Annex XV report

PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Names:	2,2-bis(bromomethyl)propane1,3-diol (BMP)
	2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA)
	2,3-dibromo-1-propanol (2,3-DBPA)
EC Numbers:	221-967-7 (BMP)
	253-057-0 (TBNPA)
	202-480-9 (2,3-DBPA)
CAS Numbers:	3296-90-0 (BMP)
	36483-57-5/1522-92-5 (TBNPA)
	96-13-9 (2,3-DBPA)

Submitted by: Norway

Date: March 2021

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The substances are proposed to be identified as substances meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to their classification in the hazard class carcinogenicity category 1B[1].

[1] Classification in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008.

Summary of how the substances meet the criteria set out in Article 57 of the REACH Regulation

BMP and 2,3-DBPA have index numbers 603-240-00-X and 602-088-00-1, and are listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class carcinogenicity category 1B (hazard statement H350: “May cause cancer”).

TBNPA has index number 603-RST-VW-Y. The Risk Assessment Committee (RAC) adopted its opinion on CLH on 11.06.2020 and the substance is included in the draft 18th ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: “May cause cancer”).

Therefore, these classifications of the substances in Regulation (EC) No 1272/2008 and in the draft 18th ATP to CLP show that they meet the criteria for classification in the hazard class:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substances: Yes

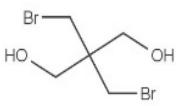
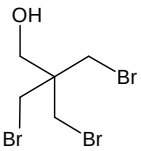
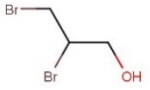
PART I

Justification

1. Identity of the substances and physical and chemical properties

1.1. Name and other identifiers of the substances

Table 1: Substance identity

	BMP	TBNPA	2,3-DBPA
EC number:	221-967-7	253-057-0	202-480-9
EC name:	2,2-bis(bromomethyl)propane-1,3-diol	2,2-dimethylpropan-1-ol, tribromo derivative	2,3-dibromopropan-1-ol
CAS number (in the EC inventory):	3296-90-0	36483-57-5, 1522-92-5	96-13-9
CAS name:	-	-	-
IUPAC name:	2,2-bis(bromomethyl)propane-1,3-diol	2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol	2,3-dibromopropan-1-ol
Index number in Annex VI of the CLP Regulation	603-240-00-X	603-RST-VW-Y	602-088-00-1
Molecular formula:	$C_5H_{10}Br_2O_2$	$C_5H_9Br_3O$	$C_3H_6Br_2O$
Molecular weight range:	261.94 g/mol (from PubChem)	324.838 g/mol (from PubChem)	217.89 g/mol (from PubChem)
Synonyms:	BMP 2,2-BBMPD 2,2-bis(bromomethyl)-1,3-propanediol FR-1138 DBNPG	TBNPA Tribromoneopentyl alcohol FR-513	2,3-DBPA Dibromopropanol 1-propanol, 2,3-dibromo-
Structural formula:			

1.2. Composition of the substances

Names: BMP, TBNPA and 2,3-DBPA

Description: organic

Substance type: mono-constituents

1.3. Identity and composition of degradation products/ metabolites relevant for the SVHC assessment

Not relevant for the identification of the substances as SVHC in accordance with Article 57(a) of the REACH Regulation.

1.4. Identity and composition of structurally related substances (used in a grouping or read-across approach)

During the CLH process the RAC applied the Read-Across Assessment Framework (ECHA, 2017) developed by ECHA for carcinogenicity of TBNPA (EC 253-057-0) based on two possible source substances, BMP and 2,3-DBPA. RAC adopted its CLH opinion on 11.06.2020 (ECHA, 2020) and TBNPA is included in the draft 18th ATP to CLP. BMP (EC 221-967-7) and 2,3-DBPA (EC 202-480-9) are already included in annex VI of CLP with harmonised classification as Carc. 1B.

1.5. Physicochemical properties

Not relevant for the identification of the substances as SVHC in accordance with Article 57(a) of the REACH Regulation.

