. The obvious assumption therefore is that degradation in the environment will be very slow, an assumption borne out by QSAR analysis and comparison with an analogous substance. However, the observed lack of degradation could have been due to high test substance concentrations and limited bioavailability in the test (no emulsifier was used). In addition, there were unexplained losses in one of the prolonged soil organism toxicity tests over 56 days. The PEC values for soil are calculated following ten years of sludge application, and so the persistence of the substance in soil is a factor in the calculations. The exposure estimates could therefore possibly be refined through the determination of degradation half-lives in soil, or a further test of aquatic degradability.
By assuming that EBP is inherently biodegradable (not fulfilling the criteria), the assumption of zero degradation in a WWTP would remain, but the soil half-life would change from 10^6 to 3,000 days at 12°C. Nevertheless, a potential risk would still be identified for the soil compartment, with no significant change to the RCRs.

The degradation rate in soil depends in part on the soil sorption coefficient, which is derived ultimately from the K_{oc} value in this assessment. Different conclusions might therefore be reached if the potential variability in K_{oc} (and HLC) was taken into account, but this analysis would become too hypothetical given the lack of real data.

It should be noted that any further test of degradation should aim to identify the degradation products if possible (see Appendix 2).

Appendix 2: Potential degradation products

A 2.1 Environmental degradation

Although EBP is not readily biodegradable, and models predict that it may be relatively persistent in the environment, eventual degradation will lead to the formation of other substances. No studies are available that have investigated this issue. This Appendix considers the sorts of substances that might be formed during degradation processes.

A2.1.1 Aerobic reactions

Although probably protected from enzyme attack through steric hindrance, the most obvious metabolic reaction under aerobic conditions would involve oxidation of the ethane bridge:

- Cleavage of the central carbon-carbon bond would produce two molecules of pentabromobenzoic acid from one of EBP. Such a reaction could involve an alcohol and then aldehyde intermediate. None of these substances has been assessed for hazard or risk under any international programme.

- Reaction at the bond with the aryl ring would produce pentabromophenol (CAS no. 608-71-9). This substance has been reviewed by WHO (2005).

- The counterpart of pentabromophenol would be pentabromophenylethanoic acid (again via alcohol and aldehyde intermediates). None of these three substances has been assessed under any international programme.

Table A2.1 presents estimated data for each of these substances (except the aldehydes, which should be readily metabolised to the equivalent carboxylate) based on the chemical structure using the EPIWIN v3.11 model (US EPA, 2000) for consistency. The lowest acute aquatic toxicity result is reported. The water solubilities are those quoted by the ECOSAR v0.99g program, and in some cases these are slightly different from those derived by other calculation methods reported by the same software. The predictions may need to be treated with caution since it is not clear whether the structures fit within the applicability domain of the models.

From the table it can be seen that all of the degradation products are predicted to be potentially persistent.

The two alcohols meet the PBT *screening* criterion for consideration as bioaccumulative (i.e. log K_{ow} >4.5). The BCFs predicted by the model also imply that they might be moderately or significantly bioaccumulative. The two carboxylic acids are unlikely to be bioaccumulative.

Table A2.1 Predicted property data for potential degradation products

Substance and SMILES code	Molecular weight, g/mol	Water solubility, mg/L	log K_{ow}	BCF	Degradation fast?	Acute aquatic L(E)C_{50} mg/L
Pentabromobenzoic acid c1(Br)c(Br)c(Br)c(Br)c(Br)c1C(=O)(O)	516.6	1.19	5.2	5.62	No	3.6*
Pentabromophenylmethanol c1(Br)c(Br)c(Br)c(Br)c(Br)c1CO	502.6	0.56	5.5	803	No	0.0002 - 0.002
Pentabromophenol c1(Br)c(Br)c(Br)c(Br)c(Br)c1O [but see main text]	488.6	0.20	6.0	3,100	No	0.08
Pentabromophenylethanoic acid 1(Br)c(Br)c(Br)c(Br)c(Br)c1CC(=O)(O)	530.6	0.26	5.9	5.62	No	0.89*
Pentabromophenylethanol c1(Br)c(Br)c(Br)c(Br)c(Br)c1CCO	516.7	0.18	6.0	1,900	No	0.06

* Chemical may not be soluble enough to measure the predicted effect.

