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METEOROLOĢIJAS CENTRS

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Tetrachloroethylene

EC No 204-825-9

CAS No 127-18-4

Evaluating Member State(s): Latvia

Dated: 3 March 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

Tetrachloroethylene was originally selected for substance evaluation in order to clarify suspected risks about:

- potential PBT with wide and dispersive use

- CMR

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

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. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

No regulatory action needed at EU level based on this evaluation.

3.1.1. Need for harmonised classification and labelling

No revision needed of the current harmonised classification based on this evaluation.

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

No need for identification of tetrachloroethylene as SVHC based on this evaluation.

3.1.3. Need for restrictions

No need for restrictions for tetrachloroethylene based on this evaluation.

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

No need for other Community-wide regulatory risk management measured based on this evaluation.

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

- Taking into consideration PBT criteria detailed in Annex XIII of REACH and by registrant submitted information, tetrachoroethylene meets criteria for persistence (P and vP), but does not meet the criteria for bioaccumulation (B or vB) and toxicity (T).

- According to human health hazards, the eMSCA concludes that in addition to harmonised classification according to Annex VI of Regulation (EC) No 1272/2008, as possible carcinogen [Carc. Category 2, H351 (Carc. Cat. 3, R40)], tetrachloroethylene meets the criteria and should be classified also as skin irritant [Skin Irrit. Category 2, H315 (Xi, R38)] and eye irritant [Eye Irrit. Category 2, H319 (Xi, R36)] as well as skin sensitizer capable of causing an allergic skin reaction [Skin. Sens. 1B, H317 (R43).

  Remark: the submitted data by the registrants do not support classification for any other CMR concerns; the evaluating MSCA does not intend to propose the substance for a revision of the harmonised classification at Community level.

- Oral route is considered as negligible as the bioaccumulation potential of this substance is very low.

- 20 ppm (138 mg/m^3) is regarded as the NOAEL (DNEL, OEL) for human repeated dose toxicity by inhalation route expressed as an 8 hours TWA value (SCOEL) as well as the proposed DNEL for worker long-term systemic exposure via the dermal route is 39.4 mg/kg bw/day (Chemical Safety Report, 2010). According to information obtained in ECETOC TRA v2 modelling for 7 possible uses of the substance as well as for its manufacture , the highest long term Risk Characterization Ratio for combined routes (inhalation + dermal) is estimated to be 0.89 not causing concerns with respect to workers' health.

- The evaluation of exposure of people living in the same building as the dry-cleaner was outside the scope of this evaluation.

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

Not applicable.