2. Harmonised classification and labelling

BMP and 2,3-DBPA are covered by Index numbers 603-240-00-X and 602-088-00-1 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	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)		
603-240-00-X	2,2-bis(bromomethyl) propane-1,3-diol	221-967-7	3296-90-0	Carc. 1B Muta. 1B	H350 H340	GHS08 Dgr	H350 H340			
602-088-00-1	2,3-dibromopropan-1-ol, 2,3-dibromo-1-propanol	202-480-9	96-13-9	Acute Tox. 4 * Acute Tox. 3 * Acute Tox. 4 * Carc. 1B Aquatic Chronic 3 Repr. 2	H302 H311 H332 H350 H412 H361f***	GHS08 GHS07 Dgr				

TBNPA has index number 603-RST-VW-Y. The Risk Assessment Committee (RAC) adopted its opinion on CLH on 11.06.2020 and the substance is included in the draft 18th ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: “May cause cancer”).

Table 3: Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008) from the RAC opinion

	Index No	International Chemical Identification	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)		
RAC opinion	603-RST-VW-Y	2,2-dimethylpropan1-ol, tribromo derivative; 3-bromo-2,-bis(bromomethyl)propan-1-ol	253-057-0	36483-57-5; 1522-92-5	Muta. 2 Carc. 1B	H341 H350	GHS08 Dgr	H341 H350			
Resulting Annex VI entry if agreed by COM	603-RST-VW-Y	2,2-dimethylpropan1-ol, tribromo derivative; 3-bromo-2,-bis(bromomethyl)propan-1-ol	253-057-0	36483-57-5; 1522-92-5	Muta. 2 Carc. 1B	H341 H350	GHS08 Dgr	H341 H350			

3. Environmental fate properties

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (a) of the REACH Regulation.

4. Human health hazard assessment

Please see Chapter 2 (Harmonised classification and labelling).

5. Environmental hazard assessment

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (a) of the REACH Regulation.

6. Conclusions on the SVHC Properties

6.1. CMR assessment

BMP and 2,3-DBPA have index numbers 603-240-00-X and 602-088-00-1, and are listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class carcinogenicity category 1B (hazard statement H350: “May cause cancer”).

TBNPA has index number 603-RST-VW-Y. The Risk Assessment Committee (RAC) adopted its opinion on CLH on 11.06.2020 and the substance is included in the draft 18th ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: “May cause cancer”).

Therefore, these classifications of the substances in Regulation (EC) No 1272/2008 and in the draft 18th ATP to CLP show that they meet the criteria for classification in the hazard class:

- carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

6.2. PBT and vPvB assessment

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (a) of the REACH Regulation.

6.3. Assessment under Article 57(f)

Not relevant for the identification of the substances as SVHC in accordance with Article 57 (a) of the REACH Regulation.

Part II

7. Registration and C&L notification status

7.1. Registration status

Table 4: Registration status of the substances (from the ECHA dissemination site)

From the ECHA dissemination site[2]	
	Registrations
BMP	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)
TBNPA	☒ Full registration(s) (Art. 10) ☒ Intermediate registration(s) (Art. 17 and/or 18)
2,3-DBPA	☐ Full registration(s) (Art. 10) ☒ Intermediate registration(s) (Art. 17 and/or 18)

7.2. CLP notification status

Table 5: CLP Notifications[3]

	Number of aggregated notifications	Total number of notifiers
BMP	8	658
TBNPA	6	141
2,3-DBPA	4	44

Links to C&L Inventory:

BMP: Classifications - CL Inventory (europa.eu)
TBNPA: Classifications - CL Inventory (europa.eu)
2,3-DBPA: Classifications - CL Inventory (europa.eu)

[2] *TBNPA, https://echa.europa.eu/registration-dossier/-/registered-dossier/7874, (accessed 23.11.2020)*
https://echa.europa.eu/registration-dossier/-/registered-dossier/6484, (accessed 23.11.2020)
BMP, https://echa.europa.eu/registration-dossier/-/registered-dossier/20506, (accessed 23.11.2020)
2,3-DBPA, https://echa.europa.eu/registration-dossier/-/registered-dossier/24666, (accessed 23.11.2020)
[3] *C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 24.11.2020)*

8. Total tonnage of the substances

Table 6: Tonnage status for the substances

Substance	Total tonnage band for the registered substances (excluding the volume registered under REACH Art 17 or Art 18, i.e. intermediates)[4]
BMP	100 - 1 000 tonnes per annum
TBNPA	100 - 1 000 tonnes per annum
2,3-DBPA	Intermediate use only

9. Information on uses of the substances

9.1. Use of the substances

Reach registration information was accessed through the dissemination site 23.11.2020. According to the REACH registrations, BMP is used at industrial sites as reactive flame retardant intermediate in the manufacture of polymer resins. It is claimed to be used as monomer in polymerisation processes at industrial site (inclusion or not into/onto article).

