RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Substance name: **Dimethyltin dichloride**
EC number: **212-039-2**
CAS number: **753-73-1**

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

Not applicable

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 is provided in section 3 of this document. Reasons outlining why a particular risk management option was not considered appropriate are included in the relevant section.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	X, OEL by SCOEL
No need for regulatory follow-up action	

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

3.1 Need for follow-up regulatory action at EU level

Based on the available data and assessments the following concerns are identified that require the consideration of additional risk management options:

- Concerns for acute toxicity to human health, skin corrosion, specific target organ toxicity to the nervous system and immune system, and reproductive toxicity. A NOAEL of 0.6 mg/kg bw/d was determined for DMTC based on neuropathology. DMTC is classified as STOT RE1, H372 and the main target organs identified are the central nervous system and the immune system.
- Concern for occupational exposure to DMTC during use in the production of other substances, in the production of glass coatings and during laboratory use. When the RMOA was initiated there also was a concern for consumer use, but this could not be further substantiated and was deemed unlikely based on the insight on uses provided in a communication with the Lead registrant.

The following possible risk management measures were considered:

a. Measures at the workplace

b. Worker legislation

c. Restriction

d. Harmonised Classification and Labelling

e. Authorisation

f. Substance evaluation

These are discussed in the sections below.

a. Measures at the workplace

Industry has to show in their REACH registration dossier that all potential risks at the workplace are adequately controlled. With improving technology, concentrations of chemicals at the workplace may decrease. DMTC is corrosive, immunotoxic, neurotoxic and suspected reprotoxic. During the handling of corrosive chemicals, the use of protective equipment is required and should be available at all times. Workers should be trained and monitored for the correct use of the protective equipment and should be aware of the hazards of the chemical. There is a threshold for the effects of concern for DMTC, which opens up the possibility for taking measures to limit exposure to below this specific threshold level.

b. Worker legislation (setting an OEL)

There is no specific European OEL available for DMTC. There is, however, some information available for organotin chemicals, including DMTC as one belonging to a group. Occupational exposure limits have been established by a number of authoritative bodies for all organotin compounds, regarded as a chemical group.

- 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).
- The American Conference of Governmental Industrial Hygienists (ACGIH) recommends two limits, an 8-hr time-weighted-average [TWA] limit 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).

Similar values have been accepted on a national level 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, and Denmark (OECD, 2006).

From the registration dossier, the data on occupational exposure do not suggest a direct concern for worker exposure. However, it should be noted that only the Glass coating process was worked out in more detail in the CSR. There is neither detailed information available on the processes involved in the use of DMTC for the production of other substances, nor on the use of DMTC as laboratory agent. Given the present uncertainty regarding the possibility of worker exposure during the use of DMTC for the production of other substances or in the laboratory, and given the fact that limit values have not been established in each individual EU Member State, deriving an OEL at community level under Directive 89/24/EC is suggested an effective and proportionate measure to address the current concern for worker exposure. If SCOEL will derive an occupational exposure limit value it is advisable that they have access to the data in the REACH registration dossier to be able to include all information available.

c. REACH Restriction Annex XVII

There is currently no specific restriction for DMTC. The European Commission Decision 2009/425/EC, of 4 June 2009 restricted the use of dibutyltin, dioctyltin and tri-substituted organotin compounds and in April 2010, this Decision was incorporated into Annex XVII of the REACH Regulation. These restrictions involve their wide commercial applications as plastic stabilizers, catalytic agents, industrial biocides, antifouling paints, glass coating, and pesticides. As of 1 July 2010, products containing tri-substituted

organotin compounds with concentrations greater than 0.1% by weight of tin are no longer allowed on the market. The use of dibutyltin and dioctyltin compounds are restricted since 1 January 2012.

Considering restriction for DMTC, either a full restriction or a targeted restriction could be considered. The current information on uses of DMTC does not indicate a reason for immediate risks for society at large. A total restriction on the manufacture and use of DMTC would prevent all (potential) health risks (including both worker exposure, potential exposure via environmental routes and exposure via imported articles). However, in the absence of indications of an immediate wide spread risk for DMTC, at this moment such a wide restriction is not an appropriate measure for the concern at hand.

