RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Substance name: **Dichlorodioctyl stannane**
EC number: **222-583-2**
CAS number: **3542-36-7**

Member State(s): The Netherlands

Dated: 10 June 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Dichlorodioctyl stannane has a harmonized classification as Acute Tox. 3 (H331: toxic if inhaled), Aquatic Chronic 3 (H412: harmful to aquatic life with long lasting effects) and STOT RE 1 (H372: causes damage to organs through prolonged or repeated exposure). The thymus is mentioned as target organ for STOT RE classification.

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.

For each conclusion selected in the table below a justification needs to be provided in section 3 of this document. Reasons outlining why a particular risk management option was not considered appropriate can also be included in the relevant section; otherwise subsections can be left blank/deleted if not relevant.

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]*	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	X

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

4.1 No need for regulatory follow-up at EU level

Due to its harmonized classification as STOT RE 1 (H372: causes damage to organs through prolonged or repeated exposure) with thymus as the target tissue, it is further evaluated whether it is feasible to propose additional risk management options.

Dichlorodioctyl stannane has been registered under REACH (intermediate use only). The substance has been evaluated as potential PBT by the UK (MSCA) and included in the list of existing substances subject to transitional measures. The conclusion of the MSCAs was that no follow-up action at EU level is required for PBT as there is currently sufficient information to conclude that the substance does not fulfill the B criterion.

In the EU no other risk assessment was performed for dichlorodioctyl stannane (next to the PBT evaluation published on the ECHA dissemination website). However, European risk assessment exercises have been undertaken for other organotin compounds for example as described in:

- RPA report (2005) prepared for the European Commission: http://ec.europa.eu/enterprise/sectors/chemicals/files/studies/organotins_3rd_report_16_sept_2005_en.pdf
- SCHER opinion about the RPA report (2005): http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_047.pdf
- OECD evaluation:
  - http://webnet.oecd.org/hpv/UI/handler.axd?id=fca20b85-a605-40ef-9dbb-1c730e63592a (Dioctyltin dichloride and selected thioesters)
- WHO evaluation: http://www.inchem.org/documents/cicads/cicads/cicad73.pdf

a. Measures at the workplace

- Directive 2004/37/EC

When handling dichlorodioctyl stannane, the registration dossier lists that PPE is required (wear safety glasses, gloves, protective working clothing and respiratory filter device). Furthermore, dichlorodioctyl stannane is used in closed systems. Occupational exposure may occur during transfer (PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities and PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)).

- Measured workplace concentrations

No information available.

- Occupational Exposure Limits

Currently, no European Harmonized OEL for dichlorodioctyl stannane (or organic tin compounds) is derived by SCOEL. For organic tin compounds in general some limits are derived by other institutes. The U.S. Occupational Safety and Health Administration (OSHA) established a Permissible Exposure Limit (PEL) of 0.1 mg/m^3 in air (measured as tin). Furthermore, the American Conference of Governmental Industrial Hygienists (ACGIH) recommends two limits, an 8-hr time-weighted-average [TWA] threshold limit value (TLV) of 0.1 mg/m^3 in air (measured as tin) and a 15-minute-average Short Term Exposure Limit [STEL] of 0.2 mg/m^3 in air (measured as tin). Furthermore, the National Institute of Occupational Safety and Health (NIOSH) derived an 'Immediately Dangerous to Life or Health'-value (IDLH) of 25 mg/m^3 (as tin). France, UK, Norway, Austria, Switzerland, Belgium, Spain, Finland and Sweden adopted similar values for 8h (0.1 mg/m^3). These member states also adopted 0.2 mg/m^3 for a short-term exposure level, with the exception of Sweden and Finland (which adopted a short-term exposure level of 0.3 mg/m^3).

In the REACH registration dossier, no DNEL is derived.

b. Working legislation (setting an OEL)

Dichlorodioctyl stannane is produced outside EU. Within the EU, dichlorodioctyl stannane is used as an intermediate, predominantly in closed circuits. From the CSR, worker exposure cannot be excluded. Given the indicated uses, worker exposure is expected to be limited but may at least occur during transfer of the substance from vessels or containers into smaller containers. Establishing a European harmonized OEL (SCOEL recommendation) will support safe handling of this substance throughout Europe.

c. REACH Annex XVII (restriction)

Restriction is not considered as an appropriate risk management option given its registered uses and the absence of information indicating a risk for society. It should be furthermore noted that a general restriction is already applicable for dioctyltin compounds in Annex XVII of REACH (EU 2006, 2007), entry number (20.6).

d. REACH Candidate list (to retrieve additional information on the use in articles)

Including dichlorodioctyl stannane in the SVHC candidate list is not considered as an appropriate risk management option. Several factors play an important role in determining whether or not a substance should be considered as an SVHC. Based on the outcome of the evaluation of Arcadis (2014), it was concluded that:

- more information was needed related to the hazard properties
    - Severity/consequences of toxic mechanisms
    - Irreversibility/reversibility of effects
    - Quantification of delay exposure at low concentration and observation of health effects
    - It is difficult to conclude if a safe level could be derived for human exposure
- the uses currently described in the registration dossier do not raise sufficient concern; also the use as an intermediate would not require authorization. Note that currently only four companies registered the substance (intermediate use only). Additional uses and use descriptors might be added to the joint or individual dossiers. Based on currently available information it is not possible to draw conclusions.
- currently it is not considered useful to prepare an Annex XV dossier for this substance. A factor which plays an important role is whether or not risks have been identified. As the substance has been registered as an intermediate and as no DNEL is available on the ECHA dissemination website, no chemical safety assessment has been performed.

Although dichlorodioctyl stannane fulfills the criteria of being an SVHC as set out in article 57 (f), due to its use as an intermediate in a closed system exposure is limited and there is no wide-dispersive use. Placing the substance on the SVHC-list is therefore not considered appropriate.

e. REACH Annex XIV (authorisation)

Dichlorodioctyl stannane is used as an intermediate in a closed system. Therefore, exposure is expected to be minimal. According to Art. 2.8b of the REACH regulation (EU, 2006; EU, 2007), substances used as intermediate are exempted from authorisation. Authorisation is therefore not an appropriate risk management option.

f. Screening of registration dossiers, CoRAP entry and substance evaluation

Based on currently available information on uses in the registration dossier, a potential human health risk cannot be identified given the limited exposure (as intermediate use). As mentioned, four companies registered the substance (intermediate use only). Future registrations might result in additional uses and use descriptors in the joint or individual dossiers. However, it is currently not considered appropriate to prioritize dichlorodioctyl stannate for substance evaluation.

Conclusions on the set of risk management options

The analysis of possible risk management options in section 5 indicates that deriving an OEL could be considered as a possible risk management option. However, in the absence of a more clear concern for workers, this risk management option is concluded no priority at this moment in time. It is concluded that none of the other risk management options discussed in section 5 are appropriate for dichlorodioctyl stannane:

- Although this RMOA argues that dichlorodioctyl stannane could fulfill the criteria of being an SVHC as set out in article 57 (f), the information in the registration dossier suggests worker exposure is limited and there is no wide-dispersive use. Placing the substance on the Candidate list with the eventual aim of authorization is therefore not considered appropriate.
- Restriction is not considered as an appropriate risk management option in the absence of information suggesting a risk for society.