BMP is used by professional workers in one component foam (OPCF) application with widespread use leading to inclusion into/onto article (indoor).

TBNPA is also used in polymer production manufacture of plastics products, including compounding and conversion. Widespread use of reactive processing aid (no inclusion into or onto article, indoor and outdoor) is registered for TBNPA for consumers. In addition to this, there is a registration of intermediate use of TBNPA.

DBPA is registered as an intermediate in manufacture of fine chemicals and of chemicals including manufacture of bulk, large scale chemicals.

Table 7: Registered uses of the substances

	Uses of BMP	Uses of TBNPA	Uses of 2,3-DBPA	Use possibly in the scope of Authorisation
Formulation		Formulation of TBNPA in mixtures ERC: 2 PROC: 1, 2, 3, 4, 5, 8a, 8b, 9, 15 PC: 32 Formulation of TBNPA in materials ERC: 3 PROC: 1, 2, 3, 4,		Yes

[4] Article 17: Registration of on-site isolated intermediates.
Article 18: Registration of transported isolated intermediates.

		5, 8a, 8b, 9, 15 PC: 32		
Industrial uses	Use as reactive flame retardant intermediate in the manufacture of polymer resins ERC: 6c (Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)) PROC: 1, 3, 4, 8a, 8b, 9, 15 PC: 32, 0, 19, 32 SU: 12	Polymer production with TBNPA ERC: 6c (Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)) PROC: 1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 21 PC: 32 SU: 12 Intermediate use ERC: 6a (Use of intermediate), ERC 7: Use of functional fluid at industrial site PROC: 3, 8b, 9 PC: 19 SU: 8, 9	No title ERC: 6a (Use of intermediate) PROC: 3, 4, 8b, 15 SU: 8, 9	
Professional uses	One component foam (OPCF) application ERC: 8c PROC: 7, 11 PC: 32 SU: 19	Outdoor use of TBNPA ERC: 8e PROC: 3, 4, 5, 8a, 8b, 10, 11, 13, 21 PC: 32 Indoor use of TBNPA ERC: 8b PROC: 3, 4, 5, 7, 8a, 8b, 10, 11, 13, 21 PC: 32 SU: 12		Yes
Consumer uses		Indoor use of TBNPA ERC: 8b, 8e PC: 32 Outdoor use of TBNPA ERC: 8e PC: 32		Yes
Article service life	-	-	-	-

Any use of a substance as on-site isolated intermediate or as a transported isolated intermediate is not subject to authorisation (i.e. REACH Title VII – Authorisation - does not apply) (Article 2(8)(b)). This is also valid for intermediates used as monomers for the synthesis of polymers.

Table 8: Information in the Nordic database SPIN[5] on use (2018)

Substance	Country	Number of preparations	tonnes	Consumer preparations
BMP	SE/FI/NO/DK	0	-	-
TBNPA	SE	3	0.8	Yes
	FI/NO/DK	0	-	-
2,3-DBPA	Not registered	-	-	-

9.2. Structure of the supply chain

Table 9: Joint submissions and companies behind REACH registrations of BMP, TBNPA and 2,3-DBPA (ECHA dissemination site, accessed 23.11.2020)

Substance	Number of registrants	Joint submissions	Number of companies supporting the joint submission	located in country
BMP	2	1	2	NL and DE
TBNPA	2	-	-	NL
2,3-DBPA	1	1	1	FR

BMP, TBNPA and 2,3-DBPA have been registered under REACH by a few companies. Still, the supply chain may be complex as the substances may be incorporated into plastic articles as flame retardants. As described in section 7.2, the number of notifiers is high, especially for BMP (the numbers of notifiers in total are 658, 141 and 44 for BMP, TBNPA and 2,3-DBPA, respectively).