Pentabromophenol also meets the PBT screening criterion for consideration as bioaccumulative (B) (i.e. log K_{ow} >4.5). WHO (2005) cites the same BCF prediction as presented in Table A2.1, which implies the substance might be moderately or significantly bioaccumulative. An OSPAR fact sheet (available from http://www.ospar.org) also reports essentially the same QSAR-derived information as provided in Table A2.1 (and also cites some measured acute toxicity data for fish and algae). However, WHO (2005) also cites an acid dissociation constant (pK_a) of 4.4, indicating that this substance would be 98-100% ionised at pH 6 and above (and 80% ionised at pH 5). The EPIWIN prediction for the sodium salt gives a log K_{ow} of 3.28. BCF predictions for ionised organic acids have not been well validated, and the bioavailability and uptake of ionising organic substances is an area of uncertainty and ongoing research. Based solely on chemical partitioning, the ionised substance would be expected to absorb more slowly into membrane lipids than the neutral molecule, greatly reducing its uptake into these phases (e.g. based on work with chlorophenols, such as Saarikoski *et al*., 1986; Stehly and Hayton, 1990; Kishino and Kobayashi, 1995). However, the uptake kinetics may be more complex (e.g. Saarikoski *et al*., 1986). Therefore, equal bioavailability and toxicity of each species is considered a conservative but defensible assumption at least at a screening level.

Predictions suggest that no acute toxicity would be expressed up to the water solubility limit for the carboxylic acids, although the other substances would all be classified as toxic to aquatic organisms based on the acute toxicity predictions. Pentabromophenol is potentially a thyroxin competitor and may accordingly accumulate in blood. It may be noted that WHO (2005) cites a measured acute L(E)C_{50} of 0.1 mg/L for fish, which is consistent with the toxicity prediction.

It should also be recognised that other degradation pathways are possible. For example, the CATABOL® program predicts that EBP would be degraded by sequential debromination *and* hydroxylation (Albemarle, personal communication). After the loss of the first bromine atom, no lower brominated diphenyl ethane compounds would be produced – all subsequent lower brominated diphenyl ethanes would have one or more hydroxyl groups. Continued degradation would lead to the rupture of first one and then the second aromatic ring. Hydroxylated metabolites are likely to be more water soluble than the parent substance, although they would still be hydrophobic until several bromine atoms had been replaced. As an illustration, the metabolite with two hydroxyl groups on each aryl ring in the meta- position to the ethane group has the following predicted properties:

SMILES code:	C(c(c(c(c(c1O)Br)O)Br)c1Br)Cc(c(c(c(c2O)Br)O)Br)c2Br
Molecular weight:	719.64
Log K_{ow}:	8.16
Water solubility:	≤6 μg/L

The reliability of EPIWIN predictions for these substances is unknown.

Other reactions may include direct nucleophilic displacement of a bromine atom with glutathione. Pentabromotoluene is also a possible transformation product.

In summary, some of EBP's potential transformation products are of concern. Definitive information on degradation pathways is therefore necessary. It should also be noted that some of the potential transformation products might be commercial substances in their own right, and that other substances might also degrade to these compounds. In other words, EBP would not be the only potential source in the environment.

