Risk Management Option Analysis Conclusion Document

Substance Name: Fatty acids, C18 unsaturated, reaction product with ammonia-ethanolamine reaction by-products

EC Number: 629-757-0

CAS Number: 1224966-15-7

Authority: NL

Date: December 2014

Version 2.1
October 2015

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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

Not relevant for the present conclusion

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.

Fatty acids, C18 unsaturated, reaction product with ammonia-ethanolamine reaction by-products has been selected for screening because of an indication for carcinogenicity from repeated dose studies and no harmonized or self-classification for carcinogenicity. However, since the substance is an irritant to both skin and eyes and the observed effect (e.g. (mild) hyperplasia) occurred only in the stomach at concentrations of 300 mg/kg bw/day or higher, this effect is most likely caused by irritation.

The reason to nevertheless evaluate this substance further was that one of the constituents (2-(2-aminoethylamino)ethanol (AEEA), CAS 111-41-1), has a harmonized classification for skin sensitization and reprotoxicity (1B).

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

Concern for Fatty acids, C18 unsaturated, reaction product with ammonia-ethanolamine reaction by-products was based on presence of the reproductive toxicant, AEEA (CAS 1111-41-1). Concentrations of AEEA in Fatty acids, C18 unsaturated, reaction product with ammonia-ethanolamine reaction by-products are low (below the threshold for C&L); this was confirmed by the Registrants. There are already protective measures for workers in place that are anticipated to also protect against exposure to AEEA. It was therefore concluded that, in the absence of an apparent hazard or concern thereof, further risk management measures are not necessary.