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Öko-Institut e.V.
Institut für angewandte Ökologie
Institute for Applied Ecology

Evaluation of small brominated alkyl alcohols for a possible RoHS restriction

Final Report

January 2017

Substance Name: Small brominated alkyl alcohols (group)

EC Number(s): 202-480-9; 202-489-8; 243-029-6; 627-179-3; 221-967-7; 622-370-8; 253-057-0; further substances not associated with EC numbers detailed in Appendix I

CAS Number(s): 96-13-9; 96-21-9; 106023-63-6; 19398-47-1; 79033-40-2; 4021-75-4; 87018-30-2; 35330-59-7; 14396-65-7; 855236-37-2; 87018-38-0; 105100-80-9; 213821-22-8; 408319-76-6; 159475-15-7; 343268-04-2; 76377-07-6; 59287-66-0; 856991-78-1; 100606-66-4; 213821-20-6; 98069-26-2; 3296-90-0; 44804-46-8; 1522-92-5; 36483-57-5; further substances not associated with CAS numbers detailed in Appendix I

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Abbreviations

BFR	Brominated flame retardant
BSEF	Bromine Science Environmental Forum
CAS number	A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CIAJ	The Communications and Information Network Association of Japan
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH)
Danish EPA	Danish Environmental Protection Agency
DTU Food	Danish Technical University, National Food Institute
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission.
EEE	Electrical and electronic equipment
EFRA	The European Flame Retardant Association
IEC	International Electrochemical Commission
IPC	Association Connecting Electronics Industries
JBCE	The Japanese Business Council
JBMIA	The Japan Business Machine and Information System Industries Association
JEITA	The Japan Electronics & Information Technology Industries Association
JEMA	The Japan Electrical Manufacturers' Association
MSDS	Material safety data sheet
n.d.	Not defined
PCB	Printed circuit board
PU	Polyurethane
PUR	Rigid polyurethane
SBAA	Small brominated alkyl alcohols
SME	Small and medium enterprises
TBBPA	Tetrabromobisphenol-A
TMC	The Test and Measurement Coalition
ZVEI	Zentralverband Elektrotechnik- und Elektronikindustrie e. V. - the German Electrical and Electronic Manufacturers' Association

Background

Hazardous substances in electrical and electronic equipment (EEE) are regulated by the RoHS Directive 2011/65/EU (RoHS 2). According to article 6(1) it is possible for member states to submit a proposal for adding new substances to the list of restricted substances of the directive. Article 6(1) and 6(2) describe the criteria and requirements for proposals for restrictions respectively.

In 2014 the Danish EPA performed a survey on brominated flame retardants (BFRs) (Danish EPA, 2014). On the basis of its results, the Danish Technical University (DTU Food) investigated possibilities of grouping BFRs in relation to substance structure and toxicological properties. One of the groupings; the small linear and branched brominated alkyl alcohols, including 2,3-dibromo-1-propanol (CAS 96-13-9) and 2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0) and 2,2-bis-(bromomethyl)-3-bromo-1-propanol (CAS 36483-57-5), was chosen for further investigation and the grouping was extended to include also theoretical compounds. The category, defined as having 3-5 carbons, 2-3 bromine atoms and 1-2 alcohol groups, comprises 62 members (Danish EPA, 2016).

The Danish EPA has commissioned Oeko-Institut e.V along with COWI AS, a project to collect, assess and present scientific data to support a proposal for restriction of small brominated alkyl alcohol in the RoHS Directive, if the data prove to be adequate.

Data has been compiled based on publicly available data and through consultation with stakeholders (both through performing a public stakeholder consultation and through direct correspondence with relevant stakeholders).

1. Identification, Classification and Labelling, Legal Status and Use Restrictions

1.1. Identification

The group of substances is defined as small brominated linear and branched alkyl alcohols with 3-5 carbons, 1-2 alcohol groups, and 2-4 bromine atoms. In the identified group the smallest member has 3 carbons, two bromine atoms and one alcohol group, such as 2,3-dibromo-1-propanol (CAS 96-13-9), and the two largest members have 5 carbons, 2-3 bromine atoms and 1-2 alcohol groups such as (2,2-bis(bromomethyl)propane-1,3-diol, CAS 3296-90-0 and 2,2-bis-(bromomethyl)-3-bromo-1-propanol, CAS 36483-57-5).

According to the Danish EPA report (2016), the substance group theoretically[1] comprises 62 members. Two substances are structurally identical but with different CAS numbers. CAS numbers have been allocated to 26 of the members (including the two substances which are structural identical). For seven of the substances, EC numbers exist. The general substance identity and composition of the various group substances is presented in Table 1-1. More detailed information is provided for the seven substances with both CAS and EC number in Table 1-2. For 19 substances there was lacking information on substance identity, they are compiled separately in Table 1-3.

A complete list of all 62 substances understood to fall in scope of the proposed group is available in Appendix I. This list is reproduced on the basis of the data available in the Danish EPA (2016) report. Some of the substances may at this point in time be theoretical.

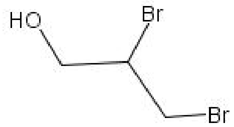
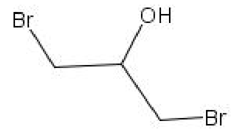
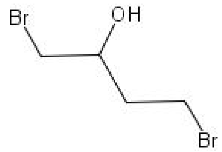
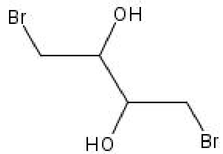
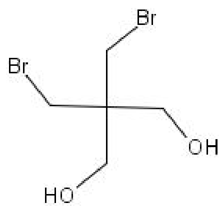
1.1.1. Name, other identifiers, and composition of the substance

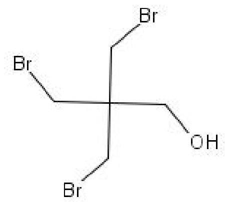
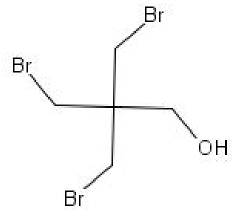
Table 1-1: Substance identity and composition

Chemical name	Small brominated alkyl alcohols (substance group)
EC number	202-480-9; 202-489-8; 243-029-6; 627-179-3; 221-967-7; 622-370-8; 253-057-0
CAS number	96-13-9; 96-21-9; 106023-63-6; 19398-47-1; 79033-40-2; 4021-75-4; 87018-30-2; 35330-59-7; 14396-65-7; 855236-37-2; 87018-38-0; 105100-80-9; 213821-22-8; 408319-76-6; 159475-15-7; 343268-04-2; 76377-07-6; 59287-66-0; 856991-78-1; 100606-66-4; 213821-20-6; 98069-26-2; 3296-90-0; 44804-46-8; 1522-92-5; 36483-57-5; further substances not associated with CAS numbers are detailed in Appendix I
Molecular formula	$C_xBr_yO_z$: x=3-5; y=2-4; z=1-2
Molecular weight range	217.9-324.8 (where data is available)

[1] The Danish EPA report (2016) identified the chemical structures of the theoretical members of the category and generated SMILES codes.

Table 1-2: Substance identity and composition

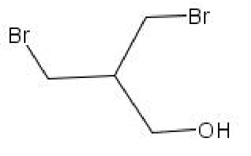
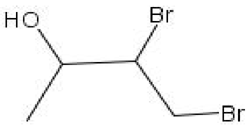
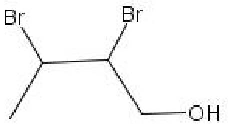
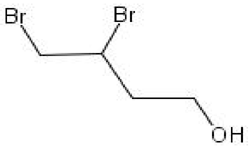
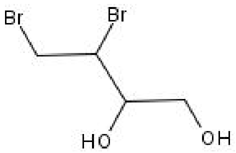
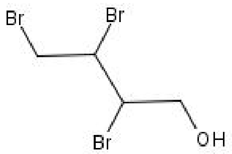
Chemical name	EC number	CAS number	IUPAC name	Index no. in Annex VI of the CLP Regulation	Molecular formula	Molecular weight	Synonyms	Structural formula
2,3-Dibromo-1-propanol	202-480-9	96-13-9	2,3-Dibromo-propan-1-ol; 2,3-Dibromo-1-propanol	602-088-00-1	$C_3H_6Br_2O$	217.9	2,3-dibromopropan-1-ol; DBP; DBP (flame retardant); 1,2-dibromopropan-3-ol; 2,3-dibromo-propyl alcohol	
1,3-dibromopropan-2-ol	202-489-8	96-21-9	1,3-Dibromo-propan-2-ol	n.d.	$C_3H_6Br_2O$	217.9	1,3-Dibromo-2-hydroxypropane;1,3-Dibromo-2-propanol; 1,3-Dibromohydrin; 1,3-Dibromopropanol;2-Hydroxy-1,3-dibromopropane; Glycerol 1,3-dibromohydrin; Glycerol a,g-dibromohydrin; NSC 636; a,g-Dibromohydrin; a-Dibromohydrin	
1,4-dibromobutan-2-ol	243-029-6	19398-47-1	1,4-dibromo-butan-2-ol	n.d.	$C_4H_8Br_2O$	231.9	-	
1,4-Dibromo-2,3-butanediol	627-179-3	14396-65-7	1,4-Dibromo-2,3-butanediol	n.d.	$C_4H_8Br_2O_2$	247.9		
2,2-bis(bromomethyl)propane-1,3-diol	221-967-7	3296-90-0	2,2-Bis(bromo-methyl)-1,3-propanediol 2,2-Bis(bromo-methyl)propane -1,3 2,2-Bis(bromo-methyl)propane	n.d.	$C_5H_{10}Br_2O_2$	262.0	Dibromo-neopentyl-glycol, 2,2-Bis(bromomethyl)-1,3-propanediol (Technical Grade)	

Chemical name	EC number	CAS number	IUPAC name	Index no. in Annex VI of the CLP Regulation	Molecular formula	Molecular weight	Synonyms	Structural formula
			-1,3-diol FR-522					
3-Bromo-2,2-bis(bromomethyl)-1-propanol	622-370-8	1522-92-5	3-Bromo-2,2-bis(bromomethyl)-1-propanol Pentaerythritol Tribromide	n.d.	$C_5H_9Br_3O$	324.8	-	
2,2-dimethylpropan-1-ol (TBNPA)	253-057-0	36483-57-5	2,2-Dimethyl-propan-1-ol, tribromo derivative 3,3,3-tribromo-2,2-dimethyl-propan-1-ol FR-513	n.d.	$C_5H_9Br_3O$	324.8	2,2-dimethylpropan-1-ol, tribromo derivative* Trisbromoneopentyl alcohol, Tribromoneopentanol; 2,2-Bis-(bromomethyl)-3-bromo-1-propanol; tribromoneopentyl alcohol	

There are several substances in this group for which EC numbers are not available and further information on identity, such as chemical name is missing. The absence of records in databases such as the ECHA Information on Chemicals database, the OECD's eChemPortal and the industry supplier's database, LookChem, gives an impression that the substances might not be available on the market.

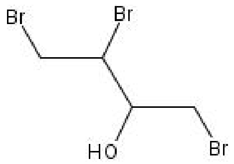
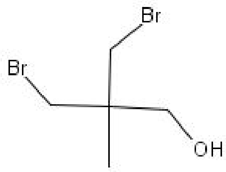
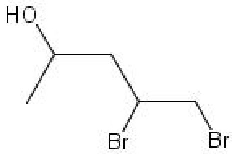
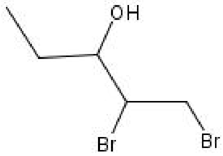
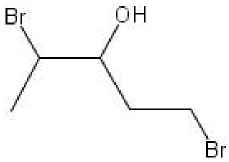
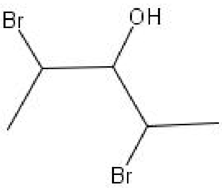
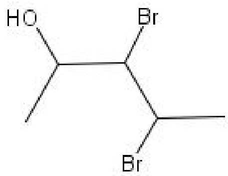
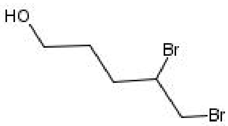
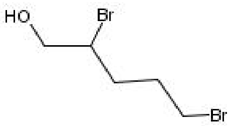
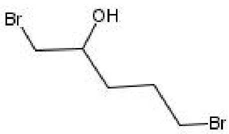
3-Bromo-2,2-bis(bromomethyl)-1-propanol (CAS 1522-92-5) and 2,2-dimethylpropan-1-ol (CAS 36483-57-5) have an identical structural formula. Therefore Danish EPA (2016) considered them as a single substance; Danish EPA (2014) also refer to these two substance as the same substance. However, they have different EC numbers and the ECHA Information on Chemicals database lists two different entries. Reports such as e.g. EFSA (2012) refer to only one CAS number.

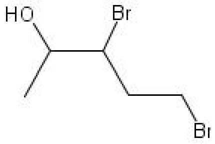
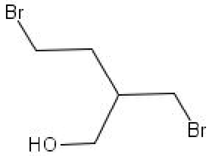
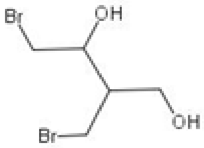
Table 1-3: SBAA with lacking information on substance identity and composition

Chemical name	CAS number	Molecular formula	Structural formula	Remarks
3-Bromo-2-(bromomethyl)-1-propanol	106023-63-6	$C_4H_8Br_2O$		No results in ECHA database and eChemPortal; however supplier are available according to LookChem[2]
3,4-Dibromo-2-butanol	79033-40-2	$C_4H_8Br_2O$		No results in ECHA database, eChemPortal and LookChem
2,3-dibromobutan-1-ol	4021-75-4	$C_4H_8Br_2O$		No results in ECHA database and eChemPortal; however supplier are available according to LookChem[3]
3,4-Dibromo-1-butanol	87018-30-2	$C_4H_8Br_2O$		No results in ECHA database, eChemPortal and LookChem
3,4-Dibromo-1,2-butanediol	35330-59-7;	$C_4H_7Br_2O_2$		
2,3,4-Tribromo-1-butanol	855236-37-2	$C_4H_7Br_3O$		

2 http://www.lookchem.com/newsell/search.aspx?key=106023-63-6

3 http://www.lookchem.com/newsell/search.aspx?key=4021-75-4

Chemical name	CAS number	Molecular formula	Structural formula	Remarks
1,2,4-Tribromo-3-butanol	87018-38-0	$C_4H_7Br_3O$		
2,2-Bis(bromomethyl)-1-propanol	105100-80-9	$C_5H_{10}Br_2O$		
4,5-Dibromo-2-pentanol	213821-22-8	$C_5H_{10}Br_2O$		
1,2-Dibromo-3-pentanol	408319-76-6	$C_5H_{10}Br_2O$		
1,4-dibromo-(R*,R*)-(9CI)-3-pentanol	159475-15-7	$C_5H_{10}Br_2O$		
2,4-Dibromo-3-pentanol	343268-04-2	$C_5H_{10}Br_2O$		
3,4-Dibromo-(2R*,3S*,4S*) -(9CI)-2-pentanol	76377-07-6	$C_5H_{10}Br_2O$		
4,5-Dibromo-1-pentanol	59287-66-0	$C_5H_{10}Br_2O$		
2,5-Dibromo-1-pentanol	856991-78-1	$C_5H_{10}Br_2O$		
2-Pentanol, 1,5-dibromo-	100606-66-4	$C_5H_{10}Br_2O$		No results in ECHA database and eChemPortal; however supplier are available according to

Chemical name	CAS number	Molecular formula	Structural formula	Remarks
				LookChem[4]
2,5-Dibromo-2-pentanol	213821-20-6	$C_5H_{10}Br_2O$		No results in ECHA database, eChemPortal and LookChem
4-Bromo-2-(bromomethyl)-1-butanol	98069-26-2	$C_5H_{10}Br_2O$		
4-Bromo-2-(bromomethyl)-1,3-butanediol	44804-46-8	$C_5H_{10}Br_2O_2$		

1.1.2. Physico-chemical properties

Physico-chemical properties are summarised for the group in Table 1-4 below, where data is available for at least 3 substances (i.e. suggesting a range). Table 1-5 provides the data available for specific substances.

Table 1-4: Overview of physico-chemical properties of SBAA

Property	Value
Physical state at 20°C and 101.3 kPa	Variable (liquid/solid)
Melting/freezing point	Range: 8°C – 109.5 °C
Boiling point	83 °C - 365.3 °C
Vapour pressure	Data available only for two substances
Water solubility	Variable (insoluble – very soluble)
Partition coefficient n-octanol/water (log P_{OW})	Range: 0.96 – 2.6
Dissociation constant	Data available only for one substance
Vapour density relative to air	Data available only for one substance
Specific gravity	Data available only for one substance

4 http://www.lookchem.com/newsell/search.aspx?key=100606-66-4

Table 1-5: Overview of physico-chemical properties

Substance (CAS)	Physical state at 20°C and 101.3 kPa	Melting/ freezing point	Boiling point	Vapour pressure	Water solubility	Partition coefficient n-octanol/ water (log P_{ow})	Dissocia-tion constant	Vapour density relative to air	Specific gravity	Sources
2,3-Dibromo-1-propanol (CAS 96-13-9)	Clear colourless liquid	8°C	219°C	0.09 mm Hg at 25°C	52 g/L at 25°C	0.96		2.12	2.12 at 20°C/4°C	TOXNET ChemIDplus[5]
1,3-dibromopropan-2-ol (CAS 96-21-9)	-	-	83 °C * 194.3°C **	-	-	-	-	-	-	*: GESTIS Stoffdatenbank[6] **: LookChem[7]
1,4-dibromobutan-2-ol (CAS 19398-47-1)	Brown viscous liquid.	-	220.1 °C	-	-	-	-	-	-	LookChem[8]
1,4-Dibromo-2,3-butanediol (CAS 14396-65-7)	Solid	82-84 °C	365.3°C	-	-	-	-	-	-	LookChem[9]
3,4-Dibromo-1-butanol (CAS 87018-30-2)	-	-	271.9°C	0.000818 mm Hg at 25°C	-	-	-	-	-	Chemnet[10]
2,2-bis(bromomethyl) propane-1,3-diol (CAS 3296-90-0)	Solid	108.5 - 109.5 °C	ca. 270°C	$1x10^{-3}$ to 4.1 x 10^{-3} Pa at 25 °C, mean=$2x10^{-3}$ Pa	Very soluble: 19.4 g/l at 20.0 ± 0.5°C	1.08	-	-	-	ECHA registration dossier[11]
3-Bromo-2,2-	Solid	64-66 °C	365.3°C	-	Insoluble	-	-	-	-	LookChem[12]

5 https://chem.sis.nlm.nih.gov/chemidplus/rn/96-13-9#physical

6 http://gestis.itrust.de/nxt/gateway.dll?f=templates&fn=default.htm&vid=gestisdeu:sdbdeu

7 http://www.lookchem.com/newsell/search.aspx?key=96-21-9

8 http://www.lookchem.com/newsell/search.aspx?key=19398-47-1

9 http://www.lookchem.com/newsell/search.aspx?key=14396-65-7

10 http://www.chemnet.com/cas/en/87018-30-2/3,4-dibromobutan-1-ol.html

11 https://echa.europa.eu/registration-dossier/-/registered-dossier/7873/1

Substance (CAS)	Physical state at 20°C and 101.3 kPa	Melting/ freezing point	Boiling point	Vapour pressure	Water solubility	Partition coefficient n-octanol/ water (log P_{OW})	Dissocia-tion constant	Vapour density relative to air	Specific gravity	Sources
bis(bromomethyl)-1-propanol (CAS 1522-92-5)										
2,2-dimethylpropan-1-ol (TBNPA) (CAS 36483-57-5)	Solid**	68,96°C*	145°C*	-	Soluble: 1.93 g/l at 20.1°C**	2.6 **	-	-	-	* GESTIS Stoffdatenbank; ** ECHA registration dossiers

12 http://www.lookchem.com/newsell/search.aspx?key=1522-92-5

1.2. Classification and labelling status

The Classification, Labelling and Packaging (CLP) regulation[13] ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of Regulation No 1272/2008 lists substances where a harmonized classification exists based on e.g. human health concerns. However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification.

Classification in Annex VI Regulation No 1272/2008

A harmonized classification according to Annex VI Regulation No 1272/2008 is available for one substance: 2,3-dibromopropan-1-ol (CAS 96-13-9), the classification according to Table 3.1 of Annex VI is presented in Table 1-6.

Table 1-6: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonized classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
602-088-00-1	2,3-dibromo-propan-1-ol; 2,3-dibromo-1-propanol	202-480-9	96-13-9	Carc. 1B Repr. 2 Acute Tox. 3 Acute Tox. 4 Acute Tox. 4 Aquatic Chronic 3	H350 H361f H311 H332 H302 H412	GHS08 GHS07 Dgr	H350 H361f H311 H332 H302 H412	--	--	--

Source: Annex VI Regulation No 1272/2008

Self-classification(s)

Where harmonised classification is not available, suppliers are obliged to decide on the classification of a substance or mixture. This CLP provision is called self-classification.

Self-classifications were retrieved for the seven substances which have an EC number. In the cases where different self-classifications appeared, the classifications most commonly notified are reproduced in Table 1-7, also referring to the total number of notifications for each substance. Notifications made only in a few cases are reproduced in cases where they include stricter classification categories. It should be noted that the fact that a classification is supported by multiple notifications does not necessarily mean that it is correct. There is no conclusive relation between the number of notifications and the correctness of classification, both in cases where the majority support a classification which is more strict and where the opposite is the case.

[13] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

Furthermore, experience has led e.g. Danish EPA (2010) to the conclusion that the lack of data on hazardous properties of chemicals makes it difficult for companies to meet their obligations to self-classify the chemicals they import or produce. In this sense, though a large number of notifications may be indicative of a large number of users, it cannot be assumed that a lack of notifications is to be concluded as a lack of use of a substance.

Table 1-7: Overview on self-classification

Substance (CAS)	Classification		No. of companies notifying this classification
	Hazard Class and Category Code(s)	Hazard statement code(s)	
2,3-Dibromo-1-propanol (CAS 96-13-9)	Acute Tox. 4 Acute Tox. 3 Acute Tox. 4 Carc. 1B Repr. 2 Aquatic Chronic 3	H302 H311 H332 H350 H361 H412	27 out of 27
1,3-dibromopropan-2-ol (CAS 96-21-9)	Flam. Liq. 3 Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2 STOT SE 3 Carc. 2	H226 H301 H315 H319 H335 H351	23 out of 27
1,4-dibromobutan-2-ol (CAS 19398-47-1)	No notifications submitted.		
1,4-Dibromo-2,3-butanediol (CAS 14396-65-7)	Skin Irrit. 2 Eye Dam. 1 STOT SE 3	H315 H318 H335	23 out of 23
2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0)	Acute Tox. 4 Eye Irrit. 2 Muta. 2	H302 H319 H341	355 out of 493
	Eye Irrit. 2 Muta. 1B Carc. 1B STOT RE 2 Aquatic Chronic 4	H319 H340 H350 H373 H413	76 out of 493
	Carc. 2	H351	27 out of 493
3-Bromo-2,2-bis(bromomethyl)-1-propanol (CAS 1522-92-5)	Eye Irrit. 2	H319	24 out of 25
	Acute Tox. 4 Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Acute Tox. 4	H302 H312 H315 H319 H332	1 out of 25
2,2-dimethylpropan-1-ol (TBNPA) (CAS 36483-57-5)	Aquatic Chronic 3	H412	69 out of 122
	Aquatic Chronic 3 Eye Irrit. 2	H412 H319	24 out of 122
	Acute Tox. 4 Muta. 2	H302 H341	15 out of 122
	Eye Irrit. 2 Muta. 1B Carc. 1B	H319 H340 H350	6 out of 122

Source: Compiled from data from: https://echa.europa.eu/information-on-chemicals/cl-inventory-database

The self-classification presented above does not point out the carcinogenic potential with a possible mutagenic/genotoxic mode of action of the substances, which the read across performed by DANISH EPA (2016) would imply. (Q)SAR predictions were performed for the members of the SBAA group (DANISH EPA 2016). Predictions for carcinogenic and mutagenic/genotoxic properties indicated that the 61 members in the category of small linear and branched brominated alkyl alcohols have a carcinogenic potential with a possible mutagenic/genotoxic mode of action. Experimental data for a small number of the members of the group is available. The experimental data supports the (Q)SAR prediction. The results of the read across leading to the proposed grouping of the SBAA are discussed in Section 1.

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

The substances described are not subject to **authorization** under REACH.

As for the substance 2,3-dibromopropan-1-ol (CAS 96-13-9), which is harmonized classified as being toxic to reproduction, entry 28 of REACH Annex XVII "**Restrictions** on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles" applies.

Entry 28 is relevant for substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008, classified as carcinogen category 1A or 1B (Table 3.1) or carcinogen category 1 or 2 (Table 3.2).