A2.1.2 Debromination

There is a potential for reductive debromination – i.e. the replacement of bromine atoms with hydrogen – by analogy with other substances such as decaBDE (see EC (2002), particularly Appendix F). This is most likely to occur via abiotic mechanisms (particularly photodegradation) or anaerobic metabolism (e.g. in sediments, WWTP or possibly in the gastro-intestinal tract of organisms). The environmental significance of the reaction for brominated flame retardants in general is still unclear despite a large number of studies. For example, hexabromocyclododecane and tetrabromobisphenol-A are both debrominated by soil and/or sediment micro-organisms under environmentally relevant conditions (KemI, 2005; EA, 2005). However, studies on decaBDE provide somewhat conflicting results and there is an ongoing debate about the significance of any degradation of that substance (EC, 2002; ECB, 2004; EA, 2007).

Section 2.2.2 of the main report states that EBP is unsuitable for HIPS applications that require the most stringent standard of UV stability. The suppliers have provided no information to substantiate this statement, but it is presumably linked to degradation. It is also relevant to note that in an analysis of a plastic pipe, the peak area ratio of two identified nona-congeners to EBP was eight times higher than in the commercial substance itself (Kierkegaard *et al*., 2004). The differences in the ratios could not be explained by the extraction or cleanup procedures, and could imply a degradation reaction.

Compounds that do not absorb UV/visible light in the range 295 to 800 nm can be regarded as insensitive to photolysis on exposure to natural sunlight. Albemarle Corporation (personal communication) has provided a UV/visible light absorption spectrum for EBP dissolved in cyclohexane (no further details are provided on the spectrum). The maximum absorbance (~0.35) occurred at a wavelength of 227 nm. Absorbance was below 0.05 at wavelengths above 290 nm. EBP's low water solubility and particle adsorption behaviour, and light

attenuation by humic materials, etc., are all expected to limit photolysis in natural waters, soils and sewage sludge. Therefore although photodegradation is a possibility, it is probably unlikely to be significant under environmentally relevant conditions in most matrices. However, house, office or car dust might contain significant levels (by analogy with decaBDE), and these have much more potential to receive sunlight exposure.

No information is available about degradation of EBP under anaerobic conditions.

Debromination, if it occurs, could involve the sequential replacement of bromine atoms by hydrogen to produce a number of different isomers, depending on the level of substitution[34]. The properties of these substances have not been measured since they are not commercially available, but they can be estimated using quantitative structure-activity relationships. Table A2.2 presents estimated data for several of these substances, based on the chemical structure using the EPIWIN v3.11 model (US EPA, 2000) for consistency. The isomerism of the molecule is irrelevant for the models that are used. In Table A2.1, the water solubility is that quoted by the ECOSAR v0.99g program, and only the lowest acute toxicity result is given.

Table A2.2 Predicted properties of polybrominated diphenyl ethanes

Substance (with SMILES code)	Mol. Wt g/mol	Vapour pressure at 25°C (x 10^{-6} mmHg)	Water solubility mg/L	log K_{ow}	BCF	Degradation fast?	Lowest acute aquatic L(E)C_{50} mg/L
Diphenyl ethane C(c(c(c(c(c1))))c1)Cc(c(c(c(c2))))c2	182.3	2,540	1.3	4.7	970	Maybe	0.34
Monobromodiphenyl ethane C(c(c(c(c(c1)Br)))c1)Cc(c(c(c(c2))))c2	261.2	143	0.23	5.6	4,300	Maybe	0.075*
Dibromodiphenyl ethane C(c(c(c(c(c1)Br)))c1)Cc(c(c(c(c2)))Br)c2	340.1	11.4	0.04	6.5	21,000	No	0.02*
Tribromodiphenyl ethane C(c(c(c(c(c1)Br)))c1)Cc(c(c(c(c2))Br)Br)c2	419.0	1.1	0.006	7.4	18,000	No	0.003*
Tetrabromodiphenyl ethane C(c(c(c(c(c1)Br))Br)c1)Cc(c(c(c(c2))Br)Br)c2	497.9	0.11	0.0008	8.3	1,100	No	0.0007*
Pentabromodiphenyl ethane C(c(c(c(c(c1)Br)Br)Br)c1)Cc(c(c(c(c2))Br)Br)c2	576.7	0.011	0.0001	9.2	65	No	7 x 10^{-5}*

* Predicted result is outside of model domain.

