Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis (RMOA)

Conclusion Document

Substance Name: 1*H*-Benzotriazole
EC Number: 202-394-1
CAS Number: 95-14-7

Substance Name: Sodium-1*H*-Benzotriazole
EC Number: 239-269-6
CAS Number: 15217-42-2

Substance Name: Potassium 1*H*-benzotriazolide
EC Number: 256-999-0
CAS Number: 51126-65-9

Authority: DE CA

Date: 26.10.2023

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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 assess whether further regulatory management measures are needed.

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. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

1*H*-Benzotriazole is currently not listed in Annex VI of the CLP regulation. However, ECHA's Risk Assessment Committee (RAC) adopted an opinion on September 15th 2022 to classify 1H-benzotriazole as Aquatic chronic 2. The corresponding inclusion into Annex VI of the CLP regulation is still pending.

2. CONCLUSION OF RMOA

A substance evaluation has been performed by the aMSCA in which it was concluded that the initial concern for ED in the environment could be confirmed. In addition, it was found that the Substance fulfils the criteria for a reproductive toxicant and a persistent, mobile and toxic (PMT), and a very persistent and very mobile (vPvM) substance, as well as the criteria as an endocrine disruptor category 1 for the environment according to CLP. This conclusion is based on the REACH and CLP data as well as other available relevant information.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	x
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

In the course of this RMOA process it was found that both, the direct uses of 1*H*-benzotriazole as such, together with its use in mixtures cause widespread and high emissions into the environment. To a smaller degree also its use for the manufacturing of articles (e.g. t-shirts, tires) and their subsequent service life has to be expected to add to these emissions. As a result of these emissions, 1*H*-benzotriazole can be found at comparatively high concentrations in the aquatic environment.

Besides its direct release into the environment, especially from de-icing activities on airplanes at airports over winter, major pathways for the emissions of 1*H*-benzotriazole into the environment are discharges from WWTPs to receiving waters. In WWTPs the removal efficacy of conventional wastewater treatment is considered to be insufficient.

The uses contributing most to the emissions from municipal and industrial WWTPs, respectively, are the use of 1*H*-benzotriazole in dishwasher products (households) and as anti-corrosives in industrial processes (e.g. cleaning and as conditioning chemicals in cooling water from cooling or refrigerating towers).

Given its persistence, mobility in the aquatic environment, toxicological profile (endocrine disrupting properties) and presence in drinking water resources, the aMSCA concludes that 1*H*-benzotriazole poses a serious hazard to the quality of drinking water resources of both bank filtrate and groundwater origin. This results in the necessity to regulate the substance in order to reduce its emissions into and hence risk for the environment.

3.1 Combining regulatory measures under CLP (CLH Dossier) and REACH (SVHC Identification & Annex XIV)

Considering the substance properties and current knowledge on the uses of 1*H*-

benzotriazole on its own and as a constituent in mixtures, the aMSCA concludes that its emissions into the environment might be best controlled via (1) a harmonised classification as Repr. 1B (H360D) as well as, according to the new hazard criteria, ED ENV (EUH430) PMT (EUH450) and vPvM (EUH451); and (2) a subsequent SVHC identification (on the basis of Art. 57f or depending on the status of the REACH revision process according to separate letters for PMT and ED)) under REACH, followed by (3) an inclusion into Annex XIV.

Using the new and old CLH hazard criteria will allow for the labelling of 1*H*-benzotriazole as a PMT, ED and reprotoxic substance. As a result, producers will be forced to substitute 1*H*-benzotriazole in order not to lose customers. Furthermore, 1*H*-benzotriazole will not be allowed anymore in consumer products in amounts >0.3%. Both will already reduce the emissions of 1*H*-benzotriazole into the environment (esp. from consumer uses, which have to be considered to be a major emission source). Conducting a CLH process will, however, most likely not have sufficient impacts on the use of 1*H*-benzotriazole in industrial applications. Therefore, further measures under the REACH Regulation will be necessary to effectively reduce 1*H*-benzotriazole emissions. Thereby, the importance of 1*H*-benzotriazole for the metalworking industry and the successful green transformation of Europe (use in electric cars and wind turbines) should be taken into account. As no alternative is currently available, it might be adequate to allow for an appropriate transition period for these industries in order for them to find alternatives or submit an application for authorization.

After the substance has been identified as PMT, vPvM, ED and reprotoxic under the CLP regulation, it should be possible to quickly identify the substance also as an SVHC under REACH and subsequently add it to Annex XIV. Considering that 1*H*-benzotriazole is mostly used within mixtures the identification as SVHC will most likely only result in a minor reduction of 1*H*-benzotriazole emissions from industrial and de-icing activities. However, it will allow to include 1*H*-benzotriazole into Annex XIV, which will lead to an effective emission reduction.

4. 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.

Follow-up action	**Date for follow-up**	**Actor**
CLH Dossier (PMT, vPvM, ED ENV, Reprotox)	2024	DE CA
SVHC Dossier	Following CLH	DE CA