SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

2-AMINOETHANOL

EC No 205-483-3

CAS No 141-43-5

Evaluating Member State(s): UK

Dated: September 2016

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process, the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. Thus this conclusion document is not reflecting an official position of ECHA. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

2-aminoethanol was originally selected for substance evaluation in order to clarify suspected risks about:

- Human health: suspected sensitiser. The substance is identified in the list of agents causing occupational asthma from the CSST (Commission de la santé et de la sécurité du travail) (updated April 2010). [The CSST is an organisation mandated by the Quebec government to oversee health and safety at work.] The justification document also noted that there was insufficient information regarding the carcinogenicity of 2-aminoethanol.

- Human exposure: wide dispersive use and aggregated tonnage (> 100,000 tpa). 2-Aminoethanol (MEA) is used in personal care products.

During the evaluation of the human exposure the following additional concerns were identified:

1. IOELVs of 2.5 mg/m^3 (8-hour TWA) and 7.6 mg/m^3 (15-minute TWA) STEL have been established for MEA under the 2nd IOELV Directive (2006/15/EC). The worker long-term inhalation DNEL for local and systemic effects calculated by the lead Registrant is higher than the 8-hour TWA IOELV and the lead Registrant has not calculated worker or consumer DNELs for short-term local effects despite the harmonised classification that exists for acute toxicity by the inhalation route.

2. The evaluating MSCA identified worker scenarios where the 8-hour TWA exposure values that have been calculated exceed the 8-hour TWA IOELV. Taking into account the lack of quantitative exposure assessments for short-term peak exposures for workers and consumers, the evaluating MSCA was concerned that the measures that are being recommended in the exposure scenarios may not be sufficient to ensure safe use.

3. The evaluating MSCA also noted the limited information that is provided to help downstream users understand the scope of each exposure scenario and that limited justification has been provided for the parameters that have been used to model exposures, particularly in relation to the consumer exposure assessment.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	
No need for regulatory follow-up action	✓

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	Tick box
Hazard and /or exposure was verified to be not relevant and/or	✓
Hazard and /or exposure was verified to be under appropriate control and/or	
The registrant modified the applied risk management measures.	✓

Human health – hazard

The initial concern for sensitisation was clarified. Based on the available animal and human data, the eMSCA concluded that MEA did not meet the criteria for classification for skin or respiratory sensitisation and no further information was necessary.

The eMSCA notes that no reliable data on carcinogenicity of MEA are available for assessment. However, no effects of concern for systemic carcinogenicity (hyperplasia, pre-neoplastic changes) were observed in the available 28-day inhalation study or two-generation reproductive toxicity study. In addition MEA was clearly negative in the submitted genotoxicity studies. Although hyperplasia and metaplasia were observed in repeat dose inhalation studies, these effects were considered of limited relevance to humans, considering the corrosive / irritant nature of MEA.

No further information on human health is requested under this substance evaluation.

Environment and environmental exposure

The low environmental hazard profile of the substance was confirmed. MEA is rapidly degradable and does not bioaccumulate, although it does exhibit limited ecotoxicity. It is not considered to be vPvB or PBT. Given this profile, a review of the environmental exposure assessment was not undertaken.

Human Health – Exposure

As part of the initial evaluation all of the human exposure information provided by the Registrants in their CSRs (as updated) was assessed by the eMSCA to determine whether the risks to human health were adequately controlled. As it has been concluded that MEA is not a sensitiser the lead health effect identified by the eMSCA is respiratory tract irritation. The eMSCA opted to use the IOELVs established in the 2nd IOELV directive as the long and short-term inhalation DNELs for workers and used these values to derive long- and short-term inhalation DNELs for the general population (consumers). This differed from the approach taken by the Registrants who had calculated a slightly higher DNEL.

For workers the eMSCA does not have any concerns where the operating conditions and risk management measures that are being used maintain exposures below the IOELVs. However, the eMSCA's comparisons between the exposure estimates it has calculated for MEA and the limit values established in the 2nd IOELV directive suggest that the measures described in exposure scenarios for MEA may not be sufficient to maintain exposures at or below these levels in all cases. (Some RCR's ≥1)

For consumers, there is the possibility that exposures during do-it-yourself (DIY) activities (e.g. laying flooring or working with concrete) with products containing MEA could rise above concentrations where local irritation may occur in the respiratory tract, particularly where use occurs in small, poorly ventilated spaces. The eMSCA considers that this has not been sufficiently investigated in the CSR.

Initially the eMSCA had prepared a draft decision requesting that the Registrants update their registrations with information/justifications/new calculations to address the additional concerns listed in section 1. In their comments the Registrants[2] accepted the recommendation to use the IOELV; agreeing to revise the exposure- and risk assessment accordingly and include the other information requested.

Since it was concluded that MEA is not a sensitiser then the remaining health effect of concern is respiratory tract irritation. The available evidence suggests that if effects arise at levels of exposure likely to be encountered in the workplace, these will be mild and unlikely to have lasting health consequences. Additionally it is likely that consumers will only occasionally perform the types of DIY activities identified and no long-term health consequences are expected from transient mild respiratory tract irritation. The eMSCA therefore does not consider that the situation is of sufficient concern to trigger regulatory risk management activity for MEA.

Given these considerations and the expectation that the above-mentioned information, which the Registrant(s) agreed to provide, will be provided in the revised CSRs the eMSCA decided to finish the substance evaluation process without issuing the Final Decision.

However, to ensure that accurate information is available in relation to the uses and the conditions of use that are supported, the Registrants should update their dossiers without undue delay giving particular attention to the "notes to Registrants" in the SEv report and communicate revised risk management measures to downstream users. In summary the Registrants are expected to:

For workers;

- provide clearer descriptions of the types of products and activities that are covered in each exposure scenario;
- confirm that exposures will not exceed the IOELVs when the operating conditions and risk management measures described in each exposure scenario are implemented correctly; and,
- provide the supporting evidence in their CSRs.

For consumers;

- provide clearer justifications for the parameters that have been used to model consumer exposure for each scenario;
- ensure that it is clear from the information provided in CSRs how local effects in the respiratory tract can be avoided during use.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable.

[2] Comments provided by the Lead Registrant on behalf of the Ethanolamines consortium and other members of the SIEF