The validity of the QSAR models for this type of structure is unknown. Based on comparisons for EBP, some of the predictions for the higher molecular weight substances (e.g., the octa- and nonabromo compounds) could be unreliable. This table should therefore be viewed with caution, but it might point to the qualitative trends that could be expected. The higher molecular weight substances are expected to be poorly water soluble, but solubility (as well as volatility) would increase with loss of bromine. The predicted log K_{ow} values are high, and significant bioaccumulation might be possible for some of the substances. Some of the substances are predicted to be highly toxic to aquatic organisms, although the log K_{ow} values tend to exceed the cut-off of the model so these predictions should be viewed with caution. Some of the substances may also be chronically toxic (data not presented; the log K_{ow} cut-off value of the model is 8.0).

[34] As with aerobic metabolism, there are also likely to be other possible reactions that may compete with any debromination pathway.

In summary, the formation of lower congeners would be a cause of concern.

A2.1.3 Summary

EBP is not readily biodegradable, and there is currently no information available to assess the likely significance of any degradation pathway. Some *hypothetical* breakdown products could be more toxic and bioaccumulative than the parent substance. Both Environment Canada and the US EPA have acknowledged the hazards of the potential degradation products (see Section 2.6.3).

Since their formation in the environment is a possibility that cannot be excluded based on current knowledge, it is recommended that further testing be carried out under environmentally relevant conditions to investigate the degradation pathways further.

A2.1.4 Possibilities for testing

The low water solubility of EBP and associated analytical problems might make degradation experiments technically difficult to perform. In addition, suitable analytical techniques would need to be developed to identify any reaction products.

In vitro measurements of metabolic potential have been successfully carried out with decaBDE (e.g. in fish liver tissue) (EA, 2007). This type of experiment might provide one way of examining the potential of higher organisms to metabolise EBP.

Measurements of chemical reactivity (e.g. addressing substitution and elimination reactions, oxidation, etc.) could provide relevant information, although a framework to use the results of such tests is not currently available.

Photodegradation is unlikely to be significant in most matrices. Given the problems with carrying out studies with decaBDE and extrapolating the results to environmental behaviour it is not recommended that this be pursued at the present time. However, further investigation of degradation on dusts may be relevant, particularly in relation to human exposure.

Experiments in water alone are also not considered relevant due to the low water solubility and high adsorption potential for organic matter. Instead the focus should be on those environmental compartments to which the substance will partition, namely WWTP sludge, sediment and/or soil.
To investigate aerobic degradation, an enhanced inherent biodegradability test could be performed using a pre-exposed inoculum. This test would help indicate whether any mineralisation could be expected; efforts should also be made to identify any biotransformation products arising from primary biodegradation. The level of degradation is likely to be low, but the results could be used to guide more detailed long-term simulation tests in sediment and/or sewage sludge.

A number of different follow-up experiments could be performed, for example OECD test guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems), and/or 311 (proposed - Anaerobic Biodegradability in Digested Sludge). In addition, recent studies that have been carried out for decaBDE under environmentally relevant conditions could provide useful model test systems for comparison, e.g. including natural reductants (EA, 2007). Studies performed in the dark and under simulated sunlight would help clarify whether photodegradation has any impact.

Such studies can be costly and time consuming and so proper experimental design and stakeholder endorsement is very important. In all cases, the following must be established:

a) substances to be analysed;
b) specific matrix and conditions of the test;
c) time frame over which degradation would be of concern (which will determine the length of the study);
d) amount and rate of degradation which is of environmental significance.

Depending on the results of such tests, the need for further information on specific properties of the metabolites and/or monitoring could also be considered.

