

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, 253-057-0, 202-480-9

CAS Numbers: 3296-90-0, 36483-57-5, 1522-92-5, 96-13-9

MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF

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)

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF THEIR CARCINOGENIC (ARTICLE 57A) PROPERTIES

Adopted on 3 June 2021

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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)

The substances are 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

Justification

1. Identity of the substances and physical and chemical properties

1.1. Name and other identifiers of the substances

Table 1: Substance identity

	ВМР	ТВИРА	2,3-DBPA	
EC number:	221-967-7	253-057-0	202-480-9	
EC name:	2,2- bis(bromomethyl)pro pane-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)pro pane-1,3-diol	2,2-dimethylpropan- 1-ol, tribromo derivative; 3-bromo- 2,2- bis(bromomethyl)pro pan-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:	$C_5H_{10}Br_2O_2$	C₅H ₉ Br ₃ O	C ₃ H ₆ Br ₂ O	
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:	Br OH	OH Br	Br OH	

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	CAS No	Classification			Spec.	Notes		
		No		Hazard Class and Category Code(s)		Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	Conc. Limits, M- factors	
603- 240- 00-X	2,2- bis(bromometh yl) propane- 1,3-diol	221- 967- 7	329 6- 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	EC No	CAS No	Classification		Labelling			Spec. Conc.	s
		Identification			Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram , Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	Limit s, M- facto rs	
RAC opinion	603- RST- VW-Y	2,2- dimethylpropa n1-ol, tribromo derivative; 3- bromo-2,- bis(bromometh yl)propan-1-ol	253- 057- 0	36483 -57-5; 1522- 92-5	Muta. 2 Carc. 1B	H341 H350	GHS08 Dgr	H341 H350			
Resultin g Annex VI entry if agreed by COM	603- RST- VW-Y	2,2- dimethylpropa n1-ol, tribromo derivative; 3- bromo-2,- bis(bromometh yl)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 18^{th} 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.

References

- 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)