Risk Management Option Analysis Conclusion Document

Substance Names:	**Amines, N-C12-14-alkyltrimethylenedi- [1]; Amines, N-C12-18-alkyltrimethylenedi- [2]; Amines, N-C16-18-alkyl (evennumbered) propane-1,3-diamine [3]; N-C 16-18-alkyl-(evennumbered, C18 unsaturated) propane-1,3-diamine [4]; (Z)-N-9-octadecenylpropane-1,3-diamine [5]**
EC Numbers:	**292-562-0 [1], 268-957-9 [2], 696-364-9 [3], 629-719-3 [4], 230-528-9 [5]**
CAS Numbers:	**90640-43-0 [1], 68155-37-3, 91771-18-5 (old) [2], 68603-64-5 (old), 133779-11-0 [3], 61791-55-4 (old), 1219010-04-4 [4], 7173-62-8 [5]**
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Date:	**2019-04-02**

Version 2.1
October 2015

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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

ECHA examined in 2016 a category of five UVCB-diamines for which the combination of a low NOAEL (0.4 mg/kg bw/day) and registered manual uses of the source substance (Amines, N-C12-14-alkyltrimethylenedi-, EC No 292-562-0) caused concern for worker safety. ECHA was of the opinion that a full compliance check would slow down the risk management process and therefore suggested to the Swedish Chemicals Agency (CA of the country of the lead registrant) to assess and initiate appropriate risk management measures.

The present RMOA was conducted to assess the need for risk management measures for these five UVCB-diamines.

The substances are to our knowledge not assessed or under evaluation in any other ongoing or completed processes at EU level.

2. CONCLUSION OF RMOA

The Swedish Chemicals Agency initially identified concerns for C12-14 and the other four members of the category as regards the DNEL-derivation and the exposure assessment for inhalation- and dermal exposure routes. We also identified data gaps according to the standard information requirements in REACH for three of the category members.

Continuous discussions with the registrant regarding issues related to the identified risk during the second half of 2017 resulted in updates of all five registration-dossiers in January 2018. The registrant derived new DNELs for inhalation and dermal exposure and re-calculated the potential exposure to workers, using new operational conditions and revised personal protective equipment. As a result, RCRs for all exposure scenarios are below 1. The registrant also filled the data gaps for reproductive toxicity and skin sensitisation.

DNEL derivation
The lead registrant adjusted the DNELs for the five substances by using the new built-in DNEL derivation tool in IUCLID 6.

Exposure assessment for dermal and inhalation routes
The lead registrant re-assessed worker exposure levels using Tier II exposure models. RCRs were kept below 1 for all scenarios by modifying (reducing) parameters relating to the amount and/or concentration of the substance that is handled in various tasks, as well as the duration of tasks. The registrant has also clarified and adjusted the level of protection of the required PPE (gloves and coveralls) and included a more detailed description on tasks with potential worker exposure.

Data gaps
The lead registrant filled the identified data gaps for reproductive toxicity and skin sensitisation by extending the original category of five diamines to a polyamine category comprising in total twelve substances.

Based on the new information and since the lead registrant was able to demonstrate safe use of the five UVCB-diamines, ECHA decided in November 2018 not to proceed with compliance checks.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
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	X

3. NO ACTION NEEDED AT THIS TIME

The information provided by the lead registrant in the updated registrations for the five UVCB-diamines leads the Swedish Chemicals Agency to conclude that there is currently no concern related to the use of the substances. No further regulatory action is therefore needed at this time, or is foreseen in the near future.

According to the lead registrant, the updated chemical safety assessments for the five UVCB-diamines have been shared with the members of the consortium and the (former) SIEF. The lead registrant has also issued new extended safety data sheets (e-SDS) for downstream users.

Registrants of the UVCB-diamines, other than the lead registrant
There are registrants of one or several of the five UVCB-diamines also in Belgium, France, Germany and Spain. According to ECHA's dissemination site[2], few of these registrations have been updated since the lead registrant made amendments to the CSR in early 2018. The Swedish Chemicals Agency therefore encourages the other registrants of the UVCB-diamines to update their registrations and issue new e-SDS for downstream users, if necessary.

[2] Accessed 20190212