Risk Management Option Analysis Conclusion Document

Substance Name(s): 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"TM) [covering any of its individual anti- and syn-isomers or any combination thereof]

EC Number(s): 236-948-9; -; -
CAS Number(s): 13560-89-9; 135821-74-8; 135821-03-3

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Dechlorane Plus meets the criteria of Article 57(e) of Regulation (EC) 1907/2006 (REACH) as it is concluded to fulfil the vPvB criteria of REACH Annex XIII and has been added to the candidate list.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	√
Harmonised classification and labelling	
Identification as SVHC (authorisation)	√
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Dechlorane Plus is imported into the EU as the substance itself with one active REACH Registrant supplying quantities of 10 - 100 tonnes/year. This is the 'only representative' of the major Chinese manufacturer. Based on the registration information, it seems likely that annual EU emissions of Dechlorane Plus to water will be well below 200 kg. A small number of non-EU companies also offer this substance for sale, so there could be a handful of other EU importers of <100 tonnes/year. Registrant numbers will be clarified by June 2018 after the final registration deadline, and their Chemical Safety Assessments will need to demonstrate minimisation of emission to reflect its SVHC status. The substance is also likely to enter the EU in imported articles but no information is available about numbers, types or amounts, so the emissions (and therefore risks) cannot be established with any certainty.

The aim of risk management is to ensure the proportionate reduction of emissions (and therefore risk). Dechlorane Plus fulfils the criteria for identification as vPvB in accordance with REACH Annex XIII and meets the relevancy criteria according to the SVHC Roadmap to 2020. Dechlorane Plus has now been included in the Candidate List, so may be prioritised by ECHA for inclusion in Annex XIV in due course. A restriction for articles could then be considered by the Commission/ECHA following the conclusion of the authorisation application process.

Once the compliance check has concluded and if an additional hazard is identified consistent with POPs designation, the Commission may seek an EU restriction to avoid implementation difficulties in the case of subsequent POPs nomination. Therefore a final decision about addition to Annex XIV should await the completion of this activity.

The eMSCA does not currently favour restriction because the level of risk is uncertain due to the lack of detailed information about all uses, amounts in articles, actual emissions and substitution potential, as well as the generally low concentrations found in the European environment. This would also make it difficult to assess the relative costs and benefits of the restriction. Such an approach might result in multiple derogations and perhaps long transitional periods. On balance, the eMSCA prefers the authorisation route because it places the responsibility on industry to provide the arguments about why they continue to need this substance.