A more targeted restriction could be to set a “condition” to the manufacture or the use of DMTC in line with the restrictions for the other organotin compounds, already listed in Annex XVII. However, also for such a more targeted restriction, in the absence of specific information on an apparent risk for workers or consumers and a concern related to specific uses, data are insufficient at this moment in time to motivate such a targeted restriction.

d. Harmonised C&L

The Committee for Risk Assessment (RAC) has adopted the opinion on proposing harmonised classification and labelling at EU level with the Index Number of 050-029-00-8. It is noted that this harmonised C&L is only for human health related endpoints. DMTC is classified as follows:

Classification:
Repr. 2
Acute Tox. 3
Acute Tox. 3
Acute Tox. 2
Skin Corr. 1B
STOT RE 1

Hazard Statement:
H361d: suspected of damaging the unborn child, specific effect, neurological effects
H301: toxic if swallowed
H311: toxic in contact with skin
H330: fatal if inhaled
H314: causes severe skin burns and eye damage
H372: causes damage to organs (nervous system, immune system)
EUH071: corrosive to the respiratory tract

In addition, DMTC has been self-classified by notifiers as Aquatic Chronic 3, H412 (harmful to aquatic life with long lasting effects).

e. Candidate list and Annex XIV entry

Since DMTC has a harmonised classification as STOT-RE 1 (nervous system, immune system) this substance may be proposed for the candidate list with the final aim of Authorization via art. 57(f) by motivating an Equivalent Level of Concern to CMR. The type of effect leading to STOT RE classification of DMTC is neurotoxicity. From human poisoning incident data it can be concluded that the effects related to exposure to methyltin dichloride compounds can be severe. It is probable that neurotoxicity can highly limit the possibility of living a normal life (working and private) with cost implications for society. However, the data are insufficient to be conclusive on the effect of DMTC. The available data are also too limited to conclude on the irreversibility of the

neurotoxic effects in humans (though in animals irreversibility has been shown).
The available data on the effects of DMTC are therefore probably not conclusive enough to meet the 'Equivalent level of Concern' in view of the current Article 57(f) (see also section 2.1). In the absence of an equivalent level of concern, Authorization is not a viable route for DMTC.

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

Some of the organotin chemicals, like Tributyltin (TBT), are known to exhibit endocrine disrupting properties. Endocrine disrupting properties might therefore also be suspected for DMTC. At present, there are indications that DMTC does have neurodevelopmental effects (H361d: suspected of damaging the unborn child, specific effect, neurological effects, ECHA, 2012). There are however no clear indications that DMTC could be an endocrine disruptor and targeted testing would be needed to address these hazard uncertainties. Such information cannot be obtained via the standard test requirements under the DMTC registration. Substance evaluation could be used to obtain more insight in possible endocrine disrupting properties of DMTC. If these additional test results would indicate to endocrine activity, this information could be used to motivate Candidate listing to identify DMTC as an endocrine disruptor. However, at present, it is concluded there is insufficient information available on an endocrine mode of action to motivate targeted testing for ED.

Conclusions on the set of risk management options

Based on the information in the registration dossier and information submitted by the registrant, a wide spread dispersive use as well as consumer exposure to DMTC is concluded unlikely. There may however still be a concern for occupational exposure to DMTC while used as laboratory agent or while used in the production of other substances as these processes lack the appropriate detail in the CSR to conclude on the absence of a concern. Therefore, it is concluded that setting an OEL is appropriate to address this concern. If the SCOEL is to set an OEL, it would be advisable to provide access to the REACH registration dossier such that SCOEL can make use of all data available. Authorisation of DMTC is concluded no option because the data available are judged too weak to meet the equivalent level of concern under art. 57f. Because there is currently no indication of an immediate risk Restriction is also concluded inappropriate.

There still may be a possibility that DMTC has endocrine disruptive effects in analogy with a number of other tin-compounds. At this moment, it is concluded that there is insufficient information on a possible endocrine mode of action to motivate targeted testing for ED under Substance evaluation. Furthermore, in the absence of indications for wide dispersive use, substance evaluation is of low priority for the Netherlands. If further insight in possible endocrine effects of DMTC or organotin-compound as a group will arise, the need to further evaluate these effects for DMTC should be reconsidered.