According to entry 28, specified substances "*shall not be placed on the market, or used,*

- as substances,
- as constituents of other substances, or,
- in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008"

The **registration** obligations applicable under REACH have so far lead to the registration of:

- 2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0); and
- 2,2-dimethylpropan-1-ol, tribromo derivative (CAS 36483-57-5)

The registration deadline by 31 May 2018 for substances manufactured or imported at 1-100 tonnes a year might result in additional registrations of SBAA, as suggested by the number of self-classifications indicating a use of the substances.

1.3.2. Other legislative measures

The U.S. EPA regulates 2,2-bis(bromomethyl)propane-1,3-diol, (CAS 3296-90-0) under the Toxic Substances Control Act (TSCA). Table 1-8 summarizes the U.S. EPA health and safety data reporting regulations (NTP 2002).

Table 1-8: U.S. EPA Regulations

U.S. EPA Regulations	
Regulatory action	Effect of regulation and other comments
40 CFR 716 – PART 716 – HEALTH AND SAFETY DATA REPORTING. Promulgated: 51 FR 32726, 09/15/86. U.S. Codes: 15 U.S.C. 2607(d). 2,2-Bis(bromomethyl)-1,3-propanediol has an effective date of 6/1/87 and a sunset date of 12/19/95.	This subpart sets forth requirements for the submission of lists and copies of health and safety studies on chemical substances and mixtures selected for priority consideration for testing rules under section 4(a) of TSCA and on other chemical substances and mixtures for which U.S. EPA requires health and safety information in fulfilling the purposes of TSCA.

Source: The regulations in this table have been updated through the 1998 Code of Federal Regulations 40 CFR, July 1, 1996; 21 CFR, April 1, 1996; 29 CFR, July 1, 1996.

Source: NTP (2002)

2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0) is a specified substance in the U.S. EPAs Emergency Planning and Community Right-To-Know Act Toxics Release Inventory. Listed substances are subject to reporting requirements (NTP 2014).

1.3.3. Non-governmental initiatives

Information as to initiatives specifically referring to the use (or to the phase-out) of the substances from the small brominated alkyl alcohol group has not been found. Nonetheless, various initiatives exist in relation to the general use of bromine in EEE, in some cases also prescribing voluntary thresholds for the presence of bromine in EEE articles. This includes among others the following:

- Green labelling schemes: the presence of hazardous substances is sometimes addressed in such schemes through criteria related to the use of various substances. In relation to bromine based substances, the for example, the Blue Angel Label requirements differ from product to product where brominated and chlorinated compounds are concerned. For hair dryers and TV sets, the criterion is that "halogenated polymers shall not be permitted. Neither may halogenated organic compounds be added as flame retardants. Moreover, no flame retardants may be added which are classified pursuant to Table 3.1 or 3.2 in Annex VI to Regulation (EC) 1272/2008 as very toxic to aquatic organisms with long-term adverse effect and labelled with Hazard Statement H 410 or Risk Statement R 50/53." Process-related, technically unavoidable impurities; fluoroorganic additives used to improve the physical properties of plastics (provided that they do not exceed 0.5 weight percent) and plastic parts less than 25 grams in mass are exempt from this rule (Blue Angel 2012). Nordic Swan requires that organic halogenated flame retardants and other flame retardants assigned one or more of the following hazard statements, or combinations, must not be added: H350, H350i, H340, H360F, H360D, H360Fd, H360Df (Osmani et al. 2014). As for SBAA, this is the case for 2,3-Dibromo-1-propanol (CAS 96-13-9), 2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0) and 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5).
- In 2009 iNEMI, the International Electronics Manufacturing Initiative, published a position statement referring to a threshold for the presence of bromine in EEE components specified to be "low halogen". The position paper supports the following definition of "low halogen" (BFR-/CFR-/ PVC-free) electronics: "*A component* must meet all of the following requirements to be Low Halogen ("BFR/CFR/PVC-Free")*:

- All printed board (PB) and substrate laminates shall meet Br and Cl requirements for low halogen as defined in IEC 61249-2-21 and IPC-4101B (refer to International Electrochemical Commission’s (IEC) and Association Connecting Electronics Industries (IPC) standards for actual requirements) saying that for non-halogenated epoxide with a glass transition temperature of 120°C degree minimum, the maximum total halogens contained in the resin plus reinforcement matrix is 1500 ppm with a maximum chlorine of 900 ppm and maximum bromine being 900 ppm.
- Non-halogenated epoxide with a glass transition temperature of 120°C minimum. The maximum total halogens contained in the resin plus reinforcement matrix is 1500 ppm with a maximum chlorine of 900 ppm and maximum bromine being 900 ppm.
- For components* other than printed board and substrate laminates: Each plastic within the component contains < 1000 ppm (0.1%) of bromine [if the Br source is from BFRs] and < 1000 ppm (0.1%) of chlorine [if the Cl source is from CFRs or PVC or PVC copolymers].”

iNEMI member companies supporting this definition include: Cisco, Dell Inc., Doosan Corporation, HP, Intel Corporation, Lenovo, Nan Ya Plastics Corporation, Senju Comtek Corp. Sun Microsystems, Inc. and Tyco Electronics.

2. Use in electrical and electronic equipment

In relation to applications and uses of the substances of the small brominated alkyl alcohol group, the following research approach has been followed:

- Data was obtained through a search of the substance CAS numbers and where available the substance EC numbers in the following databases:
  - ECHA Information on Chemicals database[14];
  - The Global Portal to Information on Chemical Substances of the OECD eChemPortal[15];
  - TOXNET-Toxicology Data Network - HSDB® (Hazardous Substances Data Bank) of the U.S. National Library of Medicine[16];
  - The National Toxicology Program, US Department of Health and Human Services; and
  - The SPIN database – Substances in Preparations in the Nordic countries[17] and information by the Danish product register provided by Danish EPA.
- Additionally, an internet research with CAS/EC numbers and relevant key words was carried out, identifying among others safety data sheets for some of the substances (most often, the combination of CAS number and the term "material safety data sheet" retrieved such documents).

Detailed information is reproduced below in relation to substances of the SBAA group for which information and data was available.

2.1. 2,3-dibromopropan-1-ol (CAS: 96-13-9), synonym: 2,3-dibromo-1-propanol

2.1.1. Function of the substance

According to the substance profile of the National Toxicology Program of the U.S. Department of Health and Human Services Secretary in its 13th Report on Carcinogens (RoC), 2,3-dibromo-propan-1-ol is used as an intermediate in the preparation of flame retardants, insecticides, and pharmaceuticals (NTP 2014a).

A monography on the substance prepared by WHO International Agency for Research on Cancer IARC in the series "Monographs on the Evaluation of Carcinogenic Risks to Humans" (WHO IARC 2000a),[18] specifies the substance to have been used as intermediate in the preparation of flame retardants, insecticides, and pharmaceuticals.

Its main use was in the production of the brominated flame retardant tris(1,2,3-dibromopropyl) phosphate that was used in textiles, commonly called "Tris" (WHO IARC 2000a; NTP 2014a). According to NTP (2014a), the chemical has also been used as a flame retardant as such.

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14 http://echa.europa.eu/information-on-chemicals

15 http://www.echemportal.org/echemportal/page.action?pageID=9

16 https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm

17 http://www.spin2000.net

18 WHO IARC (2000a): IARC Monographs on the Evaluation of Carcinogenic Risks To Humans, Some Industrial Chemicals Vol. 77; http://monographs.iarc.fr/ENG/Monographs/vol77/index.php; substance profile for 2,3-DIBROMOPROPAN-1-OL available at: https://monographs.iarc.fr/ENG/Monographs/vol77/mono77-17.pdf

2.1.2. Types of applications / types of materials

According to NTP (2014a), “Tris”, produced from 2,3-dibromopropan-1-ol, was used in the past in the fabrication of children’s clothing and other products, until it was banned from use in sleepwear in 1977 by the Consumer Product Safety Commission after studies showed that it caused cancer in experimental animals.

The IARC monography states that production of this flame retardant other than for research purposes has been discontinued (WHO IARC 2000a). MSDS available on the internet indicate “laboratory chemicals” as recommended use.[19]

2.1.3. Quantities of the substance used

2,3-dibromo-1-propanol is not registered under REACH, it is therefore understood either not to be used in the EU or to be applied in low quantities (in which case there would not be data available to establish a volume for the EU).

The European Flame Retardant Association, which represents the leading organisations who manufacture, market or use flame retardants in Europe stated in a stakeholder consultation in 2014[20] “We do not have any information about 2,3-dibromo-1-propanol, since none of the EFRA member companies manufacture this substance. We thus also believe that its use in E&E should be negligible, if it takes place at all.”

On the other hand, the case of 2,3-dibromo-1-propanol suggests that it is not always clear which (brominated) flame retardant is used within the supply chain. The Test & Measurement Coalition stated in the above-mentioned stakeholder consultation that an in-depth-survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitution would impact safety or other qualifications (e.g. for flame-retarded uses such as epoxy internal to power supplies).[21]

The IARC monography states that 2,3-dibromo-1-propanol is only produced for research purposes (WHO IARC 2000a).

In the United States, production of 2,3-dibromo-1-propanol was more than 10 million pounds in 1976, but decreased drastically after the use of “Tris” was banned in sleepwear (NTP 2014a). In 2009, 2,3-dibromo-1-propanol was produced by two manufacturers in East Asia and was available from 16 suppliers, including 9 U.S. suppliers (NTP 2014a). Reports filed in 1986, 1990, and 1998 under the U.S. Environmental Protection Agency’s Toxic Substances Control Act Inventory Update Rule indicated that U.S. production plus imports of 2,3-dibromo-1-propanol totalled 10,000 to 500,000 lb [~ 4,500-225,000 kg]; no inventory update reports for 2,3-dibromo-1-propanol were filed in 1994 or 2002 (NTP 2014a).

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19 Fisher Scientific safety data sheet at https://www.fishersci.com/shop/msdsproxy?productName=AC112890050&productDescription=2%2C3-DIBROMOPROPANOL%2C+96%25+5GR2&catNo=AC11289-0050&vendorId=VN00032119&storeId=10652

20 European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014;
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/last_contributions/final_EFRA4_answers_to_Oeko-Institute_survey_on_RoHS_04.04.2014__2_.pdf

21 Test & Measurement Coalition TMC (2014): Contribution submitted during stakeholder consultation on 04.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Diisobutylpthalate/20140404_TMC_response_to_Oeko_additional_RoHS_substances__2014-0404.pdf

2.2. 1,3-dibromopropan-2-ol (CAS: 96-21-9)

2.2.1. Function of the substance

The search for MSDS for 1,3-dibromopropan-2-ol reveals various MSDS available on the internet that indicate uses for research purposes[22], as laboratory chemicals[23] or as certified reference materials[24]. A MSDS specified by LookChem also indicates uses for research and development.[25]

2.2.2. Types of applications / types of materials

No data found.

2.2.3. Quantities of the substance used

One supplier, Apollo Scientific Ltd., has been identified in the UK, on the basis of a safety data sheet last updated in October 2015.[26] Additional suppliers exist in the UK (Fluorochem) and in the US.

2.3. 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0), Synonyms: Dibromo-neopentyl-glycol, 2,2-Bis(bromomethyl)-1,3-propanediol

2.3.1. Function of the substance

2,2-bis(bromomethyl)propane-1,3-diol has been used as a flame retardant and as an intermediate (NTP 2014b).

2.3.2. Types of applications / types of materials

According to the ECHA Information on Chemicals database,[27] 2,2-bis(bromomethyl)propane-1,3-diol is used in polymers and in the manufacture of plastic products and is also understood to be an intermediate. The substance can be found in plastic based material products such as food packaging and storage, toys and mobile phones according to the ECHA database.

EFSA (2012) lists 2,2-bis(bromomethyl)propane-1,3-diol as a novel BFR: “Novel BFRs are defined as chemicals applied as flame retardants, and with confirmed presence in materials and/or goods in concentrations above 0.1 %” (EFSA 2012).

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22 MSDS of Fluorochem Ltd., https://www.cymitquimica.com/uploads/products/10/pdf/GEG5180-msds.pdf; Santa Cruz Biotechnology, Inc.; http://datasheets.scbt.com/sds/aghs/en/sc-215371.pdf

23 MSDS of Fisher Scientific: https://www.fishersci.ca/viewmsds.do?catNo=AC406541000

24 MSDS of SPEX CertiPrep Inc.: http://www.spexcertiprep.com/MSDS/8240-G.pdf

25 http://www.lookchem.com/msds/2011-06/9/372404%2896-21-9%29.pdf

26 MSDS of Apollo Scientific Ltd.; http://www.apolloscientific.co.uk/downloads/msds/OR1061_msds.pdf

27 https://echa.europa.eu/substance-information/-/substanceinfo/100.019.971

The SPIN database shows[28] that for use categories, Finland registered the use as flame retardants and extinguishing agent in 2013 and the use categories "others" between 2004 to 2008. The SPIN database indicates an article index of 2 or 3, which means that the substance is used in articles.

According to a monography on the substance prepared by WHO International Agency for Research on Cancer IARC in the series "Monographs on the Evaluation of Carcinogenic Risks to Humans" (WHO IARC 2000b),[29] 2,2-bis(bromomethyl)propane-1,3-diol is a reactive flame retardant that is used primarily in unsaturated polyester resins for moulded products and in rigid polyurethane foams. This use is also mentioned by Rad et al. (2010).

WHO IARC (2000b) further state that the substance is increasingly used in CFC (chloro-fluorocarbon)-free foam products designed to meet more stringent standards of flame retardancy. Danish EPA (2014) confirms these applications: "Applications (as indicated by manufacturers) include use in CFC-free foam systems designed to meet more stringent standards of flame retardancy, for example in the product FR-522 produced by ICL" (Danish EPA 2014).

A product data sheet published for FR-522 by ICL[30] specifies the CAS number 3296-90-0 for this product. 2,2-bis(bromomethyl)propane-1,3-diol (FR-522, also named DBNPG, Dibromoneopentyl glycol, Dinol, Dibromopentaerythrito) is a reactive flame retardant. General information on FR-522[31] specifies that thermosetting polyester resins can be formulated over a wide range of compositions to provide a broader selection of resin properties than those available with anhydride flame retardants. Resins formulated with FR-522 have high chemical and flame resistance, minimal thermal discoloration and excellent light stability. The high bromine content of FR-522 and its ready reaction into polyurethanes make it suitable for use in rigid polyurethane foams. It is increasingly used in CFC-free foam systems designed to meet more stringent standards of flame retardancy. The ICL reactive flame retardants FR-522 and F-513 (see section2.4) may also be mixed together in some applications to achieve specific properties: "*Effective combination of properties may be achieved by use of mixtures of FR-513 which is monofunctional and FR-522 (DBNPG) which is difunctional.*"[32]

The search on safety data sheets revealed additional resin products containing the substance, e.g. Polylite 33441-00 by Reichhold[33] and CRYSTIC 356PA by Scott Bader.[34]

According to the substance profile of the National Toxicology Program of the U.S. Department of Health and Human Services Secretary in its 13th Report on Carcinogens (RoC), 2,2-bis(bromo-methyl)propane-1,3-diol is also used as a chemical intermediate in the production of pentaerythritol ethers and other derivatives used as flame retardants (NTP 2014b).

Baron et al. (2014) explain that although publically available information on 2,2-bis(bromo-methyl)propane-1,3-diol is very scarce, it is understood that low volumes are in use in the EU for the manufacture of plastic articles. Though this could include plastic articles used in EEE, the

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28 SPIN database, entry for 2,2-bis(bromomethyl)propane-1,3-diol (CAS 3296-90-0): http://195.215.202.234/fmi/xsl/spin/SPIN/maininfo.xsl?-db=SPINstof&-skip=0&-max=1&casnr.op=eq&casnr=3296-90-0&SPINnavn%3a%3anavn.op=eq&SPINnavn%3a%3anavn=&ec_nr.op=eq&ec_nr=&-lay=SPINnavn&-find

29 WHO IARC (2000b): IARC Monographs on the Evaluation of Carcinogenic Risks To Humans, Some Industrial Chemicals Vol. 77; http://monographs.iarc.fr/ENG/Monographs/vol77/index.php; substance profile for 2,2-BIS(BROMOMETHYL)PROPANE-1,3-DIOL available at: https://monographs.iarc.fr/ENG/Monographs/vol77/mono77-18.pdf

30 ICL Industrial Products: http://icl-ip.com/wp-content/uploads/2012/03/8322_usFR-522.pdf

31 ICL Industrial Products: http://icl-ip.com/products/fr-522/

32 See information under http://catalog.ides.com/Datasheet.aspx?I=43389&U=1&CULTURE=en-US&E=271137

33 MSDS Reichhold, Inc.https://www.b2bcomposites.com/msds/reichhold/33441-00.pdf

34 MSDS Scott Bader; http://www.flints.co.uk/pdffiles/crystic_356pa.pdf

information provided by stakeholders suggested that this was not the case (see information from ICL-IP Europe in section 2.3.3 below).

In a safety data sheets the following uses have been specified: laboratory chemicals; production of materials.

2.3.3. Quantities of the substance used

2,2-bis(bromomethyl)propane-1,3-diol is registered in the EU for a tonnage band of 100 – 1,000 tonnes per year by the following registrant: ICL-IP Europe B.V. (OR1), Fosfaatweg 48 1013 BM Amsterdam, the Netherlands (ECHA Registered substances database).[35]

The registrant stated in a stakeholder consultation in 2014 on "*Compilation and review of quantitative usage information concerning the various substances on the prioritised shortlist*"[36] that "*DBNPG is used solely as a reactive flame retardant in construction, and is used for > 90% in Unsaturated Polyester used for UPE sheets in roofing.*"; ICL-IP further stated that it is not used in EEE (ICL-IP Europe (2014).

The Test & Measurement Coalition states in relation to this substance that "*Brominated flame retardants not currently restricted under RoHS are still quite pervasive in the supply chain and are frequently noted in supplied article sub-components. As this substance is listed with possible use as a flame retardant for epoxy, polyester, and urethane foams, an in-depth survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitutions would impact safety or other certifications (e.g. for flame-retarded uses such as epoxy internal to power supplies.)*"

The SPIN database contains data on 2,2-bis(bromomethyl)propane-1,3-diol used in Nordic countries: Data on amounts are confidential, however there are notifications for total use e.g. in 2013 by Denmark, Finland and Norway.

According to the WHO IARC (2000b), information available in 1999 indicated that 2,2-bis(bromomethyl)propane-1,3-diol was manufactured by two companies, one in Israel and one in Ukraine.

US sources state an annual production in the USA of 2,2-bis(bromomethyl)propane-1,3-diol was estimated at over 2,300 kg (5,000 lb) in 1977 and 1979 and at 3 million to 4 million pounds in 1983. 2,2-bis(bromomethyl)propane-1,3-diol was listed by the U.S. EPA as a high-production-volume chemical in 1990, indicating that annual production exceeded 1 million pounds (NTP 2014b). NTP (2014b) further states that in 2009, 2,2-bis(bromomethyl)propane-1,3-diol was produced by three manufacturers: in the United States; in the Middle East; and in China and was available from 14 suppliers, including 7 U.S. suppliers.

According to EFSA (2012), there are more than 50 suppliers of 2,2-bis(bromomethyl)propane-1,3-diol in the world (EFSA 2012).[37]

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35 ECHA Registered substances database for 2,2-bis(bromomethyl)propane-1,3-diol at https://echa.europa.eu/registration-dossier/-/registered-dossier/7873

36 ICL-IP Europe (2014): Contribution submitted during stakeholder consultation on 02.04.2014; http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Substance_Profiles/20140402_ICL_RoHS_OKOinstitute_comments_ICL-IP_Dibromoneopentyl-glycol.pdf

37 EFSA (2012): Scientific Opinion on Emerging and Novel Brominated Flame Retardants (BFRs) in Food; EFSA Panel on Contaminants in the Food Chain; EFSA Journal 2012;10(10):2908; http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2908/epdf

Safety data sheets have been found for suppliers in the UK (Fluorochem and Scott Bader)[38], in the US and in China.

2.4. 3-Bromo-2,2-bis(bromomethyl)-1-propanol (CAS 1522-92-5) and 2,2-dimethyl-propan-1-ol (CAS: 36483-57-5), tribromo derivative, synonyms: Tribromoneo-pentyl alcohol

As mentioned above, 3-Bromo-2,2-bis(bromomethyl)-1-propanol (CAS 1522-92-5) and 2,2-dimethylpropan-1-ol (CAS 36483-57-5) have the identical structural formula. Therefore Danish EPA (2016) considered them as a single substance. However the substances have different EC numbers and the ECHA Information on Chemicals database lists two different entries. Reports such as e.g. EFSA (2012) refer to only one CAS number. Against this background and for convenience, these substances are referred to together.

2.4.1. Function of the substance

The substance is applied as a reactive intermediate for high molecular weight flame retardants, particularly in the production of phosphorus and bromine containing flame retardants, DANISH EPA (2014) indicates as an example a product named, FR-513 produced by ICL.

A product data sheet published for FR-513 by ICL[39] specifies the CAS number 36483-57-5 for this product. Tribromoneopentyl alcohol (FR-513) is a reactive flame retardant particularly suitable where thermal, hydrolytic and light stability are required. Major uses of FR-513 are as a reactive intermediate for high molecular weight flame retardants, particularly in combination with phosphorus, and as a reactive flame retardant for polyurethanes where its high solubility in the reaction mixture makes it especially useful. Its high bromine content and good compatibility in CFC-free PU systems enables high standards of fire retardancy to be reached together with good foam properties in both rigid and flexible PU. Similar information is also provided by a UNIBrom USA data sheet[40] for the product EcoFlameRetardant-B-513. In this case both CAS numbers are specified: “1522-92-5 or 36483-57-5”.

2.4.2. Types of applications

According to the ECHA information on chemicals database,[41] this substance is used in the manufacture of polymers, plastic products and chemicals and as an intermediate. ECHA has no registered data indicating the type of article into which the substance has been processed.

The SPIN database has data on amounts, which are mostly confidential; the publicly available data indicates the use category "Adhesives, binding agents" and also indicates consumer preparations for 2013, 2012, 2011 and 2010.[42] The SPIN database specifies the article index 2 and 3 for 2,2-dimethylpropan-1-ol, meaning that the substance is used in articles. According to the Danish

[38] Flourchem: http://www.fluorochem.co.uk/System/DownloadSDS?fileName=(en-GB)BR1298_3.00.pdf
Scott Bader: http://www.ecfibreglasssupplies.co.uk/images/SafetyDataSheet/1590.pdf

[39] ICL Industrial Products: http://icl-ip.com/wp-content/uploads/2012/07/FR-513-TBNPA.pdf

[40] INIBROM USA: http://www.unibromusa.com/docs/EcoFlameRetardant-B-513.pdf

[41] https://echa.europa.eu/substance-information/-/substanceinfo/100.048.218

[42] SPIN database, entry for 2,2-dimethylpropan-1-ol (CAS: 36483-57-5); http://195.215.202.234/fmi/xsl/spin/SPIN/spinuset.xsl?-db=SPINstof&-skip=0&-max=1&casnr.op=eq&casnr=36483-57-5&SPINnavn%3a%3anavn.op=eq&SPINnavn%3a%3anavn=&ec_nr.op=eq&ec_nr=&-lay=spinuse&-find

product register, the substances was used in 5 different registrations in Sweden in 2010 and 2011; however the total amount was below 500 kg.

Safety data sheets available on the internet additionally reveal the following uses:

- The company Polymer Add Pte. Ltd.[43] lists as identified uses:
  - It is reactive flame retardant for polyurethanes, where its high solubility in the system makes it especially useful.
  - It is also suitable for use in rigid polyurethane and thermoset polyester resins because of its high bromine content
  - It is used alone, as polyol in the formulations of rigid foams.
- The supplier CRC Industries Europe bvba[44] provides the PU Foam Fire Resist 2-in-1 Aerosol for sealants and isolation;
- Huntsman Advanced Materials Americas Inc. sells the product RP 6453-1 Resin as a polyurethane resin.[45]
- Fischerwerke GmbH & Co. KG indicates the use of B1-Gun Foam PUFS 750[46] for foaming at constructional elements requiring advanced fire security standards, foaming in thermal insulation composite systems between EPS heat insulation panels, gaps of maximum 70 x 20 mm (depth x width), covered with mineral plaster, ideal construction and insulation foam for filling and sealing of cavities between brick work and window frames, window sills, roller blinds chassis etc., insulating of pipeline mountings.

2.4.3. Quantities of the substance used

The substance is registered for a tonnage band of 100 – 1 000 tonnes per year by the registrant: ICL-IP Europe B.V. (OR1), Fosfaatweg 48 1013 BM Amsterdam The Netherlands and for intermediate use only by ICL-IP Terneuzen B.V. (M), Frankrijkweg 6, Havens/Docks 1205-45308 BJ 4538 BJ Terneuzen Netherlands.

