SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

1,3,5-TRIOXANE

EC No 203-812-5

CAS No 110-88-3

Evaluating Member State(s): Poland

Dated: 27 February 2014

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2013

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

1,3,5-trioxane was originally selected for substance evaluation in order to clarify suspected risks about:

- a CMR properties (Repr 2),
- a sensitizing properties,
- a suspected PBT properties
- wide dispersive use and high aggregated tonnage.

During the evaluation also other concern[s] was/were identified. The additional concern[s] was/were:

- Need for classification as an eye irritant category 2 according to CLP classification criteria

1,3,5-trioxane is manufactured in the EU or outside the EU, and is imported into the UE. The substance is used for production of polyacetals which are strong and rigid resins that replace metals in many engineering applications.

1,3,5-trioxane represents a negligible risk for consumers. FDA has approved polyacetals for food contact use.

1,3,5-trioxane is included in the list of harmonised classification and labelling of hazardous substances of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. It is classified due to its physicochemical properties and human health as flammable solid (Flam. Solid 1, H228), reprotoxic (may damage the unborn child, Repr.2, H361d) and respiratory irritant (STOT Single Exp. 3. H335).

The grounds of concern listed in justification document for the selection of the candidate CoRAP substance do not need additional clarification.

On the base of available information, 1,3,5-trioxane is not sensitizer or PBT substance. Classification regarding reprotoxicity is appropriate.

Relating the irritating effect, the assessment of available information on this endpoint led to the conclusion about the classification of 1,3,5-trioxane as an eye irritant category 2. It is important to mention that the available data is sufficient for the classification purposes and no additional studies are required.

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 (eye irritant category 2 according to CLP criteria)	X
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. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

There are available 5 study results regarding the effect of 1,3,5-trioxane on the rabbit eyes.
The results indicate moderate to severely irritation of conjunctiva and mild chemosis and corneal opacity. The observed changes were reversible within 72h to 10 days.

According to CLP classification criteria for eye irritation cat 2:

"If, when applied to the eye of an animal, a substance produces:
- at least in 2 of 3 tested animals, a positive response of:
– corneal opacity ≥ 1 and/or
calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test material and which fully reverses within an observation period of 21 days."

Three of the presented study results fulfill the above criteria thus the obtained results provide a basis for classification of 1,3,5-trioxane as an eye irritant category 2.

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

3.1.3. Need for restrictions

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

3.2. NO FOLLOW-UP ACTION NEEDED

Not applicable.

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

Indication of a tentative plan is not a formal commitment for the evaluating Member State. A formal commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier shall be made via the Registry of Intentions.

Follow-up action	**Date for intention**	**Actor**
Need for harmonised classification and labelling*	_	Poland

* proposal of extension of the classification due to the irritating effect on the eyes