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

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A CLH dossier for classification under CLP[2] of BMP as Carcinogenic cat. 1B and Mutagenic cat. 1B has been prepared by Norway and has been on public consultation. Start of the consultation was 23 May 2017, so the RAC opinion should be available by November 2018 at the latest.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	X
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

BMP is a member of the category small brominated alkyl alcohols (SBAA). Another substance in this category without CLH is CAS 36483-57-5, which contains three substructures. The final member of the SBAA category is CAS no. 96-13-9 which is already classified as Carc 1B.

If BMP is classified as proposed, we suggest to classify the substance with CAS-no. 36483-57-5 applying read across from BMP based on structural similarity. This would result in inclusion in CLP Annex VI of all the members of the category SBAA.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

All the members of the category SBAA should be included in the Candidate List based on their mutagenic and/or carcinogenic properties fulfilling the SVHC criteria (REACH Article 57a,b) when classified as described above.

BMP fulfils the toxicity criterion (T) if it meets the criteria for classification as

[2] Regulation (EC) No 1272/2008

carcinogenic (cat 1A or 1B) or germ cell mutagenic (cat 1A or 1B) as specified in REACH, Annex XIII. The available data suggests that the substance does not meet the REACH Annex XIII criteria for B and vB, but possibly for P and vP. Wide dispersive use has not been identified in the current registration and the volumes are moderate (100-1000 t). Inclusion in Annex XIV as a risk management option is not seen as realistic unless more information on use, exposure, release and emission is available.

In the CoRAP justification document for the similar substance TBNPA, wide dispersive use is described by DK. This could lead to inclusion of this substance in REACH Annex XIV if it is identified as a SVHC as a member of the category SBAA as proposed above.

The final member of the SBAA category (2,3-DBPA) is not registered in REACH and authorisation is not a possible RMO.

3.3 Restriction under REACH

No information has been retrieved on imported articles and article service life. Such information is necessary to assess the need for a possible restriction of BMP under REACH.

A restriction of BMP can only be seen as a realistic option if more information on use, exposure, release and emission from articles is available. There is a vast number of reactive flame retardants available on the market, so we assume that alternatives are available if restriction is chosen.

According to the CORAP Justification document, a restriction proposal could be relevant for TBNPA. Based on the information available as of today, a restriction proposal seems more relevant for TBNPA than for BMP and 2,3-DBPA.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for intention	Actor
Inclusion in CLP Annex VI of all the members of the category SBAA	Q3-4, 2018	Norway
SVHC Annex XV dossier for the members of the SBAA category	To be decided following harmonised classification of the members of the SBAA category	Norway