Risk Management Option Analysis Conclusion Document

Substance Name: dioctyltin dilaurate [1]; stannane, dioctyl-, bis(coco acyloxy) derivs. [2]

EC Number: 222-883-3 [1] 293-901-5 [2]

CAS Number: 3648-18-8 [1] 91648-39-4 [2]

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Date: 2020-02-11

Version 2.1
October 2015

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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

Harmonised classification of DOTL and stannane, dioctyl-, bis(coco acyloxy) derivs. as Repr. 1B (H360D) and STOT RE 1 (H372, immune system) is included in the 15th ATP to CLP Annex VI, which awaits adoption by the Commission. DOTL and stannane, dioctyl-, bis(coco acyloxy) derivs. has no previous entry in Annex VI of the CLP Regulation.

The following regulations and directives apply to DOTL and stannane, dioctyl-, bis(coco acyloxy) derivs.:

- The use of dioctyltin compounds is restricted to 0.1% by weight of tin in certain article categories sold to the general public (Regulation (EC) 1907/2006, Annex XVII, entry 20:6, REACH).
- The use of organotin compounds for certain biocidal applications in aquatic environments and for treatment of industrial waters is restricted (Regulation (EC) 1907/2006, Annex XVII, entry 20:1-3, REACH).
- There is no European Occupational Exposure Limit (OEL) for organotin compounds under Directive 2004/37/EC or Directive 98/24/EC. However, several European countries have established occupational exposure limits for organotin compounds similar to an 8 hr Time Weighted Average (TWA) limit of 0.1 mg Sn/m^3 and a 15 min average Short Term Exposure Limit (STEL) of 0.2 mg Sn/m^3 in air[2].
- Dioctyltin compounds are included in part 1 of Annex 1 to Regulation (EU) No 649/2012 concerning Prior Informed Consent (PIC).
- Organotin compounds are included in the indicative list of the main pollutants in Annex VIII, entry 3, of the Water Framework Directive (WFD) (2000/60/EC).
- Organotin compounds are included in the list of polluting substances in water in the Directive of Industrial Emissions (IED) (2010/75/EU, Annex II). Threshold values for industrial releases are defined in Regulation (EC) No 166/2006, Annex II.

[2] OECD, 2006. Organisation for Economic Co-operation and Development. SIDS Initial Assessment Meeting (SIAM) 23, Jeju, South Korea, 17-20 October 2006.

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)	x
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)

DOTL and stannane, dioctyl-, bis(coco acyloxy) derivs. are included in the 15th ATP to CLP Annex VI as toxic to reproduction in category 1B (H360D). Thus, these substances meet the criteria for SVHC, defined in Article 57(c) in REACH.

There is currently no evidence for *prima facie* risk for human health. However, there are concerns regarding uses of DOTL with potential for high exposure to industrial and professional workers. Furthermore, there are uncertainties in the registrants' read-across approach and exposure assessment. Inclusion of DOTL in Annex XIV to REACH would ensure safe use of the substance, as the applicant has to demonstrate that the risk to human health is adequately controlled for all uses equal to or exceeding a concentration limit of 0.3%.

There are indications of increasing use of DOTL, which might result from substitution of more rigidly restricted dibutyltin compounds. Inclusion of DOTL in the Candidate list and subsequent listing in Annex XIV to REACH may therefore prevent regrettable substitution. Furthermore, substances included in the Candidate list are covered by the information requirements set out in article 31 and 33 of REACH, which may provide information about the presence of DOTL in articles that are not included in the current restriction.

TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC	Aug/2020	SE