The SPIN database contains data on 2,2-dimethylpropan-1-ol used in Nordic countries: For 36483-57-5 the substance was used in 5 different registrations in Sweden in 2010 and 2011 thus giving access to the total amount (5 different registrations needed to specify the amount in the public realm), however the total amount was below 500 kg.

EFSA lists 3-Bromo-2,2-bis(bromomethyl)-1-propanol (CAS 1522-92-5) as an emerging BFR: “Emerging BFRs are defined as chemicals which are applied as flame retardants that have been identified as anthropogenic chemicals in any environmental compartment, in wildlife, in food or in humans. The use of the word „emerging“ in this definition does not imply that there is evidence for an increasing trend in the concentration of these BFRs in the environment, in food or in human samples.” According to EFSA (2012), for the substance as many as 79 commercial sources have been indicated.

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43 MSDS Polymer Add Pte; http://polymeradd.sg/36483-57-5.pdf

44 MSDS CRC Industries Europe bvba; http://www.farnell.com/datasheets/1714569.pdf

45 MSDS Huntsman Advanced Materials Americas Inc.; https://www.freemansupply.com/MSDS/Combined/Huntsman/RenPoly/RenPIM6453-1ENG.pdf

46 MSDS Fischerwerke GmbH & Co. KG; http://content.fischer.de/cbfiles/Fischer/Zulassungen/ZD_SDB_01_B1_F_%23SDE_%23AIP_%23V1.pdf

2.5. General Information for small brominated alkyl alcohols

To summarise the available information, the following sections present uses found for the various substances. Materials or products are highlighted in "**bold**" where the information collected from various sources (presented throughout this chapter), suggests a higher relevance, i.e. in the case of resin materials and in the case of EEE products and/or components.

2.5.1. Named uses in materials:

- Chemical intermediate for producing pentaerythritol ethers (CAS: 3296-90-0)
- **Epoxy** (resin) (CAS: 3296-90-0)
- Flame retardant and production of flame retardants (CAS: 96-13-9; CAS: 3296-90-0; CAS 1522-92-5 / 36483-57-5):
  - Production of tris(1,2,3-dibromopropyl) phosphate, commonly called TRIS (CAS: 96-13-9)
  - Reactive intermediate for production of high molecular weight flame retardants, particularly in the production of phosphorus and bromine containing FRs (CAS: 1522-92-5/36483-57-5)
- Plastics (CAS: 3296-90-0); (CAS: 1522-92-5 / 36483-57-5)
- Polyester (resin) (CAS: 3296-90-0)
- Polymers (CAS: 3296-90-0); (CAS: 1522-92-5 / 36483-57-5)
- Polyol in the formation of rigid foams (CAS: 1522-92-5/36483-57-5)
- **Polyurethanes** (resin) (CAS: 1522-92-5/36483-57-5)
- Resin products (CAS: 3296-90-0)
- Rigid polyurethane (CAS: 1522-92-5/36483-57-5)
- Rigid polyurethane foam (CAS: 3296-90-0; CAS: 1522-92-5/36483-57-5)
- Thermoset polyester resins (CAS: 1522-92-5/36483-57-5)
- Unsaturated polyester resins (CAS: 3296-90-0) for moulded products
- Urethane foams (CAS: 3296-90-0)

A few European manufacturers of various resins were contacted directly and asked as to the possible manufacture and/or use of SBAAs in their activities. It could be understood that at least two of the SBAA substances are used as reactive flame retardants in the production of polyurethane resins for applications in which flame retardancy is required. Though use of such resins for EEE applications could not be excluded, it was not communicated as a typical application (further detail in Section 2.5.2). The possible use of SBAAs in the production of resins used for encapsulation such as epoxy resins was not mentioned explicitly, but could not be excluded. If SBAAs are used for manufacturing such materials, they would also be expected to be applied as reactive flame retardants.

2.5.2. Named uses in applications:

- Adhesives, binding agents (CAS 1522-92-5 / 36483-57-5)
- CFC-free foam systems designed to meet more stringent standards of flame retardancy (CAS: 3296-90-0)

- Flame retardants and extinguishing agent (CAS: 3296-90-0; CAS: 96-13-9)
- Foams for construction applications with advanced fire security standards, i.e., insulation, filling, sealing, etc. (CAS: 1522-92-5/36483-57-5)
- Food packaging and storage (CAS: 3296-90-0)
- Intermediate in the production of insecticides (CAS: 96-13-9)
- Intermediate in the production of pharmaceuticals (CAS: 96-13-9)
- Laboratory chemical (96-13-9; CAS: 96-21-9; CAS: 3296-90-0; CAS: 19398-47-1; CAS: 3296-90-0)
- **Mobile phones** (CAS: 3296-90-0)
- Textiles (children's clothing – past use) (96-13-9)
- Toys (CAS: CAS: 3296-90-0)
- UPE sheets used for roofing (CAS: 3296-90-0)

The Danish Product Registry collects data among others as to the presence of certain hazardous substances in various products applied by professionals. According to the registry, two substances of the small brominated alkyl alcohol group have been reported in products on the Danish market (CAS NR. 3296-90-0 and CAS NR. 36483-57-5) in a total of three products. Currently one product is reported to be active on the Danish market, while two products have been cancelled for many years. The latest information on the active product is from 2014, where the product was being imported to Denmark in relatively small amounts. The substances are reported to have or have had the following applications: (DPR 2016)

- Use in a **sealant material** in various application areas (current use).
- Use in a product for textile surface treatment.
- Use in a plastic construction material used in plastic products.
- **Mobile phones** (CAS: 3296-90-0)

It is understood that SBAA can be used to manufacture epoxy resin mixtures and such resins are also cited to be used in the manufacture of printed circuit boards. The information above details one example of an EEE product in an SBAA may be applied or may have been applied in the past (mobile phones, CAS: 3296-90-0). In such products, it is possible that dimensions of the product and the probable use of lithium-ion batteries have led to an increase in the requirements for flame retradancy, contributing to the consideration of the use of substances from the SBAA group for various applications. Some confirmation can be found in the literature for this assumption, though SBAAs are not specifically mentioned in this respect:

According to Rakotomalala et al. (2010), "In printed wiring boards (PWBs), 80% of composite materials are graded as FR-4 by the National Electrical Manufacturers Association (NEMA). FR-4 is a glass-fibre reinforced laminate of epoxies that meets defined flame retardancy standards (i.e., UL 94-V0) [6–8]. During the first step of the fabrication of PWB, the glass is pre-treated with coupling agents such as organosilanes to improve adhesion between the inorganic glass and the organic resin [9]. In a separate container, the epoxy resin is mixed with additives such as curing agents, accelerators, fillers and flame retardants. The woven glass is then impregnated with the partially cured resin. The resulting partially cured reinforced material is known as pre-peg. Multiple pre-pegs are then thermally pressed to obtain a core. After assembly of several pre-pegs and cores, a layer of copper is electrodispersed on the surface to form a copper-clad laminat The fire resistance of the cured resin can however be improved by the addition of a flame retardant. Thus, it is important to know that every application demands a different formulation (using different resins, hardeners and fire retardants)..." The report mentions two trends that increase the requirements of flame retardancy in electronics. With the continuing miniaturisation of electronics most devices are more likely to overheat and mobile devices are also particularly vulnerable to flammability because they carry their own power (and ignition) source. The phase out of lead solders also contributes to the change in requirements as alternatives to lead soldering require a raise in processing temperatures (~40 °C) which in turns demands a higher thermal stability from the additives used. Though Rakotomalala et al. (2010) do not name substances of the SBAA group, it can be understood that industry is searching for alternatives to flame retardants used in the past as some of these have been or are expected to be phased out. Some substitutes can be expected to be non-halogenated, however others may still be within this group, suggesting that SBAAs may also be in use for such applications in some cases.

In general it is understood that the more typical applications of polyurethane (PU) foams are as insulation in construction materials as well as in the manufacture of various vehicles. These application areas are not in scope of the RoHS Directive. Nonetheless, the consultants are aware that PU foams are also used for insulation in cooling appliances. This is confirmed for example by the Ecodesign preparatory study for refrigerators (VHK 2015). Among others data is presented for various models as to the amounts of PU foam used for insulation, varying from 4.5 kilograms for a model with a net volume of 187 litres (gross volume 210 litres) to over 10 kilograms for larger models (10.1; 10.9 and 10.4 for models of a net volume of 294, 205 and 261 litres respectively or a gross volume of 334, 230 or 268 litres respectively). It should be noted that models differ in relation to various properties (for example defrosting) and thus the amount used per unit is not just related to the size of the device.

2.5.3. Information from umbrella specifications for EEE components

Oeko-Institut (2008) explains that the German Electrical and Electronic Manufacturers Association (ZVEI) publishes umbrella specifications of the EEE sector, in which typical components of different electrical and electronic product families are detailed. The Umbrella Specifications aim to comply with the request of customers for detailed material specifications on individual electronic components, semiconductors, passive components, printed circuit boards, and electromechanical components. Furthermore, the Umbrella Specifications were developed against the background of the International Material Data System (IMDS) introduced by the automotive industry. While the IMDS requires material contents data in IMDS format for each individual component, the Umbrella Specifications are based on the presentation of special product families with typical characteristics whereby the number of varying inputs will be drastically reduced. The Umbrella Specifications have been elaborated jointly by a number of electronic component manufacturers. From a screening of the current Umbrella specifications published by ZVEI[47], it has been identified that resins of relevance to SBAA are applied in certain component groups. These are specified in Table 2-1 along with relevant information reproduced from the specifications.

[47] See: http://www.zvei.org/Verband/Fachverbaende/ElectronicComponentsandSystems/Seiten/Umbrella-Specifications.aspx

Table 2-1: Use of resins in EEE components, as specified in umbrella specifications published by ZVEI

Title	Product class	Product part (IMDS: semi component)	Material (IMDS Material)	Material (Classification) ISO 22628 / VDA 231	Substance	typical mass of substance [wt%]	CAS if applicable (of material)	typical mass of material [wt-%]	Source (file name and specified date)
Metallised Film Capacitor for EMI Suppression Class X2	Metallised Polypropylene	Encapsulation	Polymer	2C	**PU/Epoxy**	24,8		58,5	EMI Suppression Class X2 Ts; 29.10.2009
			Hydroxide		Al(OH)3	37,2	21645-51-2		
			Polymer	2A	**PBT**	34,2			
			Oxide		SB2O3	1,9	1309-64-4		
			Flame retardant		**Equivalent Br**	1,9			
Metallized Film Capacitor	Film Chip Capacitor ECHU (X)	Active part	Polymer	2A	**Thermosetting resin**	100		40,9	U_Specs_Film_ECHU_X-IMDS_; Dec 09
		Termination	Polymer	2C	**Phenolic resin**	7,98	9003-35-4	12,3	
Metallized Film Capacitor	Film Chip Capacitor ECPU (A)	Termination	Polymer	2C	**Phenolic resin**	7,98	9003-35-4	13,4	U_Specs_Film_ECPU_A__IMDS; Dec 09
Metallized Film Capacitor	Film Chip Capacitor ECWU (X)	Termination	Polymer	2C	**Phenolic resin**	7,98	9003-35-4	13,4	U_Specs_Film_ECWU_X_-IMDS; Dec 09
NTC	Leaded Disks	Encapsulation	Organic Polymer	5B	Lacquer [1] or	100		4	U_Specs_NTC Leaded Disks K_S; 01.08.2009
				2C	**Epoxy Resin**[2]				
NTC	Leaded Disks	Encapsulation	Organic Polymer	5B	Lacquer [1] or	100		4	U_Specs_NTC Leaded Disks K_S_neu; 01.08.2009
				2C	**Epoxy Resin**[2]				
NTC	Leaded Disks	Encapsulation	Organic Polymer	5B	Lacquer [1] or	100		4	U_Specs_NTC Leaded Disks M_S; 01.08.2009
				2C	**Epoxy Resin**[2]				
NTC	Leaded Disks	Encapsulation	Organic Polymer	5B	Lacquer [1] or	100		4	U_Specs_NTC Leaded Disks M_S_neu; 01.08.2009
				2C	**Epoxy Resin**[2]				

Title	Product class	Product part (IMDS: semi component)	Material (IMDS Material)	Material (Classification) ISO 22628 / VDA 231	Substance	typical mass of sub-stance [wt%]	CAS if applicable (of material)	typical mass of material [wt-%]	Source (file name and specified date)
NTC	Leaded Disks	Encapsulation	Organic Polymer	2C	**Epoxy Resin**	100	25928-94-3	20	U_Specs_NTC Leaded Disks S871_S875_S881_S885; 01.08.2009
NTC	Miniature Sensor insulated leads	Leads	Organic Polymer	2A	PTFE / other thermoplastic polymer	100		33	U_Specs_NTC Miniatur Sensor insulated leads; 01.08.2009
		Encapsulation	Organic Polymer	2C	**Epoxy Resin**	100	25928-94-3	17	
NTC	Miniature Sensor uninsulated leads	Encapsulation	Organic Polymer	2C	**Epoxy Resin**	100	25928-94-3	28	U_Specs_NTC Miniatur Sensor uninsulated leads; 01.08.2009
Inductive components class A - Ω	S22	Active Part	Metal (wire)	1C	Cu	99,20%	7440-50-8	40	USpec_Inductors_231110a ; 2010 10 16
					PUR etc.	0,80%			
		Plastic	Duroplaste	2C ISO 1043	EP, PA, **PUR**, **PET**, **PBT**, Silicone, etc.	60	-	35	
		(Insulation, Encapsulation and Potting)			Fibre glass, **Flame retardant, Additive**	40			
Varistor	Disk Varistor	Encapsulation	Organic Polymer	2C	SiO2	49	60676-86-0	16	U_Specs_Varistor Disk; 01.08.2009
					Epoxy Resin	35	25068-38-6		
					Brominated epoxy	12	68929-70-1		
					Sb2O3	2,5	1309-64-4		
					Additives*)	1,5			
PTC	Switching Applications	Encapsulation	Organic Polymer	2A	**PBT GF(30) FR(17)**	100	26062-94-2	62	U_Specs_PTC Switching Applications; 01.08.2009

Source: http://www.zvei.org/Verband/Fachverbaende/ElectronicComponentsandSystems/Seiten/Umbrella-Specifications.aspx

2.5.4. Information gathered through stakeholder consultation

A stakeholder consultation was held between 23.09.2016 and 04.11.2016 to gather further information from stakeholders. Direct consultation was also carried out in some case in order to contact stakeholders with specific relevance. This section summarises input received through these methods.

Table 2-2: Summary of stakeholder contributions

Stakeholder	Summary of contribution	Comments
Bromine Science Environmental Forum – BSEF, aisbl, submitted on 14.10.2016	"We are not aware that these substances, as far as they are produced at all, are used in E&E equipment. In fact, a very similar, but narrower, consultation has been conducted in 2014 by the Oeko-Institute e.V. in the frame of the Review of Restricted Substances under ROHS2[48]. The report concluded that both Dibromo-neopentyl-glycol and 2,3-dibromo-1-propanol (Dibromo-propanol) are either not used in EEE[49] or are not used in the EU at all[50].BSEF 2016)"	It is not clear on what basis BSEF conclude from the Oeko-Institut report (Baron et al. 2014) that the two substances are either not used in EEE or not used at all. For both substances, the use of small amounts for the production of EEE in the EU could not be excluded. Nor could it be excluded whether the substances were applied in EEE through components or sub-components manufactured outside the EU, in which case a registration of the substances would not be required under REACH.
Joint contribution of the Japan Electronics & Information Technology Industries Association (JEITA), the Communications and Information Network Association of Japan (CIAJ), the Japan Business Machine and Information System Industries Association (JBMIA) and the Japan Electrical Manufacturers' Association (JEMA)	Based on consultation with their members and with other EEE associations, JEITA et al. (2016) do not expect SBAA to be present in finished EEE. They have also not heard of cases where EEE manufacturers specify the use of these substances in their products (i.e., through supplier specifications). Even if SBAAs would be used as an intermediate in the production of as the background document suggests, they would not be contained as such in the EEE. In this context it is	The contribution provided by JEITA et al. uses clear formulations concerning the possible presence of SBAA in EEE ("No", "None", "Final EEE manufacturers don't use them"). In the case of possible use of SBAA as intermediates in production, the formulations are less certain ("We don't know", "As long as we know, no"), that at least suggests a lack of information as to the use of SBAA by the supply

48 Reference provided by BSEF (2016): http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf :

49 Footnote reproduced from BSEF (2016): "*The information provided by stakeholders during the consultation further suggests that dibromo-neopentyl glycol is either not applied in EEE or applied in small amounts by manufacturers of supplied goods, thus requiring a more comprehensive supplier survey to allow a better quantification*."

50 Footnote reproduced from BSEF (2016): "*As 2,3-dibromo-1-propanol is not registered, it is understood not to be used in the EU or to be applied in low quantities; as further information was not obtained through stakeholders, the use volume cannot be concluded. Though it is used as a flame retardant, its application in the EEE sector is not known to the European Flame Retardant Association, which represents the leading organisations who manufacture, market or use flame retardants in Europe. On the other hand, the case of 2,3-dibromo-1-propanol suggests that it is not always clear which (brominated) flame retardant is used within the supply chain. The Test & Measurement Coalition states that an in-depth-survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitution would impact safety or other qualifications (e.g. for flame-retarded uses such as epoxy internal to power supplies)*."

	emphasised that "the restriction under RoHS doesn't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs in a certain level. When asked about the possible presence of SBAA in WEEE, JEITA et al. explain that if these substances are used as brominated-flame retardants in resins, then EEE manufacturers would have to provide information on them according to Article 8(2) of WEEE Directive 2012/19/EU. Based on their knowledge, these substances are not used as flame retardants because of their boiling point. JEITA et al. note that restriction will incur costs on the world industry in spite of its doubtful environmental benefit and irrespective of the actual need to substitute substances that appear to rarely be present in EEE. Some additional comments are made as to the assumed hazardousness of some of the substances in the SBAA group, the methodology for definition of the group and as to some of them possibly being theoretical.	chain. In relation to constituents of resins, JEITA et al. also note "We don't know because we are not resin manufacturers." Article 8(2) of the WEEE Directive specifies: "*Proper treatment, other than preparing for re-use, and recovery or recycling operations shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex VII.*" According to the annex, among others it is required "*1. As a minimum the following substances, mixtures and components have to be removed from any separately collected WEEE:… plastic containing brominated flame retardants*,". Thus, there is no demand in the WEEE directive for providing specific information on the flame retardants used, but the presence of a bromine contenct should be known..
The Japanese Business Council in Europe (JBCE)	JBCE states that its response during the 2014 consultation, which included feedback on the substances dibromo-neopentyl-glycol and 2,3-dibromo-1-propanol is still relevant. At the time JBCE had no indication that EEE manufacturers instructed the use of these substances. Based on the knowledge and information available to JBCE as EEE manufacturers it is not possible to provide additional information on the proliferation and/or prolongation of the use of SBAA in various components, not to make any statements as to possible use in the manufacture of resins.	
Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI - the German Electrical and Electronic Manufacturers' Association)	ZVEI (2016) have consulted with its members and has understood that substances in the SBAA group are not used in their goods. It thus does not see any concern with a possible restriction of SBAA.	
The Test and Measurement Coalition (TMC)	TMC (2016) explain that as SBAA have not been subject to any regulatory requirement so far, information about the presence of SBAA in products manufactured by its members at the homogeneous	

	material level is not yet available. The complexity of monitoring and control instruments (EEE containing thousands of spare parts) and of its supply chain (thousands of suppliers) makes it impossible to gather such information within the timeline of the current consultation. TMC further emphasizes the characteristics of industrial monitoring and control instruments and their design cycles to show the complexity of compliance of such products with a possible restriction and argue that a long transition period would be needed for this category, as has been provided in the past.	

Source: Compiled from contributions submitted to the Stakeholder consultation.

From the information provided by stakeholders it cannot be determined if SBAA are used in the manufacture of EEE. Though the various contributors show a higher confidence in their statements in relation to the possible presence of SBAA in EEE end products, a lower confidence in relation to the constituents of various resins applied to certain components suggests that industry may not always be aware of the exact substances used to produce various mixtures, particularly when these would have an intermediate role and would not remain present in the final product or component (or at least not in amount that can be detected). The lack of information from the EEE supply chain thus does not allow excluding possible use as intermediates, nor does the data provide any insight as to possible differences between substances used in EEE manufactured in the EU and for example in China or other Asian countries which are understood to manufacture a large share of EEE and EEE components imported to the EU.

2.6. Summary of information on uses of small brominated alkyl alcohols

In general it is understood that the SBAA substances could potentially be used in the manufacture of two polymeric material groups: thermoplastics and/or of thermosets.

There is only little information relating to possible uses in the manufacture of thermoplastics. Though such uses may be less common for substances with lower melting and boiling points, which are likely to vaporise during processing, it is observed that a few of the substances have a melting point around 100°C and a boiling point above 300°C and may thus be used in the production of plastic materials. Uses in thermoplastics cannot be excluded but are not assumed to be common in light of the existing information. This is also supported by the lack of knowledge of EEE OEMs as to the use of SBAAs in this area.

The second potential material group regards the use of these substances in various types of thermosets, or resins. In light of the molecular structure and in some cases lower melting and boiling points, it is understood that the characteristics of some of the substances in this group would be suitable for use as reactive constituents of various types of resins. This is also supported in some cases by general information related to the use in such materials, for example in epoxy resins, in polyurethane resins, in polyester resins and in resin products in general. There is information showing that resins are used among others in sub-components of EEE, applied for sealing and encapsulating purposes and in some cases understood to be quite common, such as in components for which umbrella specifications exist. It cannot be excluded that substances of the SBAA group are applied for such uses. There is some data to support that one of the SBAAs was used in the manufacture of mobile phones in the past and possibly also at present. The use of lithium ion batteries in mobile devices may have contributed to the increase in flame retardant properties of various components which SBAA substances could be used to provide and for which data has been found suggesting that they may be used to establish such properties in epoxy resins. There is also information showing the polyurethane foams, also a thermoset, are used in the insulation of cooling applications such as refrigerators. Assuming this application requires flame retardancy, either in relation to flammability risks related with its manufacture or related to its use, it would be possible that substances of the SBAA group could be used for establishing this quality.

From the available information it seems that there are two main areas of application that could be relevant for the SBAA group in EEE, in resins for encapsulation and/or in resins for insulation. In both possible application areas, it is understood that if SBAAs are used, it is with the purpose of achieving flame retardancy, whereas the substances would be applied as reactive additives to resin mixtures. This implies that the SBAA substance undergoes a transformation through the process and is thus not likely to remain present in this form in the final application. There is no information as possible metabolites that result from the transformation and that would be present in the final application, nor of their potential hazardousness. The uncertainty of EEE OEMs regarding this potential use may be related to the manufacture of resin mixtures by the supply chain and in some cases also the probably application of the resin in components provided by the supply chain and not by the OEM.

Information suggests that at least some resins are manufactured in the EU using SBAA substances to provide flame retardancy. This is supported for at least two substances for which REACH registration data exists. It can be expected that similar resins would also be manufactured and applied outside the EU, where it cannot be excluded that other SBAAs are also applied, however data as to the possible amounts of use of SBAAs in such cases is not available. As it is understood that components using resins may be provided to OEMs by the supply chain, it is possible that manufacture is more common outside of the EU, for example by Asian suppliers. Upon searching for material safety data sheets that included also an additional research for the Chinese market, the consultants observed that a larger number of MSDS were published by Chinese suppliers in comparison with EU and US suppliers. Though it remains to be confirmed, this may support the assumption that certain resin components are typically manufactured in Asia.

3. Human health hazard profile

The following human health hazard profile is based on the information and conclusions regarding the critical endpoints for small linear and branched brominated alkyl alcohols, including 2,2-bis(bromomethyl)-1,3-propanediol (CAS: 32-96-0), 2,3-dibromo-1-propanol / 1,3-dibromo-2-propanol (CAS 96-13-9 / 96-21-9), and 2,2-bis-(bromomethyl)-3-bromo-1-propanol (CAS: 36483-57-5 / 1522-92-5) provided in the report from DANISH EPA (2016) prepared by Wedebye *et al.,* DTU Food.

In the data search for the DANISH EPA report relevant experimental data on human health effects were found for the above mentioned three category members. In addition, information regarding existing guidance values in the form of derived no effect levels or derived minimal effect levels (DNELs/DMELs) and occupational exposure levels have been searched in the publicly available REACH registration dossiers and in the open literature. With regard to information from the REACH registration dossiers, it should be stressed that information provided by registrants has not been subject to scrutiny by ECHA or any EU expert group, or by the authors of this report. However, no DMEL values derived based on non-threshold effects were identified in the available dossiers or in the publicly available literature.