10. Current knowledge on alternatives

Possible alternatives and substitutes for small brominated alkyl alcohols are discussed in the RoHS report from Baron et al. (2017). For epoxy resins, they refer to that industry is searching for alternatives to flame retardants used in the past. This may in some cases lead to a substitution of brominated flame retardants of one type with other old types.

It is also clear that non-halogenated flame retardants are in development, i.e. metal hydroxide-based flame retardants, non-halogenated phosphorus ones and melamine-based ones (Baron et al. 2017).

[5] http://spin2000.net/

Baron et al. (2017) conclude that although the data is limited, alternatives exist and are probably also applied in some cases for encapsulating resins. For SBAAs some of the 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 therefore differ from case to case and as such it is difficult to conclude as to actual impacts resulting from the application of alternatives.

Phosphate ester flame retardants are increasing in use and are possibly an alternative to SBAA. According to PubChem, phosphate ester flame retardants are human-made chemicals added to consumer and industrial products for the purpose of reducing flammability. Phosphate ester flame retardants are composed of a group of chemicals with similar properties but slightly different structures (PubChem[6]).

11. Existing EU legislation

There are regulatory obligations for 2,3-DBPA in legislation covering occupational safety and health, cosmetic products regulation (ban) and in the waste framework directive.

From 1 March 2021, the use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays (halogenated flame retardant means a flame retardant that contains any halogen). The legal basis for the ban can be found in the Commission regulation (EU) 2019/2021 of 1 October 2019 laying down ecodesign requirements for electronic displays pursuant to the Ecodesign Directive (2009/125/EC of the European Parliament and of the Council). The ban is questioned by The International Bromine Council (BSEF) which has filed a legal challenge against the European Commission (Case T-113/20[7]). At the same time, under the Sustainable Products Initiative, the Commission has proposed to widen the scope of the Ecodesign directive beyond energy related products and make it applicable to the broadest possible range of products.

12. Previous assessments by other authorities

The report on the "Evaluation of small brominated alkyl alcohols for a possible RoHS restriction" (Baron et al., 2017) was commissioned by the Danish EPA as an activity under the RoHS directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2). This was done because it is possible for member states to submit a proposal for adding new substances to the list of restricted substances of the directive. The Baron et al. (2017) report concluded that a RoHS restriction would not be effective in changing the use patterns of SBAA in possible applications, and no further action was taken.

[6] https://pubchem.ncbi.nlm.nih.gov/compound/Tris_1-chloro-2-propyl_-phosphate
[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TN0113

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References for Part I

ECHA (2017) Read-Across Assessment Framework Reference: ECHA-17-R-01-EN Cat. number: ED-02-17-140-EN-N ISBN: 978-92-9495-758-0 DoI: 10.2823/619212 raaf_en.pdf (europa.eu)

ECHA (2018) Committee for Risk Assessment, RAC Opinion proposing harmonised classification and labelling at EU level of 2,2-bis(bromomethyl)propane-1,3-diol, EC Number: 221-967-7, CAS Number: 3296-90-0, CLH-O-0000001412-86-212/F. Adopted 8 June 2018 [04.01-ML-014.02] (europa.eu)

ECHA (2020) Committee for Risk Assessment, RAC Opinion proposing harmonised classification and labelling at EU level of 2,2-dimethylpropan-1-ol, tribromo derivative; 3-bromo-2,2-bis(bromomethyl)propan-1-ol, EC Number: 253-057-0, CAS Number: 36483-57-5; 1522-92-5. CLH-O-0000006818-61-01/F. Adopted 11 June 2020 [04.01-ML-014.03] (europa.eu)

Norwegian Environment Agency (2018) Risk Management Option Analysis Conclusion Document Substance Name: 2,2-bis(bromomethyl)propane-1,3-diol (BMP) and structurally similar substances, small brominated alkylated alcohols (SBAA). EC Number: 221-967-7, CAS Number: 3296-90-0. Authority: Norwegian Environment Agency Date: 9 May 2018 a0e45431-4b45-59de-3f2c-a309ad0187a8 (europa.eu)

References for Part II

Baron, Y.; Gensch, C.-O., Moch, K.; in cooperation with Kjølholt, J.; Hagen Mikkelsen, S (2017) "Evaluation of small brominated alkyl alcohols for a possible RoHS restriction" 2017-01-16-evaluation-sbaa.pdf (mst.dk)