A 2.2 Combustion and pyrolysis products

Any fire will produce a range of hazardous combustion products, such as carbon monoxide, cyanides, polycyclic aromatic hydrocarbons, chlorinated dioxins and furans. Flame retardants may serve to decrease the total amount of hazardous combustion products produced by fires by decreasing the overall number and severity of fires. However, brominated flame retardants (particularly the polybromodiphenyl ethers or PBDEs) have been identified as posing an additional concern because of their potential contribution to the formation of polybrominated and mixed chlorinated/brominated dibenzo-*p*-dioxins and dibenzofurans (e.g. EC, 2002). These substances are not currently well understood, but by analogy with some of their chlorinated counterparts, could be persistent, bioaccumulative and toxic.

Releases might occur from incineration or high temperature processing of plastics containing EBP and during accidental fires involving articles containing the substance (flame retardants do not prevent all fires). Factors that would likely affect the formation of brominated dibenzofurans and dibenzo-*p*-dioxins include the temperature, residence time at the temperature, the presence of oxygen, the type of polymer matrix and the presence of other additives (e.g. antimony trioxide). The following information is taken from study summaries that contain no information about the analytical methods used.

A2.2.1 High temperature processing of plastics

Some information is available about degradation during high temperature processing of polymers. Ranken *et al*. (1994) summarise an analysis of polybrominated dibenzodioxin and dibenzofuran (PBDD/PBDF) content in a sample of a ‘typical’ HIPS formulation containing EBP with antimony trioxide (the original study report has not been reviewed). The matrix was extruded and injection moulded into plaques for analysis, and then the plaques were granulated and injection moulded again four times. The analysis examined the concentration of eight 2,3,7,8- substituted congeners that are listed in the German Dioxin Ordinance. None of the substances were detected (the limits of detection varied from 0.02 to 0.30 ppb depending on the substance being analysed). The results indicated that the PBDD/PBDF concentrations did not exceed the levels specified in the Ordinance even after five thermal treatments.

UBA (2001) states that the sum of toxicologically relevant impurities (eight brominated dioxins and furans) in a synthetic material treated with EBP was below the detection limit (0.02-0.03 µg/kg). The maximum content is given as 64 µg tetra- to octabrominated dioxins and furans. The source of this information has not been checked.

A2.2.2 Controlled incineration

Ranken and Hardy (1994) summarise the results of a laboratory simulation of municipal waste incineration (the original study report has not been reviewed). A laboratory model of a municipal solid waste (MSW) incinerator was built in co-operation with a leading fire technology institution. The model used a continuous feed system, a secondary combustion system, and an auxiliary air supply and operated at temperatures 'typical' of an MSW incinerator. Plastics were incinerated under conditions that were described as representative of those practised at a commercial facility.

A sample of a 'typical' HIPS formulation containing the substance with antimony trioxide was incinerated using a secondary combustion temperature of 950°C and primary combustion temperatures of 750-850°C. The combustion products from three replicate experiments were analysed for 13 2,3,7,8-substituted polybrominated dibenzodioxins and polybrominated dibenzofurans. None were detected (the limit of quantitation varied from 0.1 to 100 ng analyte per gram of material burned (ppb), on the advice of the US EPA).

A2.2.2.1 Legislation

Under the Pollution Prevention and Control (PPC) Regulations, incineration processes in England and Wales are regulated by the Environment Agency and the local authorities. The Environment Agency is responsible for regulating all plants that burn hazardous waste as well those other plants that burn non-hazardous waste at a rate of more than 1 tonne per hour. Local authorities regulate plants burning less than 1 tonne of waste per hour. With a few exceptions like clean wood waste and forestry waste, all incinerators are subject to the requirements of Directive 2000/76/EC (the Waste Incineration Directive) from 28 December 2005. Under this Directive, all plants must comply with limits of 0.1 ng/m^3 for dioxins and 10 mg/m^3 for dust irrespective of the size of the plant or the nature of the waste. In most cases compliance requires the use of abatement for dioxins (e.g. activated carbon injection) and high efficiency dust abatement. The combination of these two measures results in dioxin levels below the prescribed limits.