3.1. 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

3.1.1. Critical endpoint

In the report from Danish EPA (2016) prepared by Wedebye et al., experimental data on human health effects was collected and the critical effect for the substance was determined based on these data.

The critical effect for 2,2-bis(bromomethyl)-1,3-propanediol is considered to be the multi-site, multispecies carcinogenic effect, most probably caused by a direct genotoxic action of the parent compound.

This conclusion is based on data from a two-year study with administration of a substance containing 78.6% 2,2-bis(bromomethyl)-1,3-propanediol in the diet to rats and mice. Here, significantly dose-related increases in the incidences of neoplasms were obtained at numerous sites in male and female rats, and to a lesser extent in mice (Danish EPA 2016).

Suggested classifications of DBNPG specified in industry notifications include classification as mutagenic and carcinogenic: Muta 1B H440/Muta 2 H341 and Carc. 1B H350/ Carc. 2 H351.

3.1.2. Existing Guidance values (DNELs, OELs)

No existing guidance values from official authorities have been identified. The following guidance values have been submitted by the industry as part of the REACH registration dossier. These values are not verified by official authorities.

Table 3-1: Guidance values for 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

Population	Description	Local / systemic effect	Exposure duration	Value	Most sensitive endpoint	Reference
Workers	Hazard via dermal route	Systemic	Acute / short term	DNEL: 100 mg/kg bw/day (AF=100)	Acute toxicity	REACH registration dossier (ECHA 2016)
		Local	Acute / short term	DNEL: 1.4 mg/cm² (AF = 20)	Acute toxicity	REACH registration dossier (ECHA 2016)

AF = Assessment factor

3.2. 2,3-dibromopropan-1-ol (CAS: 96-13-9) and 1,3-dibromopropan-2-ol (CAS: 96-21-9)

3.2.1. Critical endpoint

In the report from Danish EPA (2016) experimental data on human health effects was collected and the critical effect for the substance was determined based on these data.

The critical effect for 2,3-dibromopropan-1-ol is considered to be the multi-site, multispecies carcinogenic effect, most probably caused by a genotoxic metabolite of the parent compound.

This conclusion is based on data from a two-year study with dermal exposure of rats and mice to 2,3-dibromopropan-1-ol . Here, significantly dose-related increases in the incidences of neoplasms were obtained at numerous sites in male and female rats, and to a lesser extent in mice (Danish EPA, 2016).

The harmonised classification of 2,3-dibromopropan-1-ol include classification as carcinogenic: Carc. 1B H350.

3.2.2. Existing Guidance values (DNELs, OELs)

This substance is only pre-registered and no existing guidance values have been identified.

3.3. 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5)

3.3.1. Critical endpoint

In the report from Danish EPA (2016), experimental data on human health effects were collected and the critical effect for the substance was determined based on these data.

The critical effect for 2,2-dimethylpropan-1-ol, tribromo derivative is considered to be a possible carcinogenic effect, most probably caused by a genotoxic metabolite of the parent compound.

This conclusion is based on data from two repeated dose studies of 14 and 30 days duration, respectively. In the 30-day study renal tubular damage was observed in the kidney and generalized hyperplasia in the urinary bladder. The substance, 2,2-dimethylpropan-1-ol, tribromo derivative, has furthermore shown mutagenic/genotoxic activity *in vitro* in the presence of a metabolic activation system. (Danish EPA, 2016).

Suggested classifications of the substance specified in industry notifications include classification as mutagenic and carcinogenic: Muta 1B H340/Muta 2 H341 and Carc. 1B H350.

3.3.2. Existing Guidance values (DNELs, OELs)

No existing guidance values from official authorities have been identified. The following guidance values have been submitted by the industry as part of the REACH registration dossier. These values are not verified by official authorities.

Table 3-2: Existing guidance values for 2,2-dimethylpropan-1-ol, tribromo derivative; TBNPA (CAS: 36483-57-5 and 1522-92-5)

Population	Description	Local / systemic effect	Exposure duration	Value	Most sensitive endpoint	Reference
Workers	Hazard via inhalation route	Systemic	Long term	DNEL: 2.94 mg/m³ (AF = 150)	Repeated dose toxicity	REACH registration dossier (ECHA 2016)
			Acute / short term	Low hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
		Local	Acute / short term / long term	No hazard identified		REACH registration dossier (ECHA 2016)
	Hazard via dermal route	Systemic	Long term	DNEL: 0.83 mg/kg bw/day (AF = 600)	Repeated dose toxicity	REACH registration dossier (ECHA 2016)
			Acute / short term	Low hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
		Local	Acute / short term / long term	No hazard identified		REACH registration dossier (ECHA 2016)
	Hazard for the eyes	Local		Medium hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
General population	Hazard via inhalation route	Systemic	Long term	DNEL: 0.72 mg/m³ (AF = 300)	Repeated dose toxicity	REACH registration dossier (ECHA 2016)
			Acute / short term	Low hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
		Local	Acute / short term / long term	No hazard identified		REACH registration dossier (ECHA 2016)
	Hazard via dermal route	Systemic	Long term	DNEL: 0.42 mg/kg bw/day (AF = 1200)	Repeated dose toxicity	REACH registration dossier (ECHA 2016)
			Acute / short term	Low hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
		Local	Acute / short term / long term	No hazard identified		REACH registration dossier (ECHA 2016)
	Hazard via oral route	Systemic	Long term	DNEL: 0.42 mg/kg bw/day (AF = 1200)	Repeated dose toxicity	REACH registration dossier (ECHA 2016)

Population	Description	Local / systemic effect	Exposure duration	Value	Most sensitive endpoint	Reference
			Acute / short term	Low hazard (no threshold derived)		REACH registration dossier (ECHA 2016)
	Hazard for the eyes	Local		Medium hazard (no threshold derived)		REACH registration dossier (ECHA 2016)

3.4. Summary on health hazards

In the report from Danish EPA (2016) experimental data on human health effects for the three category members have been reviewed. Based on these data the critical effect of the substances was identified as a multiple-organ carcinogenic effect, most probably exerted by a genotoxic mode of action either by the parent compound itself (2,3-dibromo-1-propanol) or by a metabolite of the parent compound (DANISH EPA, 2016).

One category member, 2,3-dibromo-1-propanol, has a harmonised classification as carcinogenic in category 1B (Carc 1B). Some industry self-classifications include a similar classification as Carc. 1B and also Muta. 1B for 2,2-bis(bromomethyl)-1,3-propanediol, and for the 2,2-dimethylpropan-1-ol, tribromo derivative, industry has suggested classifications as mutagenic in category 2 (Muta. 2). Based on read-across justified by results of experimental data, QSAR predictions for the carcinogenic and mutagenic/genotoxic properties and the harmonised and notified classifications, the classification as carcinogenic in category 1B (Carc. 1B) should be considered for all category members.

3.5. Derivation of guidance values

As mentioned earlier, no guidance values from official authorities have been identified for the three substances. The substances are concluded to be genotoxic carcinogens in the report from DANISH EPA (DANISH EPA, 2016) and consequently a DMEL should be derived for the purpose of quantitative risk assessment. Adequate long-term studies of relevance for the critical effect are available for 2,3-dibromo-1-propanol (dermal 2-year study) and 2,2-bis(bromomethyl)-1,3-propanediol (oral 2-year study).

Based on these studies the DMEL values for 2,3-dibromopropan-1-ol and 2,2-bis(bromomethyl)propane-1,3-diol were derived based on the linearised approach as using the dose descriptor T25[51] as described in the ECHA guidance, Chapter R.8, Annex R.8-7. As the relevant exposure route for humans is by inhalation, route-to-route extrapolation was included in the derivation of the DMEL values. The resulting values are shown below.

2,3-dibromopropan-1-ol (CAS: 96-13-9)

Based on the results from the 2-year dermal NTP study (NTP, 1993) provided in the summary of the dermal long-term carcinogenisis and genetic toxicology study of 2,3-dibromo-1-propanol, the T25 dose descriptor is selected as 188 mg/kg which was the lowest dose level administered to rats. The percentage of animals developing tumours at different sites was both more and less than 25%. However, this value is considered the best estimate based on the available information.

[51] The chronic daily dose which will induce tumours in 25% of the animals.

Table 3-3: DMEL calculation for 2,3-dibromopropan-1-ol (CAS: 96-13-9)

Step 1 Identification of dose descriptor	
T25 (rat dermal)	188 mg/kg
Step 2 Modification of relevant dose descriptor	
Route-specific bioavailability: 50%[52] dermal absorption 100% absorption by inhalation	50 / 100
Adjustment of route of exposure: from rat (dermal) in mg/kg/d to rat inhalation (0.8 l/min/kg, 8h): 0.384 m³/kg/8h	1 / 0.384
Activity-driven differences: At rest / light activity: 6.7 /10 in line with the „10 m³“ approach	6.7 / 10
Differences between occupational and lifetime exposure conditions 7/5 * 52 /48 * 75 / 40 = 2.8[53]	2.8
Calculation of modified dose descriptor	T 25 of 188 mg/kg/d multiplied by 50/100 * 1/0.384 * 6.7/10 * 2.8 = 459 mg/m³
Corrected Dose Descriptor	Corrected T25: 459 mg/m³
Step 3: Application of assessment factors to get the DMEL	
Interspecies extrapolation Allometric scaling implicitly taken into account	1
Intraspecies extrapolation	Not applied
Nature of the carcinogenic process	Not applied
Point of comparison	Not applied
2.5 in cases where the T25 is used instead of the BMDL10 (EFSA draft 07.04.2006)	Not applied
High to low dose extrapolation	25,000 (linearity and 1:100.000) 5,000 (linearity and 5:100.000)
Calculation of DMEL (corrected T25 divided by overall assessment factor)	459 / 25,000 = 0.018 mg/m³ 459 / 5,000 = 0,09 mg/m³
DMEL (based on T25) associated with a lifetime cancer risk of very low concern	18 µg/m³ (1:100.000, linear) 90 µg/m³
Overall quality of DMEL	Based on default assumptions and a study with only two dose levels. Not considered a high quality DMEL.

<u>2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)</u>

Based on the results from the 2-year oral NTP study (NTP, 1996) provided in the summary of the oral long-term carcinogenisis and genetic toxicology study of 2,2-bis(bromomethyl)propane-1,3-diol, the T25 dose descriptor is selected as the lowest dose applied of 115 mg/kg which is the lowest dose level administered to female rats. More than 25% of the female rats developed tumours in the mammary glands all three dose levels. Mice were administered lower doses and approximately 25% of the animals developed tomours in the harderian gland and the lung at 70 mg/kg (male) or 80 mg/kg (female). However, the lowest dose level in rats is considered the best estimate based on the available information.

52 Default (may be too high)

53 Exposure period in study: 51 weeks (males), 52-55 (females)

Table 3-4: DMEL calculation for 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

Step 1 Identification of dose descriptor	
T25 (rat dermal)	115 mg/kg
Step 2 Modification of relevant dose descriptor	
Route-specific bioavailability: 50%[54] dermal absorption 100% absorption by inhalation	50 / 100
Adjustment of route of exposure: from rat (dermal) in mg/kg/d to rat inhalation (0.8l/min/kg, 8h): 0.384 m³/kg/8h	1 / 0.384
Activity-driven differences: At rest / light activity: 6.7 /10 in line with the „10 m³" approach	6.7 / 10
Differences between occupational and lifetime exposure conditions 7/5 * 52 /48 * 75 / 40 = 2.855	2.8
Calculation of modified dose descriptor	T25 of 115 mg/kg/d multiplied by 50/100 * 1/0.384 * 6.7/10 * 2.8 = 281 mg/m³
Corrected Dose Descriptor	Corrected T25: 281 mg/m³
Step 3: Application of assessment factors to get the DMEL	
Interspecies extrapolation Allometric scaling implicitly taken into account	1
Intraspecies extrapolation	Not applied
Nature of the carcinogenic process	Not applied
Point of comparison	Not applied
2.5 in cases where the T25 is used instead of the BMDL10 (EFSA draft 07.04.2006)	Not applied
High to low dose extrapolation	25,000 (linearity and 1:100.000) 5,000 (linearity and 5:100.000)
Calculation of DMEL (corrected T25 divided by overall assessment factor)	281 / 25,000 = 0.011 mg/m³ 281 / 5,000 = 0,06 mg/m³
DMEL (based on T25) associated with a lifetime cancer risk of very low concern	11 µg/m³ (1:100.000, linear) 60 µg/m³
Overall quality of DMEL	Based on default assumptions and a study with three dose levels. Not considered a high quality DMEL.

[54] Default (may be too high)

[55] Exposure period in study: 51 weeks (males), 52-55 (females)

4. Environmental hazard profile

The following environmental hazard profiles are based on a data/literature search primarily via OECD's eChem Portal, ECHA's REACH registration data, US EPA's ECOTOX database and the Danish (Q)SAR database complemented with a general Internet search for public available literature on the selected substances. All identified data, i.e. both experimental and predicted (QSAR) data is presented in the tables.

For two of the substances, the profile is to a certain extent based on REACH registration dossiers data available on ECHA's website. It should be noted that only limited information is presented in the publicly available summaries of the confidential substance registration reports. Furthermore, the information provided by the registrant has not been subject to scrutiny by ECHA or any EU expert group, or by the authors of this report.

4.1. 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

4.1.1. Environmental fate

Table 4-1: Data for 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

Property	Endpoint	Value	Reference
Abiotic degradation, Hydrolysis	$T_{1/2}$	> 1 year (pH 4 and 7), approx.1 year (pH 9) at 25°C	REACH registration dossier (ECHA 2016)
Biodegradation in water (screening tests)	CO_2 evolution	25 % (28d) Not readily biodegradable	REACH registration dossier (ECHA 2016)
	DOC removal	44% degradation (33 d) Inherently biodegradable	REACH registration dossier (ECHA 2016)
	BOD	3 – 33 % (28d)	Statens forurens-ningstilsyn (2008)
Bioaccumulation	BCF	<4.8 L/kg	REACH registration dossier (ECHA 2016)
		2.3 L/kg	Danish (Q)SAR Database
Sorption (soil)	Log K_{oc}	< 1.25	REACH registration dossier (ECHA 2016)
		0.69	Danish (Q)SAR Database
		1.6	EFSA (2012)
Distribution coefficient (octanol/water)	Log K_{ow}	0.41	EFSA (2012)
		1.06	Danish (Q)SAR Database
Atmospheric oxidation (OH)	$T_{1/2}$	1.2 days	Danish (Q)SAR Database

4.1.2. Environmental effects

Table 4-2: Data for 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

Compartment	Organism *Species*	Type of test	Endpoint	Value	Reference
Water	Algae *Desmodesmus subspicatus* (formerly known as *Scenedesmus subspicatus)*	(Short term) (72h)	EC_{50}	37 mg/L	REACH registration dossier (ECHA 2016)
			NOEC	12.5 mg/L	REACH registration dossier (ECHA 2016)
	Algae *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*)	(Acute) (72h)	EC_{50}	97 mg/L	Danish (Q)SAR Database
	Daphnia *Daphnia magna*	Acute (48h)	EC_{50}	> 100 mg/L	REACH registration dossier (ECHA 2016)
			NOEC	56 mg/L	REACH registration dossier (ECHA 2016)
			EC_{50}	301.9	Danish (Q)SAR Database
	Fish *Onchorhynchus mykiss*	Acute (96h)	LC_{50}	> 100 mg/L	REACH registration dossier (ECHA 2016)
	Fish *Pimephales promelas*	Acute (96h)	LC_{50}	> 447.5 mg/L	Danish (Q)SAR Database
STP	Activated sludge (Microorganisms)	Acute (3h)	EC_{50}	320 mg/L	REACH registration dossier (ECHA 2016)
Soil	Earthworm *Eisenia foetida*	Acute (14d)	LC_{50}	540 mg/kg soil dw	REACH registration dossier (ECHA 2016)
			NOEC	180 mg/kg soil dw	REACH registration dossier (ECHA 2016)

4.1.3. Existing guidance values (PNECs)

No existing guidance values from official authorities have been identified. The following guidance values have been submitted by the REACH registrant and have not been verified or approved by official authorities.

Table 4-3: Data for 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0)

Organisms	Compartment	PNEC value	Reference
Aquatic organisms	Freshwater	0.037 mg/L	REACH registration dossier (ECHA 2016)
	Marine water	0.004 mg/L	REACH registration dossier (ECHA 2016)
	Intermittent releases	0.37 mg/L	REACH registration dossier (ECHA 2016)
	STP	21 mg/L	REACH registration dossier (ECHA 2016)
	Sediment, freshwater	0.037 mg/ kg dw	REACH registration dossier (ECHA 2016)
	Sediment, marine water	0.004 mg/kg dw	REACH registration dossier (ECHA 2016)
Terrestrial organisms	Soil	0.54 mg/kg dw	REACH registration dossier (ECHA 2016)

4.1.4. PBT and vPvB assessment

Persistence (P)

Laboratory experiments show that abiotic degradation of the substance via hydrolysis is ≥ 1 year and data from the REACH dossier show that 2,2-bis(bromomethyl)propane-1,3-diol is not readily biodegradable (25% degr., 28d) but can probably be considered inherently biodegradable (44% degr., 33d). According to the available data and the PBT screening criteria reported in ECHA Guideline on PBT assessment[56], 2,2-bis(bromomethyl)propane-1,3-diol does fulfil the screening criteria for P (not ready biodegradable and inherently biodegradability is < 70%) and is therefore potentially P or vP.

This is supported by data from the Canadian domestic substance list, where the substance is categorized at persistent (Canadian DSL, n.d.)

Bioaccumulation (B)

The BCF of the substance is <<2000 L/kg and the substance does not meet the REACH Annex XIII criteria for either B or vB.

Toxicity (T)

Data are available for the acute toxicity of 2,2-bis(bromomethyl)propane-1,3-diol to fish, aquatic invertebrates and algae, where the lowest $L(E)C_{50}$ is 97 mg/L determined over 72 hours for algae. Data for chronic toxicity is also available for algae (the most sensitive species in acute/short term tests), where the 72 h-NOEC for algae is 12.5 mg/L. However, the substance has a notified classification of Carc 1B (see section 3.1.1) for human toxicity (notified by the registrant) and thus the substance may fulfil the REACH Annex XIII criteria for T.

Conclusion on assessment

The available data suggests that the substance does not meet the REACH Annex XIII criteria for B and vB, but possibly for T, P and vP.

4.2. 2,3-dibromopropan-1-ol (CAS: 96-13-9) and 1,3-dibromopropan-2-ol (CAS: 96-21-9)

4.2.1. Environmental fate

Table 4-4: Data for 2,3-dibromopropan-1-ol (CAS: 96-13-9) and 1,3-dibromopropan-2-ol (CAS: 96-21-9)

Property	Endpoint	Value	Reference
Abiotic degradation, Hydrolysis	$T_{1/2}$	*No available data*	
Biodegradation in water (screening tests)		*No available data*	
Bioaccumulation	BCF	3	HSDB (based on modelling)
		3.2	Danish (Q)SAR Database

56 https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf, page 37

Property	Endpoint	Value	Reference
Sorption (soil)	K_{oc}	4	HSDB (based on modelling)
		11.08	Danish (Q)SAR Database
Distribution coefficient (octanol/water)	Log K_{ow}	0.96	HSDB and Danish (Q)SAR database
Atmospheric oxidation	$T_{1/2}$	8 days	HSDB (based on modelling)
		5.2 days	Danish (Q)SAR Database

4.2.2. Environmental effects

Table 4-5: Data for 2,3-dibromopropan-1-ol (CAS: 96-13-9) and 1,3-dibromopropan-2-ol (CAS: 96-21-9)

Compartment	Organism *Species*	Type of test	Endpoint	Value	Reference
Water	Algae *Desmodesmus subspicatus* (formerly known as *Scenedesmus subspicatus)*	Acute (48-96h)	EC_{50}	280-550 mg/L	ECOTOX database
	Daphnia *Daphnia magna*	Acute (24-48h)	EC_{50}	185-703 mg/L	ECOTOX database
		Chronic (21d)	NOEC	9.6-16 mg/L	ECOTOX database
	Fish *Pimephales promelas*	Acute (96h)	LC_{50}	71 mg/L	ECOTOX database
STP	Activated sludge (Microorganisms)	*No available data*			
Soil	*No available data*				

4.2.3. Existing guidance values (PNECs)

No existing guidance values have been identified for 2,3-dibromopropan-1-ol (CAS: 96-13-9) and 1,3-dibromopropan-2-ol (CAS: 96-21-9).

4.2.4. PBT and vPvB assessment

Persistence (P)

There are no available data on the biotic and abiotic degradation of the substance, and it can therefore not be assessed if the substance meets the REACH Annex XIII criteria for a persistent or very persistent substance.

QSAR data for 2,3-dibromopropan-1-ol (CAS no. 96-13-9) suggest that the substance is not readily biodegradable, but the QSAR predictions are outside applicability domain and should therefore only be used as very indicative (Danish (Q)SAR database, n.d).

Bioaccumulation (B)

Data for the log K_{ow} (< 3) as well as the BCF (<<2000 L/kg) show a low potential for bioaccumulation and REACH Annex XIII criteria for both B and vB are not fulfilled for the substance.

Toxicity (T)

Data are available for the acute toxicity of the substance to fish, aquatic invertebrates and algae, where the lowest $L(E)C_{50}$ is 71 mg/L determined over 96h for fish. There are no data for chronic toxicity available for fish. A 21d chronic test with *Daphnia magna* resulted in a NOEC of 9.6 mg/L as the lowest. However, the substance has a harmonised classification of Carc 1B (see section 3.2.1) and thus the substance fulfils the REACH Annex XIII criteria for T.

Conclusion on assessment:

The substance fulfils the REACH Annex XIII criteria for T. The available data suggests that the substance does not meet the REACH Annex XIII criteria for B and vB. It is not considered possible to conclude on the possible fulfilment of the P or vP criteria for the substance based on the available data.

4.3. 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5)

4.3.1. Environmental fate

Table 4-6: Data for 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5)

Property	Endpoint	Value	Reference
Abiotic degradation, Hydrolysis	$T_{1/2}$	> 1 year (pH 4 and pH7) at 50°C 7.5 years (pH 9) at 25°C	REACH registration dossier (ECHA 2016)
Biodegradation in water (screening tests)	DOC removal	77% degradation (36d) "Readily biodegradable"	REACH registration dossier (ECHA 2016)
	CO_2 evolution	2.5% degradation (28d) "not readily biodegradable"	REACH registration dossier (ECHA 2016)
		Not ready biodegradable[2]	Danish (Q)SAR Database
		The compound has a relatively strong resistance to biodegradation and therefore classified as not readily biodegradable (0-7% degradation after 28 days)[1].	EFSA (2012)
Bioaccumulation	BCF	14.21 L/kg	REACH registration dossier (ECHA 2016) (QSAR data)
Sorption (soil)	K_{oc}	57.31 L/kg	REACH registration dossier (ECHA 2016) (QSAR data)
		315[1]	EFSA (2012)
Distribution coefficient (octanol/water)	Log K_{ow}	2.25	Danish (Q)SAR Database
		2.06[1]	EFSA (2012)
Atmospheric oxidation (OH)	$T_{1/2}$	2.1 days	Danish (Q)SAR Database

[1] Data for CAS no. 1522-92-5 / [2] Conclusion for both CAS no. 36483-57-5 and 1522-92-5

4.3.2. Environmental effects

Table 4-7: Data for 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5)

Compartment	Organism *Species*	Type of test	Endpoint	Value	Reference
Water	Algae *Pseudokirchneriella subcapitata* (formerly known as *Selenastrum capricornutum*)	(Acute) (72h)	EC_{50}	28 mg/L	REACH registration dossier (ECHA 2016)
			NOEC	2.2 mg/L	REACH registration dossier (ECHA 2016)
	Daphnia *Daphnia magna*	Acute (48h)	EC_{50}	64 mg/L	REACH registration dossier (ECHA 2016)
			NOEC	32 mg/L	REACH registration dossier (ECHA 2016)
	Fish *Cyprinus carpio*	Acute (96h)	LC_{50}	32 mg/L	REACH registration dossier (ECHA 2016)
	Fish *Cyprinus carpio*	Chronic (14d)	NOEC	5.6 mg/L	REACH registration dossier (ECHA 2016)
STP	Activated sludge (Microorganisms)	Acute (30 min)	EC_{50}	Ca. 400 mg/L	REACH registration dossier (ECHA 2016)
			EC_{20}	Ca. 20 mg/L	REACH registration dossier (ECHA 2016)
Soil	*No data*				

4.3.3. Existing guidance values (PNECs)

No existing guidance values from official authorities have been identified. Following guidance values have been submitted by the industry and have not been verified by official authorities.

