Finnish Safety and Chemicals Agency

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Toluene

EC No 203-625-9

CAS No 108-88-3

Evaluating Member State: Finland

Dated: 12 November 2013

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2012

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

CONTENTS

1. CONCERNS SUBJECT TO EVALUATION

Toluene was originally selected for substance evaluation in order to clarify suspected risks about human health. The evaluation was targeted on:

- identified uses and establishment of exposure scenarios
- dermal adsorption
- establishment of long-term inhalation DNEL for workers
- calculation of risk characterisation ratios (RCRs)

During the evaluation also other concerns were identified. The additional concerns were:

- Ototoxicity, especially in conjunction with noise, and effects on colour vision induced by toluene.

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	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	X
No need for regulatory follow-up action	

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

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

Not applicable.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

3.1.3. Need for restrictions

Not applicable.

3.1.4. Proposal for other Community-wide regulatory risk management measures

The Registrants have used EU indicative occupational exposure limit value (50 ppm) in place of long-term inhalation DNEL value for workers. The basis for the IOEL value is the SCOEL recommendation from 2001. The EU risk assessment conducted under Regulation (EEC) No 793/93 concluded 2-fold lower reference value (~20 ppm) for toluene (EU RAR, 2003). As a conclusion of the substance evaluation, the Finnish CA recommends that the Registrants take into account the reference values from the EU RAR in their chemical safety assessment and ensure that the risk management measures currently in place adequately control worker exposure to toluene. If the Registrants decide to not follow these proposals the Registrants are recommended to add adequate justifications in their registration dossier. These recommendations were communicated to the Registrants during the evaluation. The Finnish CA concluded that it was not necessary to request new information.

The Finnish CA recommends that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) will take into account results from the EU RAR (2003) and make a review on whether there is a need to update the recommendation on IOEL values for toluene.

3.2. NO FOLLOW-UP ACTION NEEDED

At the moment there is no follow up action needed under REACH Article 48.