Given the similarities between chlorinated and brominated dioxins and furans, incinerator design and abatement technologies used to control emissions of chlorinated dioxins and furans should also be effective in limiting the risk from the brominated analogues.

A2.2.3 Accidental fires

The presence of EBP is unlikely to significantly affect the total release of toxic products from accidental fires, given the large amounts of toxic products known to be formed, notably chlorinated dibenzo-*p*-dioxins and dibenzofurans. The substance is likely to represent a small part of the total halogen available in the process (see EC (2002) for further discussion).

A2.2.4 Summary

As a source of bromine, EBP can contribute to the formation of brominated dibenzo-p-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (e.g. recycling). The few experimental studies available suggest that EBP will not be a significant source of such substances. In addition, emission controls are required on incinerators by law, which should ensure that the majority of emissions are at acceptable levels.

Appendix 3: Marine risk assessment

This appendix considers the risks to the marine environment from the use and disposal of EBP. The information is presented separately from the main report in case it is of particular interest to stakeholders such as OSPAR. The local site in this assessment is assumed to be located at the coast. The number of sites in coastal regions that may actually be emitting EBP is unknown.

A3.1 Derivation of marine PECs

The methodology outlined in the TGD essentially assumes that the adsorption/desorption, degradation and accumulation behaviour in the marine environment can, in the absence of specific information for the marine environment, be adequately described by the properties of the substance relevant for the freshwater environment. The relevant properties for EBP are discussed in the main report and are summarised in Table A4.1.

Table A3.1 Adsorption and bioaccumulation properties for EBP

Property	Value
Organic carbon - water partition coefficient (K_{oc}) L/kg	1×10^6
Solid-water partition coefficient in suspended matter (Kp_{susp}) L/kg	1×10^5
Suspended matter - water partition coefficient ($K_{susp\text{-}water}$)	2.5×10^4
Fish bioconcentration factor (BCF_{fish}) L/kg	25
Biomagnification factor in fish (BMF_1)[a]	1
Biomagnification factor in predators (BMF_2)[a]	1

a) Default factors taken from the TGD.

The calculation of marine PEC values has been performed according to the TGD methods, using the EUSES 2 program. The input data are the same as those used for the freshwater calculations with one major difference: the effluent from industrial activity is assumed to enter the marine environment directly, rather than after treatment in a WWTP. The only exception to this when a substance is found in products used by the general population, where discharge via a wastewater treatment plant can be assumed. This situation does not apply to any of the local scenarios for EBP. The default dilution factor is also ten times higher than the standard river water dilution assumed for freshwater.

The resulting PEC values are given in Table A4.2 and cover marine waters, sediments, predators and top predators. No measured concentrations are available for the marine environment for comparison, although EBP has been detected in estuarine sediment in the Netherlands (see Section 3.3.1.2.2 of the main report).

Table A3.2 Estimated PECs for the local marine risk assessment

Life cycle stage	PEC local seawater (mg/L)	PEC local sediment (mg/kg wwt)	PEC oral, predator (mg/kg wwt)	PEC oral, top predator (mg/kg wwt)
Polymer processing (combined compounding and conversion site)	2.1×10^{-4}	5.6	2.7×10^{-3}	5.5×10^{-4}
Textile backcoating formulation	9.3×10^{-3}	250	0.12	0.02
Textile backcoating application	5.9×10^{-3}	160	0.07	0.01

The two textile scenarios give seawater concentrations that are greater than the solubility of the substance in pure water, so the PECs should be treated with caution.

