SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

2,2′,2″-NITRILOTRIETHANOL

EC No 203-049-8

CAS No 102-71-6

Evaluating Member State(s): UK

Dated: September 2015

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2014-15

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

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

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. 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

2,2',2"-Nitrilotriethanol (TEA) was originally selected for substance evaluation in order to clarify suspected human health risks, specifically, it was a suspected CMR (carcinogenicity) and suspected sensitiser (skin and respiratory).

The concern for sensitisation was based on the inclusion of TEA in a list of agents associated with occupational asthma by 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.] Animal studies also indicated a potential of the substance to induce skin sensitisation. The concern for carcinogenicity was founded on an increase in the incidence of liver tumours in female mice in one lifetime study. If these hazard concerns were realised, then a potential concern was also raised for human exposure, based upon wide dispersive use, consumer use and aggregated tonnage. TEA has a large production volume, widespread use in manufacturing with the potential for high exposure in workers, wide dispersive use with high release for the environment and is widely used in consumer products.

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	X

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	X
Hazard and /or exposure was verified to be under appropriate control and/or	
The registrant modified the applied risk management measures.	
other: <Please specify>	

The eMSCA considered all the information in the registration dossiers, supplemented with information provided informally by the Registrants and additional literature reviews conducted by the eMSCA.

The concern for sensitisation was clarified. On the basis of human data, including a highly exposed population (workers using water-based metal-working fluids), and animal data, the eMSCA concluded that TEA has a low potential to induce skin sensitisation and does not meet the criteria for classification. No information on respiratory sensitisation was included in the registration dossier. Two case reports of TEA being associated with occupational asthma were reported in the literature. However, considering the very high tonnages of TEA used in a wide variety of applications and over a long period of time and the absence of other reports, the eMSCA concludes that TEA is not a respiratory sensitiser. The concern was therefore clarified and no further information was requested.

The concern for carcinogenicity was also clarified. The eMSCA noted an increased incidence of hepatocellular adenoma in female B6C3F1 mice in one dermal study; however, this strain of mouse is recognised to have a very high incidence of spontaneous liver tumours. Therefore this finding does not represent a hazard in humans. In the same dermal study, an increased incidence of haemangiosarcomas in the livers of male mice of the mid-dose group was reported, which was outside the historical control range. Taking into account that the increased incidence occurred only in one sex of one species in one study and was not dose-related, the eMSCA concluded that this was most likely a chance finding that was unrelated to treatment. No information to further clarify this concern was requested.

TEA does not have a harmonised classification in Annex VI of CLP, nor did the Registrants or eMSCA conclude that it meets the criteria for classification for any human health end-points. As no hazard was identified during the evaluation, in accordance with REACH Annex I (5.0), an exposure estimation was not necessary.

No additional concerns were identified.

Overall, the eMSCA concluded that further information was not required to clarify any concerns.

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

Follow-up action	Date for intention	Actor
None		