Table 4-8: Data for 2,2-dimethylpropan-1-ol, tribromo derivative (CAS: 36483-57-5 and 1522-92-5)

Organisms	Compartment	PNEC value	Reference
Aquatic organisms	Freshwater	0.044 mg/L	REACH registration dossier (ECHA 2016)
	Marine water	0.004 mg/L	REACH registration dossier (ECHA 2016)
	Intermittent releases	0.28 mg/L	REACH registration dossier (ECHA 2016)
	STP	4 mg/L	REACH registration dossier (ECHA 2016)
	Sediment, freshwater	1.19 mg/kg dw	REACH registration dossier (ECHA 2016)
	Sediment, marine water	0.119 mg/kg dw	REACH registration dossier (ECHA 2016)
Terrestrial organisms	Soil	0.046 mg/kg dw	REACH registration dossier (ECHA 2016)
Predators	Secondary poisoning	1 mg/kg food	REACH registration dossier (ECHA 2016)

4.3.4. PBT and vPvB assessment

Persistence

There are no data available regarding the half-life of substance, and it is therefore not possible to assess whether the substance meets the REACH Annex XIII persistence (P) or very persistent (vP) criteria.

Different data regarding the biodegradability study are available. An inherent biodegradability study (OECD guideline 302B) shows a decrease in DOC concentration of 77% during a period of 36 days (from the REACH registration dossier for CAS no. 36483-57-5 (ECHA, 2016)), where results from a ready biodegradability test show that the substance is not readily biodegradable (2.5%, 28d). Other data also suggest that the substance is not readily biodegradable (QSAR data and data cited in EFSA (2012)). In a report by Statens forurensningstilsyn (2008) (the Norwegian EPA) two studies are cited, where the half-life of TNBPA is estimated to be approximately 100 year, which according to the authors suggests that TNBPA is persistent in the aquatic environment. In summary, by weight of evidence the result of the DOC-based degradation study is considered to be not reliable and is therefore not used in the PBT assessment.

Based on above data and considerations and the PBT screening criteria reported in ECHA Guideline on PBT assessment[57], it is assessed as likely that the substance fulfils the screening criteria for P (<60% biodegradation ThOD, CO_2 evolution) and is therefore potentially P or vP.

Bioaccumulation

The BCF of the substance is <<2000 L/kg and the substance does not meet the criteria for either B or vB.

Toxicity

Data are available for the acute toxicity of substance to fish, aquatic invertebrates and algae, where the lowest $L(E)C_{50}$ is 28 mg/L determined over 72 hours for algae. Data for chronic toxicity is also available for algae (the most sensitive species), where the 72 h-NOEC for algae is 2.2 mg/L. However, the substance has a notified classification of Carc 1B (see section 3.3.1) for human toxicity (notified by the REACH registrants) and thus the substance may fulfil the REACH Annex XIII criteria for T.

Conclusion on assessment

The available data suggests that the substance does not meet the REACH Annex XIII criteria for B but possibly for P and T. The substance is not considered a vP or vB substance based on available data.

4.3.5. Summary on environmental hazards

Based on the available data, 2,2-bis(bromomethyl)propane-1,3-diol and 2,2-dimethylpropan-1-ol, tribromo derivative are both considered potentially persistent or very persistent in the environment. It is not possible to make a conclusion on the potential for persistency for 2,3-dibromopropan-1-ol. None of the three substances are assumed to be bioaccumulative in the environment. The ecotoxicity of all three substances towards aquatic organisms representing three different trophic

57 https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf, page 37

levels (fish, invertebrates and algae) is found to be low. However, due to carcinogenic and mutagenic/genotoxic effects towards humans, all three substances are considered to fulfil the REACH Annex XIII criteria for toxicity.

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1. Description of waste streams

From the information collected through this project, two main application areas in which substances from the SBAA group may be used have become apparent.

The first regards the possible use of SBAAs in the manufacture of **polyurethane foams** that are applied as insulation in cooling equipment such as for example in refrigerators.

The second regards the possible use of SBAA in mixtures that are applied as **resins for encapsulation** purposes of various electronic components. Examples of such components where resins are used for encapsulation are given in section 2.5 and include for example capacitors, miniature sensors, inductive components, as well as power supplies and storage-batteries.

5.1.1. Main materials where the substance is contained

Where SBAA substances may be used in the manufacture of flame retardant insulation materials, applied in cooling devices, the material of interest is polyurethane cooling foams.

Where SBAA substances may be used in the manufacture of flame retardant encapsulation resins, it is understood that various resins may be of interest including epoxy resins.

In both cases, the SBAAs are understood to be used as reactive substances, undergoing a transformation when the final material (foam/epoxy) is manufactured. Thus it is expected that the SBAA would not generally be present in such end-products, assuming that all used substance reacts through the process. The nature of possible derivatives is not clear but is understood no longer to be associated with the SBAA group.

5.1.2. WEEE categories containing the substance

Polyurethane foams are understood to be used in various cooling devices, which would fall under:

- WEEE Annex I categories:
  - 1. Large household appliances (Annex II detail includes: large cooling appliances, refrigerators, freezers, other large appliances used for refrigeration, conservation and storage of food)
  - 8. Medical devices (Annex II detail includes: freezers)
- WEEE Annex III categories:
  - 1. Temperature exchange equipment (Annex IV detail includes: refrigerators, freezers, Equipment which automatically delivers cold products, air conditioning equipment… and other temperature exchange equipment using fluids other than water for the temperature exchange.

Encapsulation resins are understood to be applied to components attached to printed circuit boards. Though it is not clear in what cases SBAAs would be the flame retardants used for such applications, printed circuit boards are a component used in practically all electrical equipment. In this respect all WEEE categories would be relevant. In particular there is mention of use of one of the SBAAs in mobile phones, suggesting that applications of higher relevance may be EEE devices with internal storage batteries.

It is noted that in light of the reactive properties of the substances used in the above cases that SBAAs present in the final product is not expected to be common, though it cannot be excluded where a full reaction does not occur.

5.2. Applied waste treatment processes

In relation to insulation **polyurethane foams** applied in cooling devices the Ecodesign preparatory study for refrigerators (VHK 2015) provides information as to the destiny of PU foams used in refrigerators. PU foams are a thermoset material, processed from two main components, which in itself makes the recycling of the material very difficult. "*End-of-life PUR can be recycled chemically (costly and potentially polluting) or mechanically (crushed and compressed to form wood-like blocks) … In the case of refrigerating appliances, the PUR foam is stuck between the steel cabinet and the PS inner-liner and cannot be dismantled. The most used solution, also to recover the foaming agent responsibly, is to shredder —in a special, closed environment— the base cabinet to fine grains, recovery the steel parts through magnetic separation and incinerate (with heat recovery) the PUR-PS particles that remain. This means that also the PS will not be recycled, but only used for heat recovery.*"

In relation to **encapsulation resins** used in components attached to PCBs article 8(2) of the WEEE Directive requires among others in Annex VII "1. As a minimum the following substances, mixtures and components have to be removed from any separately collected WEEE:… printed circuit boards of mobile phones generally, and of other devices if the surface of the printed circuit board is greater than 10 square… centimetres". It is not clear to what degree this requirement is carried out in practice. Some printed circuit boards may be recycled separately and some shall be processed with the rest of the device for example through a shredder. In both cases the processes target the recovery of various metals. It is possible that some of the resins would remain in fractions sent to metal recovery facilities (copper, aluminium etc.). It is less probable that the resin is separated as a fraction of its own. Metal recovery facilities shall usually process relevant waste streams among others thermally with the use of incinerators. The temperatures for example in the recovery of copper are relatively high and thus most organic substances would probably be contained. Where such equipment is not collected as EEE to begin with it shall probably be collected as municipal waste. In such cases the resins would probably reach incinerators, which have much lower temperatures and which may impact SBAA and their derivatives differently. Additional detail is provided in Section 591.

As for possible waste from the manufacturing process, data sheets of relevant materials provide the following information as to treatment of waste:

- Mixtures containing 2,2-bis(bromomethyl)propane-1,3-diol (CAS: 3296-90-0):
  - Polylite 33441-00 by Reichhold[58] -"This material and containers that are not empty, if discarded, would be regulated as a hazardous waste under RCRA. Treatment and/or disposal must be completed at a RCRA-permitted Treatment, Storage and Disposal Facility (TSD). The storage and transportation of RCRA hazardous wastes are also regulated by the USEPA. The recommended method of disposal is by controlled incineration in a unit with an acid scrubber to remove free hydrogen bromide, or dispose of in a chemical landfill as approved by current laws and regulations."

[58] MSDS Reichhold, Inc.https://www.b2bcomposites.com/msds/reichhold/33441-00.pdf

- CRYSTIC 356PA by Scott Bader[59] – "Waste to be treated as controlled waste. Disposal to licensed waste disposal site in accordance with local Waste Disposal Authority… Dispose of waste and residues in accordance with local authority requirements. Make sure containers are empty before discarding (explosion risk). Absorb in vermiculite or dry sand and dispose of at a licenced hazardous waste collection point."
- FR-522 by ICL[60] - "Treat the solid waste and packaging waste via an incinerator equipped with an adequate gas cleaning system or send to a controlled landfill. Observe all federal, state and local environmental regulations when disposing of this material"

- Mixtures containing 2,2-dimethyl¬propan-1-ol (CAS: 36483-57-5):
  - FR-513 by ICL[61] - „Treat the solid waste and packaging waste via an incinerator equipped with an adequate gas cleaning system or send to a controlled landfill."

5.2.1. Initial treatment processes applied to the WEEE containing the substance of concern

Table 5-1: Initial treatment processes applied

Initial treatment processes	The substance is present in appliances belonging to:					
	Cat1	Cat2	Cat3	Cat4	Cat5	Cat6
For WEEE collected separately						
Collection and transport	x	x	x	x	x	x
Dedicated treatment processes for cooling & freezing appliances	x					
Dedicated treatment processes for screens		x				
Dedicated treatment processes for lamps			x			
Manual dismantling	x	x		x	x	x
Shredding (and automated sorting)	x			x	x	x
For WEEE not collected separately						
Landfilling (of residual waste)		x	x		x	x
Mechanical treatment (of residual waste)		x	x		x	x
Incineration		x	x		x	x
Uncontrolled treatment in third countries	x	x		x	x	x

[59] MSDS Scott Bader; http://www.flints.co.uk/pdffiles/crystic_356pa.pdf

[60] ICL IP: http://icl-ip.com/products/fr-522/

[61] ICL Industrial Products: http://icl-ip.com/wp-content/uploads/2012/07/FR-513-TBNPA.pdf

5.2.2. Treatment processes applied to wastes derived from WEEE containing the substance of concern

Table 5-2: Treatment processes for wastes derived from WEEE

Treatment processes for wastes derived from WEEE treatment	The substance is present in the following main component/material								
	Ferrous metals	Non-ferrous metals	Plastics	Electronic components	Cables	Glass	Powders	Fluids	Others
Under current operational conditions in the EU									
Storage of secondary wastes									
Shredding and automated sorting of secondary wastes			x	x					x
Recycling of ferrous metals									
Recycling of NE metals									
Recycling of plastics			x						
Recycling of glass									
Recycling as building material									
Landfilling of residues									
Incineration of residues			x	x					x
Co-incineration of residues			x	x					x
Dedicated processes for hazardous residues			(x)	(x)					(x)
Under uncontrolled conditions									
Acid leaching									
Grilling/desoldering									
Uncontrolled combustion									
Uncontrolled dumping of residues			x	x					x

5.3. Waste treatment processes relevant for assessment under RoHS

5.3.1. Initial treatment processes applied to the WEEE containing the substance of concern relevant for assessment under RoHS

Relevant components from cooling equipment collected as WEEE are assumed to be shredded for the most part.

Relevant encapsulated components shall be processed with printed circuit boards. In some cases these shall be shredded. As the processes target the recovery of various metals, some epoxy resins may be sent to recovery facilities for specific metals (for example copper, aluminium, etc.).

In cases where EEE is not collected as WEEE, it can be expected to be collected with municipal waste.

5.3.2. Treatment processes applied to wastes derived from WEEE containing the substance of concern relevant for assessment under RoHS

Polyurethane foams shall finally be treated through incineration.

In all cases it is assumed that the epoxy materials shall finally be treated through incineration.

5.4. Releases from (relevant) WEEE treatment processes

Where polyurethane or epoxy resins are treated with WEEE and incinerated, it is expected that the heat of such thermal processing is sufficient and that the processes shall be well contained. As the SBAAs are used as reactive flame retardants, amounts that remain in the final EEE (incomplete reaction) are assumed to be negligible. It is not clear what the fate of derivatives would be in such cases, however an estimation has been carried out and is detailed in Section1.

For EEE collected with municipal waste, where the treatment of municipal waste includes incineration, temperatures of the thermal processes may be lower. In such cases certain emissions may incur should SBAAs remain in the EEE in light of incomplete reaction. It is not clear what the fate of derivatives would be in such cases, however an estimation has been carried out and is detailed in Section1.

6. EXPOSURE ESTIMATION DURING WEEE TREATMENT

6.1. Basis of exposure estimation

The substances:

The results of the survey of uses for the selected SBAAs in Section 1 show that there is no information/data indicating any actual use of the substance dibromo-1 propanol (CAS 96-13-9 and 96-21-9) in the EU, while the substances 2,2-bis(bromomethyl)-1,3-propanediol (CAS 3296-90-0) and 3-bromo-2,2-bis(bromomethyl)-1-propanol (CAS 36483-57-5) are both registered in the 100-1000 tonnage band by one registrant under the REACH Regulation.

It is therefore assumed for the purpose of this exposure assessment that only the two latter substances are relevant to consider further and, as a worst case, the magnitude of their manufacture and use will be set at 1000 tonnes/year for each of the two substances.

The uses/applications:

Based on information from industry, as described in Section 2, production of flame retarded thermal insulation materials for the construction industry, in particular rigid polyurethane foam, appears to be by far the most important application area for the two substances. Both are used as reactive flame retardants (or intermediates). For one of the substances, the manufacturer ICL has indicated that production of rigid PU for roofing etc. accounts for 90 % of the total tonnage, i.e. an application not considered to fall under the scope of the RoHS Directive (not EEE). No such information exists for the other substance, which, however, chemically is closely related to the first substance. Therefore, for the purpose of this exposure assessment the pattern of uses is assumed to be the same.

Nevertheless, it cannot be excluded that there is also some use for production of flame retarded rigid PU thermal insulation of electrical products such as refrigerators and freezers, i.e. EEE.

Another application area also mentioned by the manufacturers is use of the substances as reactive flame retardants in thermoset resins, assumed to be mainly epoxy resins. Such resins may be used for encapsulation purposes (production of FR-4 laminates) in the manufacturing of printed circuit boards (PCBs), i.e. a usage area of relevance to EEE.

Thus, 90 % of the production volume of the selected flame retardants appears to be used for non-EEE applications within the construction industry, leaving only a maximum of 10 % for other purposes including EEE. As a worst case scenario, 10 % corresponding to max. 100 tonnes/year per substance is assumed to be used for these two purposes in total, e.g. 5% of either substance for each of these two applications, assuming (based on product information) that the substances are used as reactive flame retardants/intermediates for both applications.

With regard to the possible amount in PCBs it is necessary also to consider the import of EEE consumer products from countries outside the EU, which constitute the major part. For the purpose of this rough exposure assessment it is assumed that the imported amount does not exceed the amount produced within the EU for use in PCBs by more than a factor of 10, i.e. in the worst case a total amount of 1000 tonnes/year.

The contents in flame retarded products:

Based on information in product data sheets from manufacturers such as ICL, Reichhold and Scott Bader (referred in Section 1), it is assessed that the maximum amount of reactive SBAA flame retardant used to produce flame retarded laminates for printed circuit boards is 2 % w/w.

Additional product information from ICL[62] and Great Lakes Solutions[63] indicates that for manufacturing of flame retarded polyurethane foams the required content of SBAAs is a bit higher, assessed to be in the range 3-5 % w/w. I.e. the maximum (worst case), which will be used in the exposure assessment, is 5 % w/w.

The two substances, 2,2-bis(bromomethyl)-1,3-propanediol (CAS 3296-90-0) and 3-bromo-2,2-bis(bromomethyl)-1-propanol (CAS 36483-57-5), are both used exclusively as reactive flame retardants or intermediates. I.e. virtually all of the added SBAAs will undergo fast reactions in the polymer matrix and thus be transformed and bound in a way that generally is considered to be irreversible. The literature review has not found any indication that back-transformation of reacted flame retardants takes place during handling and treatment of WEEE.

However, although the reaction efficiency of the SBAAs in the polymer matrix is almost 100 %, there may still be a small amount of unreacted (residual) SBAA molecules left in the polymer matrix. No data on quantification of residual SBAA molecules have been identified. Residual SBAA molecules could slowly be released by evaporation or other mechanisms either during the service life of the flame retarded products or during the waste treatment and disposal phase, WEEE phase (including possible re-cycling processes). No specific information on this has been obtained for the selected SBAAs, but in the draft EU risk assessment report for the brominated flame retardant TBBPA (tetrabromobisphenol-A) (ECB, 2007), the level of residual TBBPA in finished epoxy resins is assumed to be <0.02 % by weight of the resin or < 0.06 % of the amount of TBBPA used to make the resin. The original reference for these values is stated to be information from industry. No other quantitative information on residual monomer levels of reactive brominated flame retardants has been identified, including possible residual levels in PUR foam.

Therefore, for the purpose of exposure assessment in this dossier, a maximum level of residual SBAA in resins for PCBs as well as in PUR foams for refrigerators etc. of 0.02 % by weight of the resin (i.e. 200 mg/kg) and max. 0.06 % by weight of the SBAA itself will be used. A total amount of 1000 tonnes will be used for SBAAs in products imported from outside the EU. This means that overall for the EU, in the worst case a maximum amount of 0.0006 x (2 x 2 x 50 + 1000) tonnes/year = 0.72 tonnes/year will be present in EEE products flame retarded with SBAAs. This amount could be slowly released from these products over time.

There is no specific information available regarding release rates for SBAAs from printed circuit boards or rigid polyurethane foam, or monitoring data for air concentrations in the working environment. However, results referred in the EU risk assessment report for TBBPA indicate that in the waste treatment and disposal phase, unreacted monomer is still present in the products being dismantled prior to either re-cycling or incineration. As no further quantitative information is available, it is assumed for both printed circuit boards and for PU foam in refrigerators etc. that 50 % of the unreacted residuals will be released during the use phase (corresponding to 360 kg/year

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[62] http://icl-ip.com/wp-content/uploads/2011/12/513PUflexible.pdf

[63] http://greatlakes.com/deployedfiles/ChemturaV8/GreatLakes/Flame%20Retardants/FR%20Brochures/CPI%20Polyurethanes%20Technical%20Conference%20Presentation.pdf

in the EU for the two substances together) and 50 % would still be present in the flame retarded EEE products when the products reach the WEEE phase[64].

6.2. Human exposure estimation

In this dossier, only the possible exposure of humans related to the handling, treatment and disposal of WEEE with contents of SBAAs is addressed. Waste from two different product types are considered; (1) waste from use in laminated printed circuit boards and (2) waste from use of rigid PU foam in refrigerators and similar products.

As appears from section 6.1, the total amounts of unreacted SBAAs available for potential exposure of humans in the WEEE phase are small, in the worst case a maximum of 360 kg/year for the two selected substances together. Thus, assuming that the EEE use of the two substances is distributed evenly between the uses in PU foam and printed circuit boards, respectively, there will be a worst case amount in the EU, to which humans could be exposed, of 180 kg/year per use area. However, as the total content is not likely to be released into the work environment air, the actual amount to which humans may be exposed is considered to be less than 180 kg.

Printed circuit boards contain various rare and precious metals that to a large extent can be recovered at the end-of-life of the products. There seems to be two main technical ways to extract the metals from the matrix (ECB, 2006 and US EPA, 2015):

- Pyrolysis at high temperature (>1200 ˚C) by which all the organic material will disappear leaving the metals to be extracted from the ashes, slags and possibly also collected vapour condensates.
- Shredding of the laminate from the printed circuit boards followed by extraction of the metals from the boards and disposal by incineration of the shredded, flame retarded resin-containing laminate.

Both types of processes could lead to release to air and thereby inhalation exposure of workers. However, the potential exposure levels are assumed to be low considering that:

- The major part of possible residual monomer left in the EEE products is likely not to be released to the air during these short-duration processes but will remain in the polymer matrix until combustion/pyrolysis at high temperature and be destroyed in the process.
- If it is assumed that 10% of the residual amounts are released, this would correspond to 18 kg/year. This amount would be distributed between several different facilities in the EU over a production year.
- The possible exposure levels would be further reduced if proper ventilation and other technical measures to avoid vapour and dust generation are taken.

Refrigerators and similar products using rigid polyurethane foam for thermal insulation are dis-assembled mechanically to separate the cabinets and electrical parts etc. from the insulation foam, which cannot be re-cycled and therefore is sent for disposal by incineration. Exposure of workers to dust as well as to vapours can result from the disassembly operations at exposure levels similar to or more likely less than what can be expected from the use in epoxy resins.

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64 The products with laminated printed circuit boards (e.g. consumer products such as mobile phones and tablets etc.) will typically have a shorter use-life than refrigerators and freezers etc. but on the other hand typically reach higher temperatures than the rigid PU foam in refrigerators, which are not in direct contact with the electrical parts.

Following the above considerations, it is concluded that the exposure levels for neighbouring residents will also be very low.

6.3. Environmental exposure estimation

Overall, the environmental exposure resulting from handling, treatment and disposal of WEEE materials containing SBAA flame retardants is considered to be low, partly because the total amount available for exposure in the WEEE phase is low (total of 360 kg/year for the two substances together in all of EU) and partly because most of the relevant waste materials will be treated either by pyrolysis at re-cycling plants or by incineration at large municipal waste incineration plants. The amount of residual monomer in waste PCBs that can be released to the surroundings (via the working environment) during treatment/re-cycling processes is assessed to be max.18 kg/year, see Section 6.2, while the release from handling of waste PU foam is assessed to be less.

The WEEE disposal treatment processes of relevance in relation to SBAAs are briefly described in Section 6.2 and in all cases the environmentally most relevant pathway is via combustion of the flame retarded material. It is, however, considered unlikely that any SBAA will survive pyrolysis at >1200 ˚C when printed circuit boards are destroyed by pyrolysis with the aim to recover rare/precious metals. Therefore, the main pathway of potential interest is via incineration at municipal waste incineration plants where the combustion temperature is somewhat lower.

Rigid PU foam waste as well as shredded laminate from printed circuit boards will in most cases be disposed of by incineration in municipal incineration plants. According to Directive 2000/76/EC on incineration of waste[65] (implemented in Danish legislation by Statutory Order no. 1451 (2012) on incineration of waste[66]) a certain minimum temperature of 850 ˚C during a minimum of 2 seconds must be achieved to comply with the regulatory performance criteria. If hazardous waste with a content of more than 1 % of halogenated substances is incinerated, the temperature must be >1100 ˚C. At the same time, measures to mitigate unacceptable emission levels for certain pollutants in the stack gases, not least dioxins and a range of heavy metals, must be installed at the incineration plants.

Although 850 ˚C is significantly lower than the abovementioned pyrolysis temperature of >1200 ˚C it is still a high temperature, which is assessed to result in a considerable degree of thermal degradation of the SBAA substances. However, it cannot be completely excluded that low levels of SBAAs are not degraded and therefore may be present in the MSW plant stack gas, but the total amount potentially emitted to air via MSW plants is assessed to be less than the 18 kg/year emitted during the handling, treatment and disposal operations prior to pyrolysis or incineration.

Wastewater from the cleaning of gases at MSW plants must be treated properly to avoid pollution prior to release into the aquatic environment or pre-treated prior to discharge to the public sewerage system. The amounts of SBAAs potentially ending up in wastewater are assessed to be small as the major part will be destroyed thermally prior to cleaning of the combustion gases.

Possible amounts of PU foam waste or WEEE with SBAAs not being treated/disposed of at waste incineration plants are considered to be negligible in the EU member states. If, theoretically, such waste should be disposed of in a landfill, the percolate from landfill facilities in the EU cannot be

[65] Directive 2000/76/EC of The European Parliament and of The Council of 4 December 2000 on the incineration of waste, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0076&from=EN

[66] Danish Statutory Order no. 1451, 20.12.2012 on waste incineration, available at https://www.retsinformation.dk/pdfPrint.aspx?id=144087

discharged directly to the environment but will normally be transported via the public sewerage system to a sewage treatment plant (STP) for treatment and disposal. In principle, treatment can also take place locally at the landfill facility.

7. IMPACT AND RISK EVALUATION

The roughly estimated worst case amounts of SBAAs used for EEE applications in the EU that potentially could be released in the waste phase either to the working environment or to the external environment in an untransformed form are assessed to be in the range 18-36 kg/year, see sections 6.2. and 6.3. Consequently, the possible local occupational, residential or environmental concentrations will be very low, although they are not possible to quantify with any certainty with the information available for the SBAA substances.