A3.2 Derivation of marine PNECs

A3.2.1 PNEC for water

No toxicity data are available for saltwater organisms (see Section 4.1.2, main report). In the absence of any measured toxicity in acute tests with freshwater organisms, it is not possible to derive a $PNEC_{saltwater}$. It is assumed that the substance is not toxic up to its water solubility limit.

A3.2.2 PNEC for sediment

The $PNEC_{sediment}$ for the marine environment can be estimated from the $PNEC_{sediment}$ for freshwater by using an additional assessment factor of 10 to account for the higher diversity (and therefore potential sensitivity) of marine organisms. Therefore, the $PNEC_{sediment(standard)}$ is $\geq$ 6 mg/kg wet weight.

A4.2.3 PNEC for predators

The PNEC for secondary poisoning ($PNEC_{oral}$) is ≥ 220 mg/kg in food (as for the main assessment).

A3.3 Risk characterisation for the marine environment

The risk characterisation ratios for water, sediment and predators/top predators are shown in Table A4.3.

Table 3.3 Estimated RCRs for the local marine risk assessment

Life cycle stage	Seawater	Sediment	Predator	Top predator
Polymer processing (combined compounding and conversion site)	-	□ 0.9	<0.01	<0.01
Textile backcoating formulation	-	□ **41**	<0.01	<0.01
Textile backcoating application	-	□ **26**	<0.01	<0.01

It is presumed that there will be no risks for marine waters. No risks are identified for polymer processing, or for predatory organisms in any scenario. Since the PECs for food are estimated using water concentrations that are generally higher than the solubility in pure water, the RCRs are likely to be conservative. The assumption of a higher fish BCF would not change the conclusion (see Appendix 1).

A potential risk cannot be excluded for both textile scenarios for marine sediment. However, the PNEC is actually a limit value (i.e. it is based on toxicity tests in which no effects were seen) and could be much lower. In addition, both current suppliers have stated that none of their textile customers are close to the coast or a river estuary, and so these risks appear to be hypothetical in any case.

Uncertainties and refinements

As for freshwater, the marine water concentrations are above the measured solubility in pure water for the textile scenarios, which suggests they are overestimated. If future customers were located at the coast, improved information on releases and fate parameters would allow the assessment to be revised, as suggested for the freshwater assessment.

In terms of effects, a prolonged sediment organism toxicity test could also be considered after the exposure assessment has been revised with better information.

A3.4 Overall conclusions of the marine risk assessment

It is considered unlikely that releases from polymer processing will give rise to risks. There is some concern for marine sediment organisms for two textile scenarios, although no significant effects have yet been observed in sediment organism toxicity tests. This assessment could be refined with the same types of information that are required for the freshwater assessment, although the marine scenario appears to be hypothetical at the moment given the small number of current textile users and the fact that none are located near the coast.

Appendix 4: Impact of increasing consumption

EBP is marketed as an alternative to decabromodiphenyl ether (decaBDE), and European consumption has been on the increase in recent years (see Section 2 of the main report). It is therefore prudent to assess whether the hypothetical removal of decaBDE from the market and its partial replacement by EBP would have any impact on the conclusions of the risk assessment. Greater consumption of EBP, particularly in the textile market, could also occur if more countries adopt fire standards similar to those of the UK.

The total annual EU consumption of decaBDE was assumed to be 8,300 tonnes in 2004 (ECB, 2004). The split was 5,800 tonnes for plastics (mainly for electrical and electronic equipment) and 2,500 tonnes for textiles. A further 1,300 tonnes of decaBDE was assumed to be imported annually into the EU in finished (or partly finished) articles.

Taking account of the existing consumption of EBP, it would seem reasonable to set the annual supply level of EBP at 10,000 tonnes for the purposes of this hypothetical assessment. This would leave some tonnage for other replacement substances. It can also be assumed that the split between the uses is the same as for decaBDE, i.e. 70% in polymers (7,000 tonnes) with the rest in textiles (3,000 tonnes).

