REPUBLIC OF SLOVENIA
MINISTRY OF HEALTH
CHEMICALS OFFICE OF THE REPUBLIC OF SLOVENIA

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

HDI oligomers, isocyanurate

EC No 931-274-8

Evaluating Member State: Slovenia

Dated: 18 September 2015

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. 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

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.

CONTENTS

1. CONCERN(S) SUBJECT TO EVALUATION

HDI oligomers, isocyanurate was originally selected for substance evaluation based on following initial grounds of concern: Environment/Suspected PBT; Exposure/Wide dispersive use; Aggregated Tonnage.
The evaluation was limited to PBT properties and thus human health was not evaluated.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusion, 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. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

No need for harmonised classification and labelling.

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

No need for identification as a substance of very high concern, SVHC.

3.1.3. Need for restrictions

No need for restrictions.

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

No need for other Community-wide regulatory risk management measures.

3.2. 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:	

Based upon the detailed evaluation of available information (registration dossiers, Chemical Safety Reports, other scientific evidence described in studies and literature), the evaluating Member State, Slovenia, was in the position to clarify the above listed concerns. The available information is sufficient and reliable to conclude on these concerns. It could be established that the above listed concerns are not confirmed and the substance under evaluation is not considered a PBT or vPvB substance.

Consequently, there is no need to take any follow up action concerning the evaluated concerns.

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

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