In light of these findings based on worst case exposure scenario assumptions, it is not found meaningful to try to establish specific risk assessment scenarios or perform risk evaluations for these scenarios. Based on the available information and the described worst case assumptions, the overall assessment is that, if evaluated, the risk to humans and the environment would turn out to be very low/negligible.

Information from risk assessment of other flame retardants used in electronics may be used to support the qualitative assessment. TBBP-A is also applied as a reactive flame retardant in glass-fibre/epoxy resin laminate and epoxy resins for encapsulation of certain electronic components at a concentration of around 2%. For the purpose of risk characterisation the European Union Risk Assessment Report (RAR) suggests a "reasonable worst case" 8-hour TWA inhalation of 50 µg/m³ inhalable TBBP-A based on EASE modelling (based on measurements) and other measured personal data from an HSE survey.

With regard to the environment, SBAAs have been found to have only low-moderate toxicity to aquatic organisms (acute EC50's >10 mg/L and chronic NOECs >1 mg/L) and not to be bioaccumulative. However, they may be sufficiently persistent to fulfil the P-criterion in a PBT assessment.

8. ALTERNATIVES

8.1. Availability of substitutes / alternative technologies

According to Zevenhoven (2004), as early as 2004 the use of brominated flame retardants (BFRs) in polyurethanes was in decline for environmental and health reasons, and flame retardants based on (organo-)phosphorus or nitrogen alternatives were becoming more common. PU foams are often flame-retarded using phosphate polyols, which contain ~10 %-wt phosphorus. The open cell structure of PUF foams makes flame retardation difficult, and increasing the tendency of the foam to char is an important effect. For PUR foams additive flame retardants are used.

The share of encapsulation resins applied in EEE for which SBAAs are used as resin constituents is not clear. From the available data (see detail below), it can be understood that for obtaining flame retardancy in such applications also other brominated flame retardants can be used (in the past tetrabrombisphenol A (TBBPA) is understood to have been common) as well as various non-halogenated flame retardants.

US EPA (2015) specifies that in 2008, the majority of PCBs produced worldwide met the V0 requirements of the UL 94 fire safety standard. This standard was usually achieved through the use of brominated epoxy resins in which the reactive flame retardant TBBPA forms part of the polymeric backbone of the resin. While alternative flame-retardant materials are used in only a small percentage of FR-4 boards, in 2008, the use of alternatives was increasing and additional flame-retardant chemicals and laminate materials were under development. US EPA specifies that the in 2008, TBBPA was used to make the epoxy resin base material in more than 90 percent of FR-4 boards while alternative flame-retardant materials were used in only 3-5 percent of FR-4 boards.

According to Baron (2014), "*TBBPA is used as a reactive component of flame-retarded epoxy and polycarbonate resins, which accounts for approximately 90% of the use of TBBPA. The two main applications for epoxy resins are:*

- *Epoxy resins in printed circuit boards (rigid or reinforced laminated printed circuit boards most commonly based on glass fibre reinforced epoxy resin (designated FR4-type): used in nearly all types of EEE. From the consultant's prior experience, it can be stated that printed circuit boards (PCB) are mainly imported.*
- *Epoxy resins to encapsulate certain electronic components, e.g. plastic/paper capacitors, microprocessors: used in plastic/paper capacitors, microprocessors, bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors) on the printed circuit board.*

The information from the Joint Submission of the TBBPA registration at ECHA indicates a total tonnage band of 1,000 to 10,000 tonnes per annum. This is a clear decrease compared to the amounts identified in the Oeko-Institut study in 2008 that estimated the demand for EEE at a total of around 40,000 tonnes per year (based on data for 2003/2005) "

In relation to epoxy resins, it can be understood that industry is searching for alternatives to flame retardants used in the past. In some cases this may lead to a substitution of brominated flame retardants of one type with other types; however it is also clear that non-halogenated flame retardants are in development for such purposes. Rakotomalala et al. (2010) mention that since disputable additives can leach out of a polymer while being processed and/or while being used, there is always a potential health risk when such systems are used. In addition to the environmental and end-of-life issues, this has led to strong efforts in replacing halogenated systems. Data is presented by Rakotomalala et al. that shows that bromine based flame retardants only have a 10% market share in relation to flame retardants used for EEE, with non-halogenated substitutes showing a total larger market share such as metal hydroxide based flame retardants (56%), non-halogenated phosphorus ones (9%) and melamine based ones (3%). Some information is further provided as to such potential substitutes:

- "***Metal hydroxides*** *such as, aluminium hydroxide (ATH) and magnesium hydroxide (MDH) have several positive effects when applied as a flame retardant. They are very cheap, easy to obtain, non-toxic and environmentally friendly. Nonetheless very high loadings are required to obtain flame retardancy (~30–60%). Such high loadings have detrimental effects on the properties of the end product… Aluminum-oxide-hydroxide (AlOOH or boehmite) has a much higher thermal stability and can be applied in epoxy systems that undergo lead-free soldering... lead-free soldering required higher processing temperatures which demands higher thermal stability from the additives used. Prior to lead-free soldering a sample would pass the delamination test at 260°C. However, the currently used system for PWB consisting out of a novolac epoxy resin and DICY as a hardener must endure 288 °C without delaminating. Metal hydroxides are often used as synergists with phosphorus based flame retardants (e.g., metal phosphinates).*"
- The information related to **phosphorus substitutes** is quite general and does not clarify what substances could be used for epoxy resin applications. Some data is however provided suggesting that at least some of these alternatives would be more expensive: "*Organophosphorus compounds provide good physical properties and require less loading compared to regular fillers (e.g., ATH). However, a broad application is only gradually taking place since these are still more expensive than conventionally used flame retardants (e.g., ATH or TBBPA). Nonetheless, the production of phosphorus flame retardants on industrial scale will contribute to reduce their price*". In relation to the use of such flame retardants as reactive additives, it can be understood that at the time of writing (2010) there was only a limited amount of industrially relevant reactive phosphorus flame retardants.

8.2. Hazardous properties of substitutes

In general, when substituting one brominated flame retardant for another, the change in hazardousness shall be determined by the substance to be applied as alternative, resulting in either a higher, similar or lower toxicity.

As an example for a BFR alternative, it can be understood from Rakotomalala et al. (2010) that TBBPA was in common use in the past in epoxy resins. TBBPA has also been the subject of preliminary prioritization for RoHS restriction (Baron 2014). TBBPA was included in the OSPAR List of Chemicals for Priority Action in 2000. TBBPA is considered to meet all three of the OSPAR criteria for the PBT (persistent, bioaccumulative and toxic) assessment, although it should be acknowledged that it is a borderline case for the bioaccumulation criterion OSPAR (2011). It was also added to the SIN list 1.0 in September 2008 because reprotoxic and endocrine disruptive effects were reported.[67] However, TBBPA does not meet the criteria for a PBT or a vPvB substance under REACH and there is currently no initiative within ECHA concerning TBBPA. Regardless of the toxicity of TBBPA, it seems that its application in EEE epoxy resins may be decreasing as suggested in the data presented in section 8.1

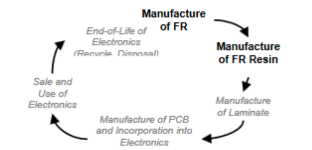
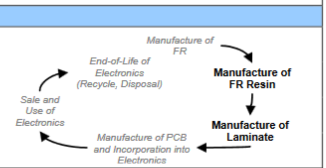
[67] See SIN list database: http://w3.chemsec.org/

As explained above, **metal hydroxides** such as, aluminium hydroxide (ATH) and magnesium hydroxide (MDH) are understood to be non-toxic and environmentally friendly. "***Phosphorus flame retardants*** *(organic and inorganic) are in general not harmful and do not tend to form toxic gases since phosphorus is mostly locked into the char. Under thermal stress, the major part of phosphorus is oxidised to phosphorus pentoxide (P_2O_5) which then hydrolyses to polyphosphoric acid ($H_xP_yO_z$). Polyphosphoric acid in particular plays an important role in creating carbonaceous char. Phosphorus flame retardants that react via the gas phase form phosphorus containing radicals and gases such as PO and PO_2 derivatives respectively. The newly formed PO and PO2 derivatives can be rapidly oxidised to .P_2O_5 which in turn forms polyphosphoric acid…"* Rakotomalala et al. (2010)

In a report published by US EPA 2015, ten flame-retardant chemicals and resins for FR-4 laminate materials for PCBs were evaluated in relation to their hazardous properties. It is explained that the level of available human health and environmental information varies widely by flame-retardant chemical. Little information exists concerning many of the alternative flame-retardant materials evaluated and thus EPA used the tools and expertise developed for the New Chemicals Program to estimate the potential impacts of flame retardants when no experimental data were available. Results of the evaluation are reproduced in Table 8-1 and Table 8-2 below.

Table 8-1: Screening Level Hazard Summary for Reactive Flame-Retardant Chemicals & Resins

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H, and VH)* were assigned using values from predictive models and/or professional judgment.
♦ TBBPA has been shown to degrade under anaerobic conditions to form bisphenol A (BPA; CASRN 80-05-7). BPA has hazard designations different than TBBPA, as follows: MODERATE (experimental) for reproductive, skin sensitization and dermal irritation. § Based on analogy to experimental data for a structurally similar compound. ‡ The highest hazard designation of any of the oligomers with MW <1,000. ¥ Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.9)	CASRN	Human Health Effects											Aquatic Toxicity		Environmental Fate		Exposure Considerations
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation	Availability of flame retardants throughout the life cycle for reactive and additive flame-retardant chemicals and resins
Reactive Flame-Retardant Chemicals																	
Tetrabromobisphenol A	79-94-7	L	M	L	L♦	M	L	L	L♦		M	L♦	VH	H	H	M	
DOPO	35948-25-5	L	*M*	L	*L*[§]	*M*	*M*	L	M		M	VL	L	*M*	*H*	*L*	
Fyrol PMP	63747-58-0	L	*L*[§]	*L*[§]	*M*[§]	*M*[§]	*M*[§]	*M*[§]	L		L	L	*H*[‡]	*H*[‡]	*VH*	*H*[‡]	
Reactive Flame-Retardant Resins																	
D.E.R. 500 Series[¥]	26265-08-7	*L*	*M*	*M*	*M*	*M*	*M*	*M*	H		*M*[‡]	*M*[‡]	*L*	*L*	*VH*	*H*[‡]	
Dow XZ-92547[¥]	Confidential	L	*M*[‡]	*M*[§]	*M*[‡]	*M*[‡]	*M*[‡]	*M*[‡]	H	*M*[‡]	VL	L	*L*	*H*	*VH*	*H*[‡]	

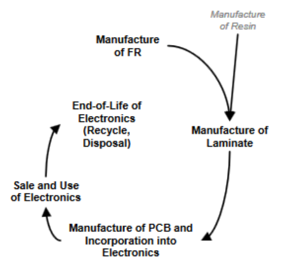
Note: This table contains hazard information for each chemical; evaluation of risk considers both hazard and exposure. Variations in end-of-life processes or degradation and combustion by-products are discussed in the US EPA (2015) report but not addressed directly in the hazard profiles. The caveats listed above must be taken into account when interpreting the information in the table.

Source: US EPA (2015)

Table 8-2: Screening Level Hazard Summary for Additive Flame-Retardant Chemicals

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics (*VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.
[R] Recalcitrant: Substance is comprised of metallic species (or metalloids) that will not degrade, but may change oxidation state or undergo complexation processes under environmental conditions. [§] Based on analogy to experimental data for a structurally similar compound. [¤]Concern linked to direct lung effects associated with the inhalation of poorly soluble particles less than 10 microns in diameter. [^] Depending on the grade or purity of amorphous silicon dioxide commercial products, the crystalline form of silicon dioxide may be present. The hazard designations for crystalline silicon dioxide differ from those of amorphous silicon dioxide, as follows: VERY HIGH (experimental) for carcinogenicity; HIGH (experimental) genotoxicity; MODERATE (experimental) for acute toxicity and eye irritation. [¥] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.9)	CASRN	Human Health Effects											Aquatic Toxicity		Environ-mental Fate		Exposure Considerations
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation	Availability of flame retardants throughout the life cycle for reactive and additive flame-retardant chemicals and resins
Additive Flame-Retardant Chemicals																	
Aluminum Diethylphosphinate[¥]	225789-38-8	L	*L*[§]	L	L	*M*[§]	*M*[§]	*M*[§]	L		L	VL	M	M	*H*[R]	*L*	
Aluminum Hydroxide[¥]	21645-51-2	L	*L*[§]	L	*L*[§]	L	M	*M*[§]	L		VL	VL	L	L	*H*[R]	*L*	
Magnesium Hydroxide[¥]	1309-42-8	L	L	L	L	L	*L*	L	L		M	L	*L*	*L*	*H*[R]	*L*	
Melamine Polyphosphate[1¥]	15541-60-3	L	*M*	*M*	*H*	*M*	*M*	*M*	*L*		L	VL	L	L	*H*	*L*	
Silicon Dioxide (amorphous)	7631-86-9	L[^]	L[^]	L[^]	L	L	*L*[§]	H[¤]	L		L[^]	VL	L	*L*	*H*[R]	*L*	



[1] Hazard designations are based upon the component of the salt with the highest hazard designation, including the corresponding free acid or base.

Note: This table contains hazard information for each chemical; evaluation of risk considers both hazard and exposure. Variations in end-of-life processes or degradation and combustion by-products are discussed in the US EPA (2015) report but not addressed directly in the hazard profiles. The caveats listed above must be taken into account when interpreting the information in the table.

Source: US EPA (2015)

8.3. Data basis for alternatives and uncertainties

Though it can be understood that alternatives exist and are probably also applied in some cases for encapsulating resins, there is lacking data to enable an understanding as to the share of encapsulation resins using SBAAs and using alternative flame retardants. For SBAAs it can be understood that some of these substances used for manufacturing epoxy resins are reactive and would be transformed through the manufacturing process, whereas others are additive and shall remain in the end-product. The fate in the case of alternatives may differ from case to case and as such it is difficult to conclude as to actual impacts resulting from the application of alternatives.

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

It can be understood that the substances 2,2-bis(bromomethyl)-1,3-propanediol (CAS 3296-90-0) and 3-bromo-2,2-bis(bromomethyl)-1-propanol (CAS 36483-57-5) are registered in the EU in compliance with the REACH regulation. Data was not available that implies that other SBAA substances are in use in the EU in general and more specifically in the manufacture of EEE components. It is thus assumed that should substances of the SBAA group be restricted for use in EEE under the RoHS Directive that the use of these two substances in the manufacture of EEE could be affected. As the applications of relevance for both of these applications are understood to be as reactive flame retardant, it is concluded that only trace amounts may be present in final products, assuming an incomplete reaction during the production of the resin. Available estimations for the level of residual TBBPA in finished epoxy resins is assumed to be <0.02 % by weight of the resin (ECB, 2007 as referred in a report by US EPA, 2015). In the exposure estimation is Section 1, these values have been taken into consideration for the two SBAA substances.

Though the threshold above which use of a RoHS substance is restricted may vary, 0.02 % by weight is considered a very low concentration (at present, cadmium which has the lowest threshold is restricted above 0.01%, while all other substances are restricted below 0.1%. In light of the low to negligible risk of emissions estimated in Section 1, it is assumed that it would be difficult to justify a threshold below the 0.1% level. In this case, a restriction would not have actual implications for SBAAs used in polyurethane foam or resin applications. It is possible that some manufacturers would prefer to phase-out these substances as a precautionary action, possibly reducing the amounts used, however in lack of the applicability of the restriction it is assumed that most manufacture would not be influenced by the restriction. Should a lower threshold be determined, this would require substituting SBAAs with other alternatives, assuming that the residual amounts would indeed be above the threshold. As information suggests that a variety of alternatives are available on the market, it is assumed that substitution would be possible, with the costs and benefits depending on the alternative chosen and on the possible need to adjust the formulations of resin mixtures in order to establish a comparable or a higher performance level of the resin in the end-application.

In lack of quantitative data, the following sections provide a qualitative estimation as to possible impacts.

9.2. Impact on chemicals industry

Assuming a restriction would affect the use of SBAAs in EEE applications; this would have implications for the manufacturers of SBAAs as well as for the formulators of the polyurethane foam mixtures and resin mixtures.

From information available for the two substances, it is understood that both are manufactured by ICL Industrial products: FR-522 is based on the substance 2,2-bis(bromomethyl)-1,3-propanediol (CAS 3296-90-0) and also called dinol. FR-513 is based on the substance 3-bromo-2,2-bis(bromomethyl)-1-propanol (CAS 36483-57-5) and also called trinol. In both cases, the compounds consist of above 98% of the specified substance in light of impurities. Public information suggests that ICL is the sole manufacturer of both flame retardants[68]. Though this suggests that in terms of flame retardant manufacturers that only this company may be negatively impacted by a phase out in EEE, it is understood that only a small portion of the total volume produced is used for EEE applications (below 10%), and thus impacts would be restricted. Furthermore, ICL also produces substances (magnesium hydroxide and different phosphorus based flame retardants[69]) that may be suitable as alternatives, possibly offsetting negative impacts.

Depending on the alternatives chosen to replace the SBAAs, formulators of PU foam and of resin mixtures may need to change the formulation of mixtures, including testing and recertifying the performance of new formulations. This would result in one time investment costs and depending on the price of alternatives (more expensive/less expensive) the costs of producing the formulations could change. Additionally an administrative burden is expected in light of the need to update documentation of formulations.

9.3. Impact on EEE producers

It is assumed that EEE producers would require alternative PU foams or resins to have at least comparable performance to the SBAA ones. In this sense, a phase-out of SBAAs would mainly be expected to have an impact on EEE producers in relation to the possible change of the price of PU foams and resins. Additionally an administrative burden is expected in light of the need to update documentation of products.

9.4. Impact on EEE users

If the prices of alternative formulations should change, this may impact the price of products. In cooling products using PU foams, this impact may be more significant as larger amounts of foams are used per product, whereas as the significance for epoxy resins can be expected to be smaller. Nonetheless, the total amounts of SBAA applied in these applications (between 2 to 5% of the resin) are relatively small and likewise the impact on product price is expected to be more or less negligible. As it appears that various alternatives exist and are also used at resent at differing degrees, it is not assumed that problems should occur in terms of supply of certain products.

9.5. Impact on waste management

The various methods for treating relevant EEE waste are not understood to be a result of the use of SBAAs. The shredding and incineration of PU foams is related to the difficulty of dismantling the material from within the components in which it is contained. Though a change in flame retardant may affect exposures and in this sense also the motivation for recycling, it is assumed that for the most part, alternatives would be similar or preferable in relation to the risk of exposure, and thus it is assumed that the waste management practices would not change. Similarly, the main motivation for waste treatment of PCBs is understood to be the recovery of various metals. Here too the change in flame retardant is not expected to change the waste management methods.

9.6. Impact on administration

A change in regulation always results in a certain burden of compliance, in terms of administration of the legal change of the Directive and its transposition to national law of EU countries. If the

68 See http://www.globes.co.il/en/article-icl-management-threaten-57-more-layoffs-1001026226

69 See http://www.tri-iso.com/documents/ICL_Flame_Retardants__Brochure.pdf

transition period provided for the regulation change would not suffice to accompany the phase-out, it is possible that some exemptions may be requested from the substance restrictions and that these would have a further administrative burden. As the availability of alternatives is apparent, it should however be noted the likelihood for exemption requests is low and can also be expected to be short termed. Though manufacturers of products with longer design phases such as medical devices and monitoring and control devices may need more time for a transition, this is expected to be accommodated through a longer transition period, making exemptions for such products also less likely.

In the case of a restriction of a chemical substance, further administrative costs can be expected to incur in relation to enforcement of the new restrictions and the need to adapt and to operate market surveillance of compliance.

9.7. Total socio-economic impact

As explained at the onset of this chapter, the small amounts of SBAAs potentially present in EEE products raises doubt as to the effectiveness of a possible restriction and thus as to the incurrence of actual impacts. Should a restriction be introduced with a particularly strict threshold, some costs could be expected, however most of these are expected to be relatively low and often also temporary.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

There is limited information as to the actual use of SBAAs in the manufacture of EEE and its components. The registered amounts of 2,2-bis(bromomethyl)-1,3-propanediol (CAS 3296-90-0) and 3-bromo-2,2-bis(bromomethyl)-1-propanol (CAS 36483-57-5) in the EU suggest that these substances are applied in the manufacture of various articles, with available information showing that the substances are mainly in use in non-EEE applications. Though these substances may also be applied in production that takes place outside the EU, there is no data as to actual amounts in use, though the substances and applications can be expected to be similar.

In areas where the substances could be in use (PU foams used for insulation in cooling devices and epoxy resins used in PCBs and various electronic components with encapsulation), it can be understood that they would be applied as reactive flame retardants and would for the most part not remain in SBAA form in the final product. Though residual amounts may be present, an estimation of exposure suggests that potential emissions in the use phase and in the treatment of waste could be expected to either be very low or negligible.

The low potential for presence in the final articles suggests that a RoHS restriction would not be effective in changing the use patterns of SBAA in possible applications. Should a very low threshold be set to ensure the effectiveness of a restriction, it seems that the potential for emissions in the use phase and the waste phase would not justify this action. Against this background it would not be recommended to pursue a restriction under the RoHS Directive of SBAA.

Though SBAA may have various derivatives that remain in the end product, data is not available to allow identifying these derivatives or their nature in terms of possible impacts on the environment and thus a restriction of such substances cannot be considered on the basis of the available data..

There are hints that SBBA may be applied especially in cooling products using PU foams for thermal insulation as well as in components of mobile devices equipped with internal storage-batteries like mobile phones etc. Against this background market surveillance activities could focus especially on this product group in order to verify the application of SBBA.

