Risk Management Option Analysis Conclusion Document

Substance name: 2-ethylhexyl 10-ethyl-4,4-dimethyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate

EC number: 260-829-0
CAS number: 57583-35-4

By: **The Netherlands**
Date: **December 2015**

Version 2.1
October 2015

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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

DMT(2-EHTG) has a harmonized classification under the CLP Regulation. Its related substance MMT(2-EHTG) is on the CoRAP by the NL-CA for 2015.

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.

DMT(2-EHTG) was selected for a risk management analyses based on its classification as STOT RE1 for neurotoxicity in combination with wide dispersive use as heat-stabilizer in PVC. As neurotoxicity can be of equivalent concern to CMR article 57a - c, the RMOA considered DMT(2-EHTG) as possible SVHC based on REACH article 57(f). The toxicity profile and classification of DMT(2-EHTG) are based on the toxicity of its main metabolite DMTC. However, in the process of conducting the RMOA, new information was provided by the registrants on DMT(2-EHTG) questioning the formation of DMTC as the main metabolite. Instead, new data on the metabolism of DMT(2-EHTG) under gastric conditions suggest the formation of DMTEC. Hence, the read-across to the toxicity of DMTC seems no longer appropriate for DMT(2-EHTG). At present there is no information available on the possible CMR properties or repeated dose toxicity of DMT(2-EHTG) or DMTEC.

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	X
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 Other Union-wide regulatory measures

Because read-across to the toxicity profile of DMTC seems no longer appropriate, a data gap can be identified for various toxicity endpoints of DMT(2-EHTG). The NL-CA concludes that substance evaluation isn't the most appropriate instrument to obtain further insight in the toxicity of DMT(2-EHTG) because of the data requirements already established under REACH.

The NL-CA concludes that it is the responsibility of the Registrant to update the Registration dossier for DMT(2-EHTG) in line with their newly obtained information. **Compliance Check (CCH) could be considered if the Registrant will not update the registration dossier adopting an alternative approach to the read-across from DMTC, i.e. by proposing a new read-across candidate or by submitting a testing proposal to address the current data-gaps.**

The NL-CA stresses that the best RMO for DMT(2-EHTG) should be revisited once new information on its toxicity or the toxicity of (one of) its metabolites becomes available, or if the interpretation of the newly presented gastric data changes as a consequence of

ongoing discussion with regard to other organotin compounds. In addition to these, the RMO for DMT(2-EHTG) may be revisited in the light of further grouping initiatives regarding organotin compounds for the purpose of risk management.