At this level of supply, it would be unreasonable to expect that all formulation and application of textile backcoatings would be confined to a single EU region (as assumed in the main assessment). In this case, it will be assumed that 10% of the tonnage for textiles is used in a single region. For simplicity, the calculations have otherwise been made using the same assumptions as in the main report, so the same criticisms will apply.

Details of the calculations are given in the confidential annex to this report. Based on the assumptions used, the worst case local site for each application will typically use the same amount regardless of tonnage, with the possible exception of textile backcoating formulation. The main effect of this assumed higher tonnage is therefore to increase the releases at the regional level, mainly from textile products in service, and at the continental level. The assumptions behind these releases are highly uncertain in any case, but there is no substantial effect on the overall risk characterisation ratios (they are slightly higher) and the conclusions of the main assessment are not affected.

The environmental fate and behaviour of EBP appears to be very similar to decaBDE, so in simplistic terms, increased usage of EBP to around the same volumes as decaBDE would probably lead to similar exposures in the same media, given the similarity in use pattern and physico-chemical properties. However, EBP has not been on the market as long as decaBDE, and there is heightened awareness in the industry about reducing point source releases of this type of substance. In particular, both current European suppliers have recently added EBP to their product stewardship programmes. The scope for widespread emissions at the same level as decaBDE should therefore be lower. Clearly significant differences in degradation rate or metabolism would also influence this conclusion.

Given the drawbacks of the available models for determining the environmental concentrations of highly hydrophobic substances like EBP, further work that might be useful if EBP becomes more widely used could include:

- A survey of EBP concentration in sewage sludges; and
- A substance flow analysis for EBP in the waste stream.

Appendix 5: Data collection and peer review process

This report has been produced using publicly available data gathered and assessed by the Environment Agency. Additional information, including original study reports, has been submitted voluntarily by Albemarle Corporation and Chemtura Corporation.

The Environment Agency has been keen to ensure that the data used in this report are as complete and accurate as possible. Original reports and literature articles for key studies were assessed for reliability wherever possible (it is clearly indicated where this was not the case).

The initial data review began in October 2005. The scientific literature was last searched in February 2007 using Web of Knowledge and Cambridge Scientific Abstracts (as well as Google®). The search terms were the CAS number and partial chemical names.

Drafts of this report have been circulated to key stakeholders in UK, European and US Industry for comment (the final opportunity for comment closed in September 2006), as well as members of the UK and international chemical regulatory communities (including the Advisory Committee on Hazardous Substances). All comments received have been addressed in the final report where appropriate. A full list of consultees is included at the end of this Appendix.

In addition, certain technical aspects of the report were peer-reviewed by an independent expert group set up by the Environment Agency for this purpose in September 2006. Again, this report addresses those comments. The experts were:

Professor Å Bergman (Stockholm University, Sweden);
Assistant Professor H Stapleton (Duke University, USA); and
Dr A Sweetman (Lancaster University).

Their comments have not been published but are available on request.

LIST OF ORGANISATIONS CONSULTED

INDUSTRIAL ORGANISATIONS

Albemarle Corporation
British Apparel and Textile Confederation
British Association for Chemical Specialities
British Chambers of Commerce
British Chemical Distributors and Traders Association
British Plastics Federation
Chemical Industries Association
Chemtura Corporation
Euratex
European Plastics Converters
Plastics Europe
Textile Finisher's Association
Textile Institute

UK GOVERNMENT BODIES

Advisory Committee for Hazardous Substances
Department of the Environment, Food and Rural Affairs
Department of the Environment, Northern Ireland
Department of Health
Department of Trade and Industry
Food Standards Agency
Health and Safety Executive
Health Protection Agency
Natural England
Pesticides Safety Directorate
Scottish Environment Protection Agency
Scottish Executive
Veterinary Medicines Directorate
Welsh Assembly

REGULATORY AUTHORITIES

Environment Canada
European Union Technical Committee for New and Existing Substances

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