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12. Appendix I: List of substances identified in the scope of the „small brominated alkyl alcohols“ group

Table 12-1: Appendix I: List of substances identified in the scope of the „small brominated alkyl alcohols“ group

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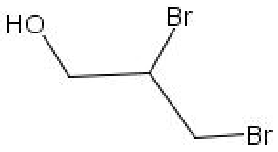
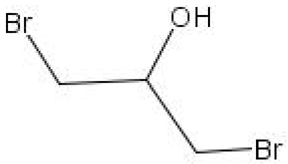
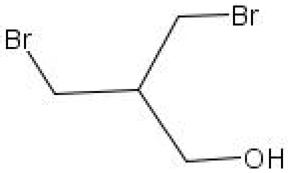
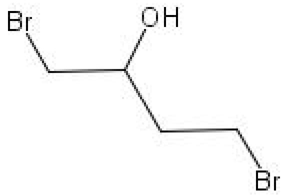
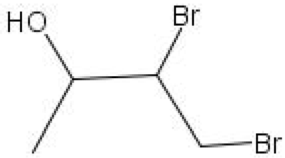
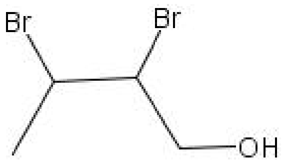
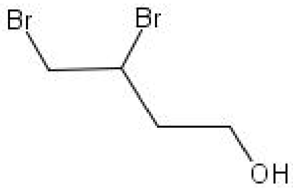
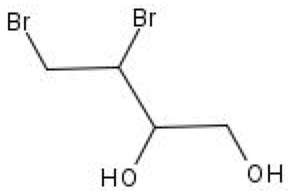
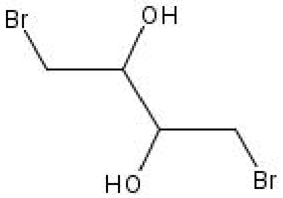
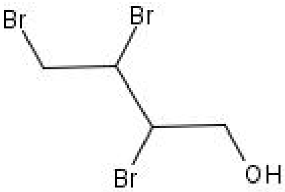
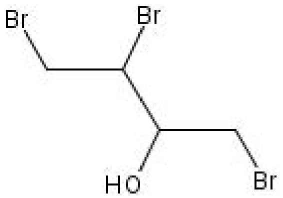
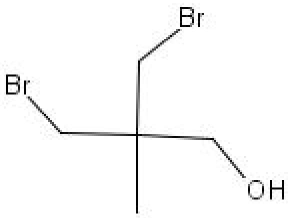
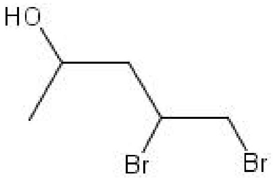
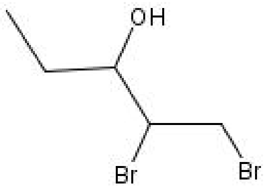
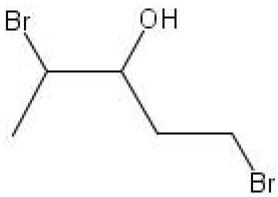
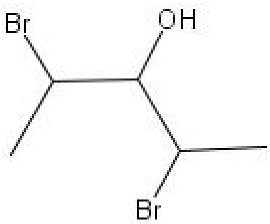
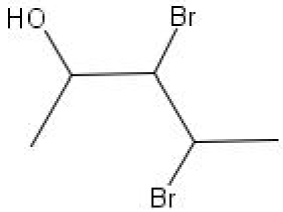
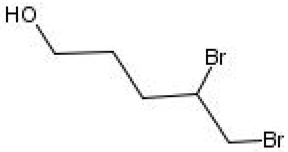
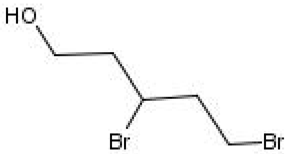
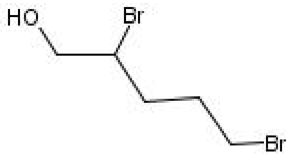
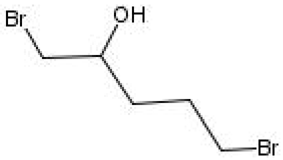
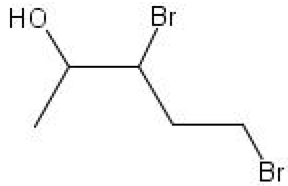
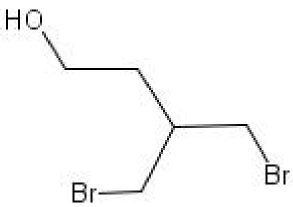
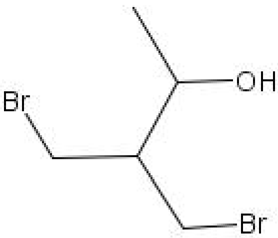
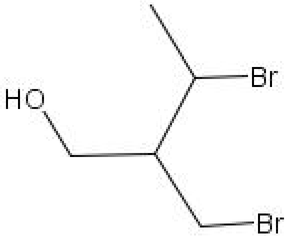
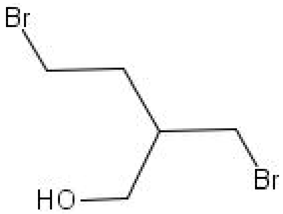
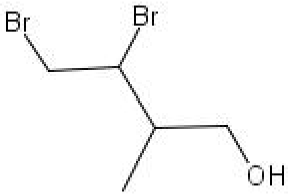
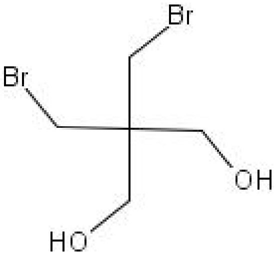
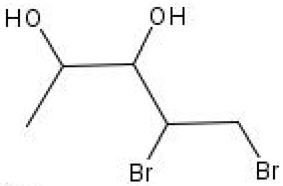
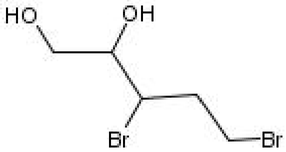
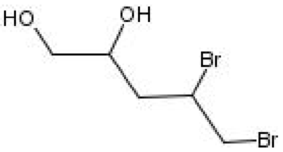
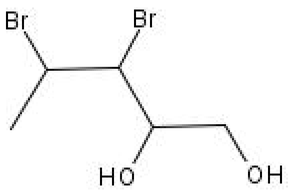
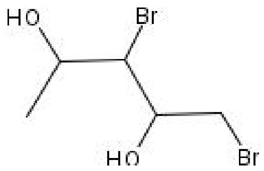
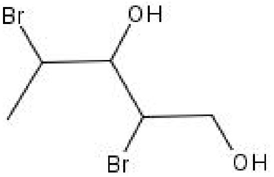
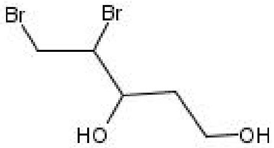
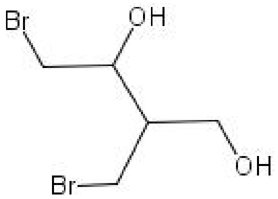
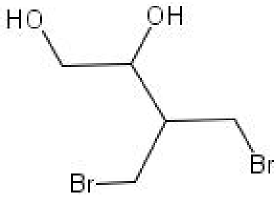
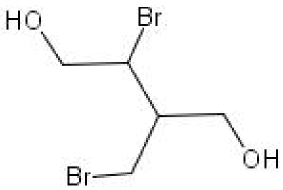
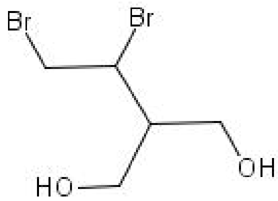
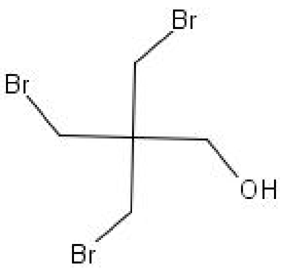
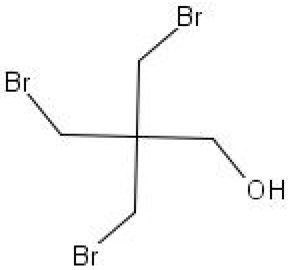
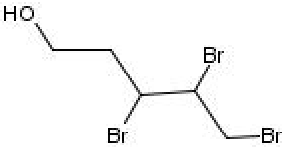
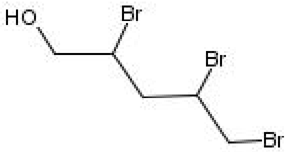
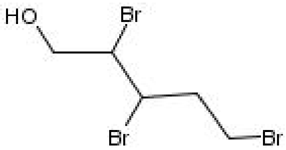
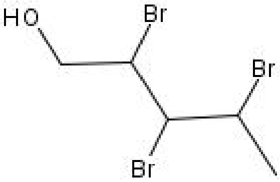
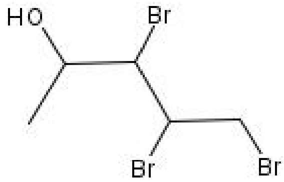
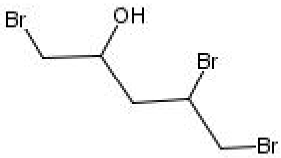
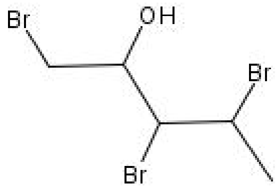
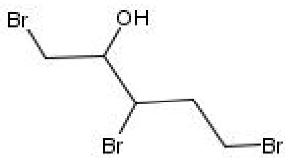
	96-13-9	202-480-9	2,3-dibromopropan-1-ol, 2,3-dibromo-1-propanol
	96-21-9	202-489-8	1,3-dibromopropan-2-ol
	106023-63-6		3-Bromo-2-(bromomethyl)-1-propanol
	19398-47-1	243-029-6	1,4-dibromobutan-2-ol
	79033-40-2		3,4-Dibromo-2-butanol
	4021-75-4		2,3-dibromobutan-1-ol
	87018-30-2		3,4-Dibromo-1-butanol
	35330-59-7		3,4-Dibromo-1,2-butanediol

Structure	CAS number	EC number	Name
	14396-65-7	627-179-3	1,4-Dibromo-2,3-butanediol
	855236-37-2		2,3,4-Tribromo-1-butanol
	87018-38-0		1,2,4-Tribromo-3-butanol
	105100-80-9		2,2-Bis(bromomethyl)-1-propanol
	213821-22-8		4,5-Dibromo-2-pentanol
	408319-76-6		1,2-Dibromo-3-pentanol
	159475-15-7		1,4-dibromo-(R*,R*)-(9CI)-3-pentanol
	343268-04-2		2,4-Dibromo-3-pentanol

Structure	CAS number	EC number	Name
	76377-07-6		3,4-Dibromo-(2R*,3S*,4S*)-(9CI)-2-pentanol
	59287-66-0		4,5-Dibromo-1-pentanol
	No CAS		
	856991-78-1		2,5-Dibromo-1-pentanol
	100606-66-4		2-Pentanol, 1,5-dibromo-
	213821-20-6		2,5-Dibromo-2-pentanol
	No CAS		
	No CAS		

Structure	CAS number	EC number	Name
	No CAS		
	98069-26-2		4-Bromo-2-(bromomethyl)-1-butanol
	No CAS		
	3296-90-0	221-967-7	2,2-bis(bromomethyl)propane-1,3-diol Synonyms: Dibromo-neopentyl-glycol
	No CAS		
	No CAS		
	No CAS		
	No CAS		

Structure	CAS number	EC number	Name
	No CAS		
	No CAS		
	No CAS		
	44804-46-8		4-Bromo-2-(bromomethyl)-1,3-butanediol
	No CAS		
	No CAS		
	No CAS		
	1522-92-5	622-370-8	3-Bromo-2,2-bis(bromomethyl)-1-propanol

Structure	CAS number	EC number	Name
	36483-57-5	253-057-0	2,2-dimethylpropan-1-ol, tribromo derivative Synonym: Tribromoneopentyl alcohol
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		

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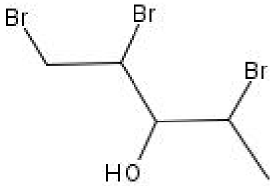
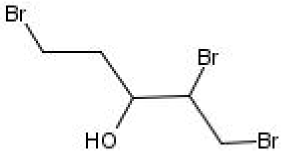
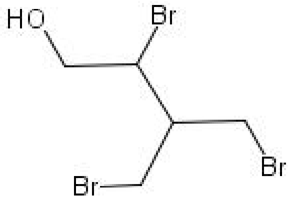
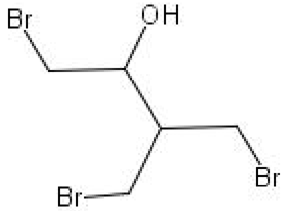
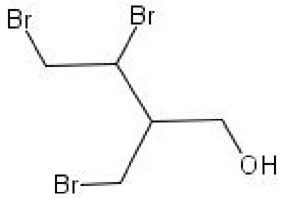
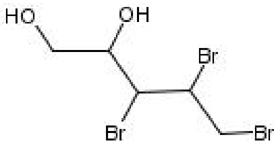
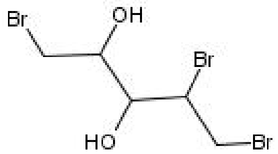
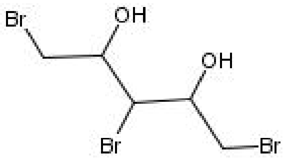
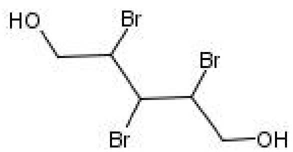
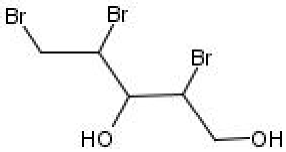
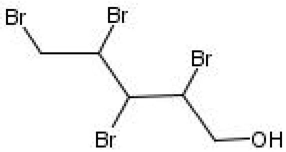
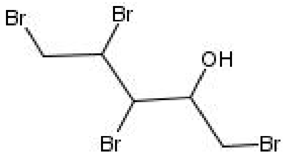
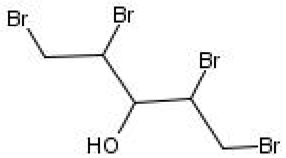
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		
	No CAS		

Structure	CAS number	EC number	Name
	No CAS		
	No CAS		
	No CAS		
	No CAS		

13. Appendix II: Stakeholder contribution to stakeholder consultation

The following contributions (in order of submission date) have been submitted during the consultation:

- Contribution of the Bromine Science Environmental Forum – BSEF, aisbl, submitted on 14.10.2016
- Contribution of the Japan Electronics & Information Technology Industries Association (JEITA), the Communications and Information Network Association of Japan (CIAJ), the Japan Business Machine and Information System Industries Association (JBMIA) and the Japan Electrical Manufacturers' Association (JEMA) submitted on 28.10.2016
- Contribution of the Test and Measurement Coalition (TMC) submitted on 28.10.2016
- Contribution of the Japanese Business Council in EUROPE (JBCE), submitted on 29.10.2016
- Contribution of the Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI - the German Electrical and Electronic Manufacturers' Association), submitted 4.11.2016, pdf

The original contributions are documented on the following pages.

"Stakeholder Consultation on a Possible Restriction of Small Brominated Alkyl Alcohols under the RoHS Directive"

Background

BSEF is the global bromine producers's association. We would like to respond to the "Stakeholder Consultation on a Possible Restriction of Small Brominated Alky Alcohols under the RoHS Directive" which is conducted by the Oeko-Institut e.V. and COWI AS on behalf of the Danish EPA.

Response

The objective of the consultation is to evaluate if the available data support a proposal for restriction of small brominated alkyl alcohol in the RoHS Directive. We are not aware that these substances, as far as they are produced at all, are used in E&E equipment.

In fact, a very similar, but narrower, consultation has been conducted in 2014 by the Oeko-Institute e.V. in the frame of the Review of Restricted Substances under ROHS2[1]. The report concluded that both Dibromo-neopentyl-glycol and 2,3-dibromo-1-propanol (Dibromo-propanol) are either not used in EEE[2] or are not used in the EU at all[3].

BSEF Secretariat, Brussels **14 October 2016**

About BSEF

BSEF is international bromine producers' association. Established since 1997 we have been working to foster knowledge on the uses and benefits of bromine-based solutions for society and economy. We strongly believe in science and innovation. Through investments in research and development BSEF members create robust bromine-based technologies meeting the needs of society.

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[1] http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf

[2] "The information provided by stakeholders during the consultation further suggests that dibromo-neopentyl glycol is either not applied in EEE or applied in small amounts by manufacturers of supplied goods, thus requiring a more comprehensive supplier survey to allow a better quantification."

[3] "As 2,3-dibromo-1-propanol is not registered, it is understood not to be used in the EU or to be applied in low quantities; as further information was not obtained through stakeholders, the use volume cannot be concluded.Though it is used as a flame retardant, its application in the EEE sector is not known to the European Flame Retardant Association, which represents the leading organisations who manufacture, market or use flame retardants in Europe.
On the other hand, the case of 2,3-dibromo-1-propanol suggests that it is not always clear which (brominated) flame retardant is used within the supply chain. The Test & Measurement Coalition states that an in-depth-survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitution would impact safety or other qualifications (e.g. for flame-retarded uses
such as epoxy internal to power supplies)."

Input to 2016 Consultation 2 - DEPA Substance Review: SBAA

Stakeholder consultation held as part of a study to review a possible restriction of the substance group of small brominated alkyl alcohols under Directive 2011/65/EU (RoHS 2)

Name and contact details

1. Contact Information:

Name: _____________Hiroyuki Ishii______________________

Organisation: Japan Electronics & Information Technology Industries Association (JEITA)

E-mail: __________h-ishii@jeita.or.jp______________

Telephone: _______+81-3-5218-1054_____________

This contribution to the questionnaire is submitted by JEITA as Japan 4EE secretariat:

- JEITA (Japan Electronics & Information Technology Industries Association)
- CIAJ (Communications and Information Network Association of Japan)
- JBMIA (Japan Business Machine and Information System Industries Association)
- JEMA (Japan Electrical Manufacturers' Association)

2. Area of activity (more than one is possible):

■ Industry

□ Retail/distribution

□ Rent/repair business

■ Industry/business association

□ RoHS enforcement

□ RoHS analysis

□ Environmental NGO

□ Consumer NGO

□ Institute/consultancy

□ EU Member State Representative

□ International agency / organisation

□ Other (please specify):

Dear RoHS exemption evaluation team,

28, October 2016

(1) Firstly, we would like to provide our fundamental position on restrictions under RoHS Directive as follows:

A) About the use of SBAA in EEE

We have shared the information on current study with our members with the reference to the "Study for the Review of the List of Restricted Substances under RoHS 2" published in August 2014, and asked for their knowledge on SBAA. In addition, we have consulted to Japanese suppliers' industrial associations which might use EEE-related applications of SBAA.

As long as we know through the hearing, SBAA does not seem to be used in finished EEE. We have not heard any cases where an EEE manufacturer uses or requires for its suppliers to use SBAA in its products. In addition, even 2,3-dibromo-1-propanol (Dibromo-propanol), which is probably one of the substances triggering this consultation, is mainly used as an intermediate in the production of flame retardants, insecticides, and pharmaceuticals and has not been registered under REACH yet[1]. On the other hand, the restriction under RoHS doesn't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs in a certain level.

Thus, we recognise that SBAA would not be widely used in EEE in large quantities, and as the result, we don't have any concrete information on application, volume or what are required under detailed questions.

Furthermore, we have doubt about that some SBAAs on "Table 1-3 SBAA with lacking information on substance identity and composition" really exist as stable substances on themselves. Their hazard also seems to be only based on assumption, not to speak of SBAA without identification by CAS numbers. We feel serious doubt whether regulating such substances under RoHS could reduce the environmental load. A RoHS restriction is justified

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[1] Study for the review of the list of restricted substances under RoHS 2 - Analysis of impacts from a possible restriction of several new substances under RoHS 2
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf

2,3-dibromo-1-propanol (Dibromo-propanol) *(Page 16)*
4.6.2 Uses and quantities
Dibromo-propanol is not registered under REACH and was not expected to be registered by the second deadline, June 1st 2013.21. This means that, if it is still used, it is used in the EU in quantities lower than 100 tonnes. The European chemical Substances Information System (ESIS) database does not contain any reporting concerning dibromo-propanol submitted by EU Industry.
The major use of 2,3-dibromo-1-propanol is as an intermediate in the production of flame retardants, insecticides, and pharmaceuticals, and it has been used as a flame retardant. 2,3-Dibromo-1-propanol was used in the production of tris(2,3-dibromopropyl) phosphate, a flame retardant used in children's clothing and other products.

only when a substance is proven to be hazardous. For a substance group, it should be necessary to show that all of the family is hazardous. In this case, at least some of them are hardly present in finished EEE and therefore, their hazards (if any) will not occur by EEE.

Please note that restriction will incur costs on the world industry in spite of its doubtful environmental benefit, even if such substances are rarely present in EEE and the EE industry don't have to "substitute" them. This issue should be assessed from the socioeconomic point of view according to Article 6(2)(g) of RoHS Directive.

B) Description of identifiers (such as EC number or CAS number) to identify chemical substance

The description of "small brominated alkyl alcohols (SBAA)" seems to be very vague, especially in situation where there is no common understanding on coverage of "small". (Does it mean $C_{3\text{-}5}$?) At least, it is not a widely-recognised word, and the identification of substances should be clearly described in order to identify restricted substances precisely.

Some substances have many different chemical names. We afraid that only description of a chemical name may often cause unnecessary confusion in the identification. And it would make quite difficult to get hold of a substance in a final product without precise identification by CAS number etc. Downstream manufacturers would be hardly able even to gather information on the substance through supply-chain without identifiers.

The proposal under this consultation requires restriction of a certain group of substances as a whole, therefore it might be considered that providing exhaustive list of identifiers for each substance would be impossible. However, current proposal includes many substances which are uncertain whether they are used as stable industrial chemicals or not, even in those listed under a certain identifier. (We will separetely describe our concerns about grouping below.) We believe that the consideration on possible restriction under RoHS should be done for identified substances which are widely used in EEE, only if the significant risk is reduced and if its possible benefit to the society outweighs the cost by the restriction of these substances in EEE, according to Article 6(2) and Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive.

Clarification of the restricted substances would be indispensable both for authorities and for the industry to comply with EU RoHS Directive which requires management based on „homogeneous material", appropriately. Regulation on substances without identifiers or precise identification may require an additional and enormous workload for them. Hence Japanese EEE industry considers that any substances under discussion should be always identified clearly, whether it is discussed under RoHS.

C) About the grouping of „similar substances“

We believe that the grouping of substances must be done according to internationally-agreed scientific approaches provided by OECD Guidance. However, we cannot know about the criteria or justification of the current-proposed grouping, because background information provided for this consultation does not seem to provide efficient information on the grouping.

The Commission was reviewed the definition of a group of similar substances under RoHS 2 Substance Restrictions WG. Though the final guidance has not yet been published, the draft versions of the guidance (Nov., 2014) was basically in line with the OECD Guidance. OECD Guidance has been also incorporated in "Guidance on information requirements and chemical safety assessment" of ECHA and used in REACH.

To keep the legislative consultation scientific and transparent, the basic information on justification of grouping should be provided first, because it would be one of the ground of the consultation. Arbitrary grouping may cause confusion in the whole industry of the world, make the scientific grounds of the law vague, and as a result, even prevent the effective risk reduction.

D) Concerns on the way of reviewing possible restriction under RoHS

The RoHS Directive 2011/65/EU currently does not set procedures for reviewing substances proposed as candidates for restriction under RoHS from Member States, and as a result, the way is not standardised, and consultation was done via separated consultation like MCCP from Sweden and is done via RoHS consultation pack at this time. We know that this issue is not only about this consultation but the issue which the Commision has to consider, but we afraid that such situation might reduce transparancy and predictability.

In addition, only within 60 days period for contribution, all we can do is to reply to the consultation solely based on the materials at our hand and our knowledge.
We industry would like to request to set at least 180 days (same as the period set for the consultation of draft dossiers by RAC/SEAC under REACH) as the period for comments on possible new proposal of restriction in the future consultation so that we may give more useful input to the consultation after more-detailed review. We believe full consideration among all the stakeholders would make the RoHS Directive contribute to European sustained development.

(2) Concerning our answer for your question in the consultation, we respond as follows (in blue font) :

Questions and Answers:

3. Applications in which small brominated alkyl alcohols are in use:

The following uses have been found in the literature for a number of substances from the "small linear and branched brominated alkyl alcohol" group:

- ***Materials**: Used in epoxy, polymers, polyester resins, polyvinyl, phenolic resins, styrene- butadiene rubber (SBR), and latexes, polyester, as additive in polystyrene foams (EPS), in the production of rigid polyurethane (PUR /PU) foam, in the preparation of flame retardants for plastics and synthetic fibers;*

- ***Applications**: Used in insecticides, and pharmaceuticals, in cellulosic acetate fabrics and acrylic fabrics, in paper coatings, paints, clothing, insulation, furniture, automobile interior parts & water floatation devices, packaging, draperies, institutional bedding, toys, doll clothing, wigs, mobile phones, unsaturated polyester sheets in roofing. Possible use in resins (epoxy, phenolic) used for encapsulation in capacitors, power supplies, etc.*

a) *Please provide information concerning products and applications in which small brominated alkyl alcohols are in use, or used in conjunction with other substances for example in the manufacture plastics or of resins.*

Our answer: Listed substances or similar substances as such would be rather limited in finished EEE, based on our knowledge as manufacturers. EEE manufacturers do not instruct suppliers to use these substances. Listed applications do not seem specially to relate to EEE, therefore we wonder why these substances are proposed for restriction under RoHS Directive.

Even if this substance would be used as an intermediate in the production of some materials as the background document says, it would not be contained as such in the EEE. Furthermore, the restriction under RoHS doesn't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs.

The previous report from Oeko, "Study for the Review of the List of Restricted Substances under RoHS 2 Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2 (Revised Final Version)[2] says that dibromo-neopentyl glycol is

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2 http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/20140806_Substance_Review_revised_version_final_plus_Dossier.pdf

Dibromo-neopentyl glycol *(Page 15)*
4.5.4 Summary

either not applied in EEE or applied in small amounts by manufacturers of supplied goods and that the application of the 2,3-dibromo-1-propanol is in the EEE sector is not known. We consider that the situation would not be changed since then.

Therefore, our answers to each small question are as follows:

	Small questions	Our answer
I.	*Which substance is used (see Annex I)?*	None.
II.	*Is the substance used as intermediate (reactive) or as additive in the named application?*	We don't know.
III.	*Quantity/concentration of substance used (weight and % weight in the homogenous material).*	None.
IV.	*Is application relevant to the EEE sector or not?*	As long as we know, no.
V.	*Does manufacture take place in the EU or elsewhere?*	We don't know. Final EEE manufacturers don't use them.

b) *From the available information reviewed so far, it seems that the use of small brominated alkyl alcohols in EEE is more common as a constituent of various resins, for example of epoxy resins, phenolic resins, etc. This is also supported by the physical-chemical properties of most of the substances in the group and their tendency to vaporize.*

I. *Do you support this view?*

Our answer : As long as we know, no.

II. *Please provide information to support your view.*

Our answer : Based on our knowledge as manufacturers

c) *In a few cases, substances of the group have a larger molecular structure as well as higher melting and boiling point. Information supports that such substances may be in use in the production of*

Although publically available information on dibromo-neopentyl glycol is very scarce, it is understood that low volumes are in use in the EU for the manufacture of plastic articles. Though this could include plastic articles used in EEE, the information provided by stakeholders suggests that this is not the case. It is understood that the low volume of this chemical used in the EU (100 to 1000 tonnes per year) is mainly applied (above 90%) in unsaturated polyester (UPE) used for UPE sheets in roofing.
The information provided by stakeholders during the consultation further suggests that dibromo-neopentyl glycol is either not applied in EEE or applied in small amounts by manufacturers of supplied goods, thus requiring a more comprehensive supplier survey to allow a better quantification.

