Risk Management Option Analysis Conclusion Document

Substance Name: Dibutylbis(pentane-2,4-dionato-O,O')tin

EC Number: 245-152-0

CAS Number: 22673-19-4

Authority: Swedish Chemicals Agency (KemI)

Date: 7 January 2020

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

Dibutylbis(pentane-2,4-dionato-O,O')tin, herein referred to as DBTP, is an organotin compound which is included in the following EU legislations;

- Dibutyltin compounds are restricted in mixtures and articles where the concentration is greater than the equivalent of 0.1 % by weight of tin for supply to the general public (Regulation (EC) 1907/2006, Annex XVII, entry 20:5, REACH).

- Dibutyltin compounds are 'Severely restricted' concerning export and import of hazardous chemicals of certain uses (Regulation (EU) 649/2012, Annex I, Part I, PIC).

- ECHA's Risk Assessment Committee (RAC) has adopted an opinion on a proposed harmonised classification of DBTP as Repr. 1B (H360DF) and STOT RE 1 (H372)[2]. DBTP is included in the 14th ATP to Regulation (EC) 1272/2008 (CLP) Annex VI (index number 650-056-00-0) recently adopted by the European Commission.

- Due to the harmonised classification of DBTP as Repr. 1B (H360FD), the substance will soon not be placed on the market or used as a substance, as a constituent of other substances, or in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than the generic concentration limit of 0.3% as specified in Part 3 of Annex VI to the CLP Regulation (REACH Regulation, Annex XVII, entry 30).

- Organotin compounds have been selected amongst those which present a significant risk to or via the aquatic environment and therefore included in an indicative list in the Water Framework Directive (Directive 2000/60/EC, Annex VIII, entry 3) with related provisions (Directive 2008/105/EC, Directive 2006/11/EC, Directive 2010/75/EU, Regulation 166/2006/EC, Regulation 782/2003/EC).

- There is no European Occupational Exposure Limit (OEL) for organotins under Directive 2004/37/EC or Directive 98/24/EC, only national OELs of 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 by Australia, Belgium, United Kingdom, Germany, Finland, France, Korea, Austria, Ireland, Sweden, Spain, Singapore, Philippines, New Zealand, Malaysia, Switzerland, Taiwan, Norway, Italy, Hong Kong, the Netherlands, Denmark and the U.S. (OECD 2006, OSHA 2019, ACGIH 2019).

[2] RAC opinion, adopted 5th of December 2017, CLH-O-0000001412-86-184/F.

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)

The concern for DBTP is due to its properties as toxic to the reproductive system and the immune system. Hence, it has a harmonised classification as Repr. 1B (H360FD) and STOT RE 1 (H372, immune system) based on a read-across (category) approach mainly to dibutyltin dichloride (DBTC, EC/CAS no 211-670-0 / 683-18-1).

DBTP has one registrant and 162 companies have notified the substance in the Classification and Labelling inventory. The substance has wide dispersive use, is manufactured within a medium tonnage band (100-1000 tpa) and is used in a large number of products within different sectors. Consequently, DBTP meets the SVHC Roadmap 2020 relevance criteria for potential SVHC identification. Moreover, DBTP is considered to have similar properties and/or uses as DBTC, which is already included in the Candidate List as toxic for reproduction (Article 57c).

While there is no *prima facie* evidence for an unacceptable risk connected with the current uses of DBTP, there is potential concern related to the exposure of professional workers including pregnant workers. It is therefore considered appropriate to initiate regulatory risk management.

Based on the above and the current EU legislations concerning DBTP, the Swedish Chemicals Agency finds that the most appropriate risk management option is inclusion of DBTP in the REACH Candidate list according to Article 57c, for eventual inclusion in Annex XIV to the REACH Regulation.

4. 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 identification	February 2020	Member State Sweden