

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** **N-(butoxymethyl)acrylamide (NBMA)**

**EC Number:** **217-442-7**

**CAS Number: 1852-16-0**

**Authority: Swedish Chemicals Agency**

**Date: 24 August 2021**

**DISCLAIMER**

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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]](#footnote-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.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

### 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.

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

### Need for follow-up regulatory action at EU level

### Harmonised classification and labelling

N-(butoxymethyl)acrylamide, NBMA, is a structurally similar analogue to acrylamide. NBMA has no harmonised classification. We consider that one appropriate regulatory risk management option for NBMA could be harmonised classification as Carc. 1B and Muta. 1B based on an analogue read-across approach from acrylamide.

The registrant already self-classifies the substance as Carc. 1B and Muta. 1B, however, only one third of the notifiers self-classifies NBMA as such. Thus, a large proportion of companies handling NBMA does not classify and label the substance appropriately. For hazards of highest concern such as carcinogenicity and mutagenicity, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This further justifies a potential need for harmonised classifications that will apply to all companies. In addition, the harmonised classifications will have effects on other EU legislations which may further add to the risk reduction of the substance. A proposal for a Skin Sens. 1A harmonised classification based on read across from acrylamide could also be considered.

In the EU, acrylamide has a binding occupational exposure limit value (BOELV). It could be further investigated whether the BOELV entry for acrylamide can be broadened to include other acrylamide analogues that meet the criteria of being mutagenic and carcinogenic.

With harmonised classification, including Muta. 1B and Carc. 1B, the substance may be subject to SVHC identification and inclusion in the Candidate List (and authorisation).

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| --- | --- | --- |
| **Follow-up action** | **Date for follow-up**  | **Actor** |
| Harmonised classification Muta 1B, Carc 1B |  |  |

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> [↑](#footnote-ref-1)