2,3-dibromo-1-propanol (Dibromo-propanol) *(Page 17)*
4.6.4 Summary
As 2,3-dibromo-1-propanol is not registered, it is understood not to be used in the EU or to be applied in low quantities; as further information was not obtained through stakeholders, the use volume cannot be concluded.
Though it is used as a flame retardant, its application in the EEE sector is not known to the European Flame Retardant Association, which represents the leading organisations who manufacture, market or use flame retardants in Europe. On the other hand, the case of 2,3-dibromo-1-propanol suggests that it is not always clear which (brominated) flame retardant is used within the supply chain. The Test & Measurement Coalition states that an in-depth-survey of the supply chain, including SME custom part suppliers, would be required to determine exposure and whether substitution would impact safety or other qualifications (e.g. for flame-retarded uses such as epoxy internal to power supplies).

plastic parts made of polymers such as polyurethane.

I. Do you support this view?

Our answer : We don’t know because we are not resin manufacturers. The restriction under RoHS doesn't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs.

4. Umbrella specifications:

From umbrella specifications, published by the German Electrical and Electronic Manufacturers Association (ZWEI), it can be understood that the following components make use of various types of resins.

Our general answer to the Questionnaire 4:

Listed substances or similar substances as such would not be rather limited in finished EEE, based on our knowledge as manufacturers. EEE manufacturers do not instruct suppliers to use these substances.

Even if this substance would be used as an intermediate in the production of some materials as the background document says, it would not be contained as such in the EEE. Furthermore, the restriction under RoHS doesn't apply to the substances used or produced in production process, such as intermediate etc., if they are not contained in finished EEEs.

5. Alternatives and possible substitutes for small brominated alkyl alcohols:

Please see our general answer to the Questionnaire 4.

6. End-of-Life of EEE containing small brominated alkyl alcohols:

Our general answer to the Questionnaire 6:

Listed substances or similar substances as such would not be used in EEE, based on our knowledge as manufacturers.

If these substances are used as brominated-flame retardants in resin, we would have to provide information on them according to Article 8(2) of WEEE Directive 2012/19/EU, but as long as we know these substances are not used as flame retardants because of their boiling point.

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Test & Measurement Coalition

Contribution to the Stakeholder Consultation on a possible restriction of small brominated alkyl alcohols (SBAA)

28 October 2016

Introduction to T&M Coalition

The Test & Measurement Coalition represents an ad-hoc group of companies active in producing Category 9 industrial type products. The Coalition includes six leading companies in the sector including Agilent Technologies, Anritsu, Fluke Corporation, Keithley Instruments, National Instruments, and Tektronix. We estimate the coalition membership represents roughly 60% of the global production of industrial test and measurement products and other Category 9 industrial equipment including chemical analysers.

Since 2008, the Test & Measurement Coalition has been actively participating in the different studies on possible restrictions of new RoHS substances: Öko-Institut study prior to the RoHS recast (2008), Austrian Environmental Agency[1] study on substance methodology (2012) and the study conducted by Öko-Institut on the possible restriction of several new substances under RoHS 2 (2014). We are pleased to provide our comments and recommendations in the context of the current consultation on the possible restriction of small brominated alkyl alcohols (SBAA).

Summary

As per our previous submission, we would like to stress that:

- RoHS substance restrictions do not yet apply to products in Category 9 industrial. Because of the specificity of the design process and the high reliability requirements, our products have been given a transitional period till mid 2017 for compliance with the current RoHS substances.

1 http://www.umweltbundesamt.at/rohs2

- As SBAA have not been subject to any regulatory requirement so far, information about the presence of SBAA in our products at the homogeneous material level is not yet available. The complexity of our products (EEE containing thousands of spare parts) and our supply chain (thousands of suppliers) makes it impossible to gather this information within the timeline of the current consultation.

- Our products are expected to become RoHS compliant through our ongoing efforts to eliminate uses of the current RoHS substances. Our member companies have been working on product conversion since 2005 to be able to ensure RoHS compliance by 2017.

- If the scope of the RoHS restriction is extended to include SBAA, Category 9 industrial should be granted sufficient transitional periods in order to limit negative impact of withdrawal of products on the economy and innovation.

- The earliest possibility for Category 9 industrial to comply with new substance restrictions is 7 years from the date when the new restrictions are introduced This will be consistent with the approach taken so far for new RoHS restrictions (e.g. the restriction of the phthalates) and will respect the natural design cycles of our products. This will be also in line with the circular economy approach encouraging efficient use of resources and extended product lifetime.

Specificity of Category 9 industrial equipment

Our products include a wide range of sophisticated electronic instruments such as signal generators, logic analyzers, oscilloscopes, spectrum analyzers, digital multimeters, chemical and biological analyzers etc. The instruments are used by laboratories (for research and compliance evaluation), universities (for technical training, education, and research), manufacturers (for product development and manufacturing of their products), and governmental agencies (for conformance verification). They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex systems of all types.

Category 9 industrial EEE products are very different from consumer goods high volume products.

- Test & Measurement products have a long product life up to 30 years and 10 years on average. Frequent redesign is not common for the sector, further emphasizing the need for extended transition periods to achieve compliance with existing resources.
- Test & Measurement products are extremely complex and there are a limited number of highly qualified engineers available to work on redesign. This will divert significant resources from the development of new, innovative products.
- Redesign often presents significant technical challenges that take time to resolve – it can be 1-2 years before a new product can be released and 0.5-1 year for an enhancement. A significant amount of the time is required for environmental and safety testing of new designs.
- 25-30% of the components used in Test & Measurement products are custom designed for our instruments. As many of our members use around 100,000 different parts today this means redesign and testing of several thousand custom parts for each company.
- Where RoHS compliant components are available, they require extensive testing to verify their long-term reliability when used in Test & Measurements products.
- Material substitutes meeting our customers' reliability criteria are limited in some instances. For example a domestic household product with expected life of five years has more material options for anti-corrosion coating than a Test & Measurement product for outdoor use which customers expect to work reliably for ten years or more.
- Historically, material or component substitutions have been validated through a number of tests under extreme conditions. Testing programmes can last one or two years.

- Category 9 industrial products' contribution to the stream of waste electrical and electronic equipment (WEEE) is insignificant – Category 9 products represent only 0.25% by weight of the total WEEE in the waste stream. Category 9 industrial sector products represents an even smaller fraction.

The specific needs of Category 9 industrial taken into account in RoHS 1 and RoHS 2

Exclusion from the scope of RoHS 1

Category 9 was initially excluded from the scope of RoHS 1. At the time of the preparation of RoHS 1, the European Commission concluded that there was a lack of sufficient knowledge of the supply chain and waste flows of this category. In addition, it was noted from the very beginning that it would be difficult for this industry sector to comply with the directive's strict deadlines given the complexity of the products and the critical applications. This caution has been amply justified by the subsequent efforts required to identify and validate acceptable alternative materials suitable for long-lived, high reliability equipment and to transition large numbers of custom parts frequently sourced from SME suppliers – a task still in process of completion for RoHS 2.

Specific conditions foreseen for Category 9 industrial in RoHS 2

The Commission proposal brought Category 9 industrial into scope; but in the decision to do so did not suggest the extension of the substance scope at the time of the RoHS recast. The Commission proposed a long transitional period for Category 9 industrial products, extending to mid-2017. The Commission impact assessment[2] recognised that Category 9 industrial products are "produced in low numbers or have critical applications and hence increased testing and reliability requirements." The Commission estimates that "the cost of RoHS compliance for some complex products could be as high as 7-10% of turnover (new product) or 1-10% (modification of existing product). A large part of this cost is attributable to the long development, testing and approval cycles of the more complex products. This is why a staged introduction for these products is proposed allowing the compliance conversion to take place in the framework of existing resources and product development cycles."

Numerous amendments to the Commission text were proposed by the Parliament and the Council during the RoHS recast. Even so, the date of compliance for Category 9 industrial and the specific exemptions have not been put in to question.
Moreover, the specificity of Category 9 was recognised by the Greens. In her report of December 2009, the rapporteur MEP Jill Evans, Greens, proposed an amendment[3] introducing new substance restrictions. Her amendment explicitly excluded Category 9 while foreseeing transitional periods for the other categories.

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[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2930:FIN:EN:PDF

[3] Jill Evans report, Amendment 31: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-430.424+03+DOC+PDF+V0//EN&language=EN

Long transitional periods granted for Category 9 industrial for the new RoHS restrictions: DEHP, BBP, DBP and DIBP

The longer innovation cycles for monitoring and control instruments have been taken into account by the European Commission while introducing the restriction of the use of DEHP, BBP, DBP and DIBP. To avoid negative economic impact and allow smooth transitioning of Category 9 industrial to RoHS, the Commission decided on longer transitional periods. The restriction will start applying to our category as of 22 July 2021[4].

Information about the presence of SBAA *in our products at the homogeneous material level is not yet available*

Gathering information about the presence of the SBAA in Category 9 products would require at a minimum a complete resurvey of the supply chain and, for SME custom part suppliers, the development of new processes and data management resources that have not been required for the current list of substances.
Due to the nature of the current list of restricted substances, Category 9 industrial companies have been able to assume some of this burden on behalf of suppliers as simple screening methods (e.g. XRF) have been available to cross-check compliance in house, but this would not be the case for the proposed priority substances.

Our products contain thousands of compounds provided by thousands of suppliers. If we are to start conducting a detailed investigation of the supply chains, it will take several years before we will be in a position to establish with a reasonable degree of certainty the presence of the substances in the large number of custom parts utilized.

The lack of sufficient information in the supply chain was sufficient reason to exclude Category 9 from the scope of RoHS 1. We believe it is a serious reason to grant a sufficient transitional period of a minimum of 7 years to Category 9 from the date the new substance restrictions are implemented .

Long term reliability of alternatives should be evaluated for Category 9 Industrial

If SBAA are confirmed to be eligible for RoHS restriction, the availability of alternatives should be evaluated prior to regulatory decision. The research into alternatives for these substances, testing and evaluation of available substitutes and defining of transition programmes has not been done as SBAA are not part of the current RoHS scope while our companies are focusing all efforts on the implementation and verification of substitutes for the existing RoHS substances. In the preparatory phase of the RoHS recast we submitted substantial amount of information to the Commission, including very detailed company specific confidential information about internal substitution programmes, status of research, results and prospects, costs and investments, and human resources dedicated to RoHS conversion activities.

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[4] http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-2067-EN-F1-1.PDF

Our products have long life times of 10 years on average with many remaining in service for up to 30 years. Substitutes need to be tested to meet customers' expectations of long term reliability of products capable of consistently meeting published specifications. These requirements go substantially beyond those of consumer goods applications. Accelerated life testing can only result in a compression factor of 7 – hence 30 year reliability requires at least 4 years of testing. Furthermore unlike consumer goods manufacturers Test and Measurement companies have thousands of products and yet relatively small but expert engineering staffs. This places human limitations on the ability to transition that are not felt by other companies. The design cycle in consumer goods is between 6 months to a year whereas in Test & Measurement it can be as long as 3 to 5 years, or even longer if specific regulatory regimes require additional verification testing.

The Test and Measurement sector has invested millions of Euros in systems and data to support the development of RoHS compliant products with a view to meeting the intended compliance dates. Many products have already been introduced which have been designed to meet the substance restrictions. The investment in these product developments, the material compliance systems and supporting component data is all thrown into question if the new substance restrictions are to be added. 25-30% of parts used in T&M products are of non-generic design – this compares to less than 1% in consumer products – and not infrequently the substitution of one new RoHS compliant part can force additional substitutions and redesigns when a sub-component is not a true 'drop-in' replacement for the non-RoHS version.
In the context of further substance restrictions, the introduction of adequate transitional periods for is therefore essential for Category 9 industrial.

The consequence of premature inclusion of Category 9 industrial in new substance restrictions will cause massive disruptions in the production and use of T&M equipment across Europe. This will be also contrary to the circular economy approach as it will force the obsolescence of products with very mong life time that have just been redesigned.

If it is decided that SBAA are RoHS relevant and restriction is introduced for all RoHS Categories, then Category 9 industrial monitoring and control equipment will require a transitional period of a minimum of 7 years from the date of the implementation of the restriction. This will be in line with the regulatory approach taken so far for our Category:

- When RoHS II was discussed and adopted by the EU institutions in 2010/2011, the 7 year horizon was taken into consideration when deciding on the deadline of 22 July 2017 for transitioning to RoHS compliant products;
- This transitional period assumes the need for exemptions utilizing the standard 7 year validity period for Category 9 industrial EEE;
- It is consistent with the longer design cycles typical for our category;
- The latest restriction decision granted long transitional periods till 22 July 2021 for Category 9 industrial.

We hope this paper provides useful information about the challenges category 9 industrial would face will potential new RoHS restrictions and sufficient justification for the need of adequate transitional periods. We remain at your disposal for further clarifications and information in this respect.

Stakeholder Consultation on a Possible Restriction of Small Brominated Alky Alcohols under the RoHS Directive

Stakeholder Questionnaire

1. Background

Hazardous substances in Electrical and Electronic Equipment (EEE) are regulated by the RoHS Directive 2011/65/EU (RoHS 2). According to article 6(1) it is possible for member states to submit a proposal for adding new substances to the list of restricted substances of the directive. Article 6(1) and 6(2) describe the criteria and requirements for proposals for restrictions respectively.

In 2014 the Danish EPA performed a survey on brominated flame retardants (BFRs). On the basis of its results, the Danish Technical University (DTU Food) investigated possibilities of grouping BFRs. One of the groupings; the small linear and branched brominated alkyl alcohols (hereinafter SBAA), including:

- 2,3-dibromo-1-propanol (2,3-DBPA);
- 2,2-bis(bromomethyl)-1,3-propanediol (DBNPG); and
- 2,2-bis-(bromomethyl)-3-bromo-1-propanol (TBNPA);

was chosen for further investigation and the grouping was extended to include also theoretical compounds. The category, defined as having 3-5 carbons, 2-3 bromine atoms and 1-2 alcohol groups, comprises 61 members. Predictions for carcinogenic and mutagenic/genotoxic properties indicated that the 61 members in the category of small linear and branched brominated alkyl alcohols have a carcinogenic potential with a possible mutagenic/genotoxic mode of action. Experimental data for a small number of the members of the group is available. The experimental data support the (Q)SAR prediction.

The Danish EPA has thus commissioned a project to collect, assess and present scientific data to support a proposal for restriction of small brominated alkyl alcohol in the RoHS Directive, if the data prove to be adequate. Oeko-Institut for Applied Ecology and COWI AS have been requested by DEPA to perform the evaluation.

For this purpose, a stakeholder consultation is being held as a means of collecting further information and data as to the substances of interest and their relevance to the EEEE sector. A background report has been prepared for the consultation, to provide stakeholders with a first basis of relevant data and information on the substances of interest. This information shall be supplemented by further information to be provided from various sources.

The objective of this consultation and the review process is thus to collect and to evaluate information and evidence for the preparation of a substance assessment dossier for the small brominated alkyl alcohol (SBAA) group, based on the dossier template[1] proposed by the Austrian

[1] Please see proposed template under: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Substance_Review/Diisobutylpthalate/RoHS_AnnexII_Dossier_May_2013.docx

Umweltbundesamt GmbH, and based on the applications in which SBAAs are in use in general and in EEE, as well as the range of quantities in which they are applied.

The following questions have been formulated to gather more information in this regard. Input provided shall be used to prepare a substance group assessment dossier for SBAA. If you would like to contribute to the stakeholder consultation, please answer the following questions. In case parts of your contribution are confidential, please clearly mark relevant text excerpts or better yet, provide your contribution in two versions (public/confidential).

2. Questions

1. Contact Information:

Name: Mr. Shinya Sasaki
Organisation: Japan Business Council in Europe (JBCE)
E-mail: sasaki@jbce.org
Telephone: +32 (0) 2 286 5330

2. Area of activity (more than one is possible):

- ☐ Industry
- ☐ Retail/distribution
- ☐ Rent/repair business
- ☒ Industry/business association
- ☐ RoHS enforcement
- ☐ RoHS analysis
- ☐ Environmental NGO
- ☐ Consumer NGO
- ☐ Institute/consultancy
- ☐ EU Member State Representative
- ☐ International agency / organisation
- ☐ Other (please specify): ___________________________

3. Applications in which small brominated alkyl alcohols are in use:

The following uses have been found in the literature for a number of substances from the "small linear and branched brominated alkyl alcohol" group:

- **Materials**: Used in epoxy, polymers, polyester resins, polyvinyl, phenolic resins, styrene-butadiene rubber (SBR), and latexes, polyester, as additive in polystyrene foams (EPS), in the production of rigid polyurethane (PUR /PU) foam, in the preparation of flame retardants for plastics and synthetic fibers;

- **Applications**: Used in insecticides, and pharmaceuticals, in cellulosic acetate fabrics and acrylic fabrics, in paper coatings, paints, clothing, insulation, furniture, automobile interior parts & water floatation devices, packaging, draperies, institutional bedding, toys, doll clothing, wigs, mobile phones, unsaturated polyester sheets in roofing. Possible use in resins (epoxy, phenolic) used for encapsulation in capacitors, power supplies, etc.

a) Please provide information concerning products and applications in which small brominated alkyl alcohols are in use, or used in conjunction with other substances for example in the manufacture plastics or of resins. Possibly provide input in tabular form, referring to the following:

I. Which substance is used (see Annex I)?
II. Is the substance used as intermediate (reactive) or as additive in the named application?
III. Quantity/concentration of substance used (weight and % weight in the homogenous material).
IV. Is application relevant to the EEE sector or not?
V. Does manufacture take place in the EU or elsewhere?

In 2014 JBCE provided input on the Substance Prioritisation consultation, as part of the Substance Review study by Öko-Institut:
http://rohs.exemptions.oeko.info/index.php?id=213

Our response included feedback on the substances **dibromo-neopentyl-glycol** and **2,3-dibromo-1-propanol**. At the time we had no indication that EEE manufacturers instructed the use of these substances.

We feel that these comments are still relevant.

b) From the available information reviewed so far, it seems that the use of small brominated alkyl alcohols in EEE is more common as a constituent of various resins, for example of epoxy resins, phenolic resins, etc. This is also supported by the physical-chemical properties of most of the substances in the group and their tendency to vaporize.

I. Do you support this view?
II. Please provide information to support your view.
Based on the knowledge and information available to us as EEE manufacturers we are not aware of these uses.

c) In a few cases, substances of the group have a larger molecular structure as well as higher melting and boiling point. Information supports that such substances may be in use in the production of plastic parts made of polymers such as polyurethane.

I. Do you support this view?
II. Please provide information to support your view.
We can not make any statements on the above as we are not involved in these production processes. In view of RoHS' objectives and conditions for potential restriction of hazardous substances we would however advise that only consideration should be given to those substances which are contained in the finished EEE and cause particular concern during the waste phase.

4. Umbrella specifications:

From umbrella specifications[2], published by the German Electrical and Electronic Manufacturers Association (ZWEI), it can be understood that the following components make use of various types of resins.

Title	Product class	Product part (IMDS: semi component)	Material (IMDS Material)	Material / Substance
Metallised Film Capacitor for EMI Suppression Class X2	Metallised Polypropylene	Encapsulation	Polymer	PU/Epoxy
			Hydroxide	Al(OH)3
			Polymer	PBT
			Oxide	SB_2O_3
			Flame retardant	Equivalent Br
Metallized Film Capacitor	Film Chip Capacitor ECHU (X)	Active part	Polymer	Thermosetting resin
		Termination	Polymer	Phenolic resin
Metallized Film Capacitor	Film Chip Capacitor ECPU (A) / ECWU (X)	Termination	Polymer	Phenolic resin
NTC	Leaded Disks	Encapsulation	Organic Polymer	Lacquer [1] or
				Epoxy Resin [2]
NTC	Miniature Sensor insulated leads	Leads	Organic Polymer	PTFE / other thermoplastic polymer
		Encapsulation	Organic Polymer	Epoxy Resin
NTC	Miniature Sensor uninsulated leads	Encapsulation	Organic Polymer	Epoxy Resin
Inductive components class A –Ω	S22	Active Part	Metall (wire)	Cu
				PUR etc.
		Plastic	Duroplaste	EP, PA, PUR, PET, PBT, Silicone, etc.
		(Insulation, Encapsulation and Potting)		Fiber-glass, Flame retardant*, Additive*
Varistor	Disk Varistor	Encapsulation	Organic Polymer	SiO_2
				Epoxy Resin
				Brominated epoxy
				Sb_2O_3
				Additives*)
PTC	Switching Applications	Encapsulation	Organic Polymer	PBT GF(30) FR(17)

a) The specifications have been screened in reference to the mention of specific materials in which the use of SBAA is understood to be common. It has been assumed that the specifications

[2] See http://www.zvei.org/Verband/Fachverbaende/ElectronicComponentsandSystems/Seiten/UmbrellaSpecifications.aspx

are comprehensive in relation to the component for which they have been prepared. However please specify:

I. If further use of SBAA is made in these components (for example where manufacture may differ).
II. Additional components where SBAA are in use in EEE. Especially for example in transformer sockets, in sealing, etc.
Based on the knowledge and information available to us as EEE manufacturers we are unable to provide additional information on the proliferation and/or prolongation of the use of SBAA in these and other components.

b) It is understood that small brominated alkyl alcohols can be used as constituents for the manufacture of resins such as those detailed above. Please refer to Annex I of this document (list of small brominated alkyl alcohols included in the group under review) and detail:

I. Small brominated alkyl alcohols in use (or in use in the past) in the manufacture of the components mentioned above as well as the quantities and concentrations in which these substances are applied (data can be provided in tabular form for example as proposed below).
II. If your view is that other constituents are used to manufacture resins for such components, please clarify what constituents are used.
Based on the knowledge and information available to us as EEE manufacturers we are unable to make any statements on the manufacturing of resins.

5. Alternatives and possible substitutes for small brominated alkyl alcohols:

a) Where the substitution of small brominated alkyl alcohols is already underway in the various applications, please elaborate which chemical or technological alternatives may be relevant for this purpose.

b) How is the trend of use expected to change over the coming years.

c) Please provide details for alternatives in relation to toxicity aspects, comparability in relation to various properties, relevant areas of application, etc.

d) Please provide data and information as to the costs of substitution relevant for various applications (costs of alternatives, costs of adaptations to design, etc.). If relevant, please estimate how this may impact the industry sector active in the manufacture of the various applications (manufacturers, suppliers, etc.) as well as other actors (retailers, consumers, etc.).

e) If relevant, please elaborate on areas where substitution is difficult. In this regard please explain what efforts have been made and provide information and test results to support why substitution is not feasible at this time.

f) Please provide information whether substances of the “small linear and branched brominated alkyl alcohol” group may be used as substitutes for other brominated flame retardants, particularly those used in EEE components and products.

Based on the knowledge and information available to us as EEE manufacturers we are unaware of the substitution processes and trends to, on the one hand replace SBAA in applications or on the other hand use SBAA as a substitute for other brominated flame retardants.

6. End-of-Life of EEE containing small brominated alkyl alcohols:

a) Please provide information as to the treatment of waste EEE (WEEE) containing small brominated alkyl alcohols. In this respect please refer to:

b) Practiced treatment methods for WEEE; including collection and treatment practices relevant for specific products and/or components (for example, printed circuit boards);

c) Risk of emissions or releases during treatment;

d) Risks of emissions or releases of small brominated alkyl alcohols from WEEE, when treated improperly (for example open combustion).

Based on the knowledge and information available to us as EEE manufacturers we have no indication that SBAA are used in EEE.

In case these substances would be present as brominated flame retardants in plastic parts of EEE information would need to be provided to allow selective waste treatment according WEEE Directive 2012/19/EU Article 8(2).

In case parts of your contribution are confidential, please clearly mark relevant text excerpts or provide your contribution in two versions (public / confidential).

Finally, please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that Oeko-Institut can contact you in case there are questions concerning your contribution.

Thank you.

[About JBCE]
Created in 1999, **the Japan Business Council in Europe (JBCE)** is a leading European organization representing the interests of almost 70 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, railway, textiles and glass products. Building a new era of cooperation between the European Union (EU) and Japan is the core of our activities. www.jbce.org

Contribution delivered per email and copied to separate document for convenience:

Subject: Stakeholder Consultation on a Possible Restriction of Small Brominated Alky Alcohols under the RoHS Directive

As far as we know, the German Electrical and Electronic Manufacturers‘ Association does not see any concern with a possible restriction of SBAA.

After talking to several member companies and asking them about their concerns, we have understood that substances in the SBAA group are not used in their goods.

Kind regards

Burak Karakaya
Manager Environmental Policy

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German Electrical and Electronic Manufacturers' Association
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