MINISTERIUM FÜR EIN LEBENSWERTES ÖSTERREICH

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)[1]

EC No -

CAS No -

Member State: Austria

Dated: 29 August 2014

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] The concentration ratio between DOTE and MOTE in the reaction mass can differ depending on the manufacture of the mixture and depending on the technical needs. DOTE is the toxicologically relevant substance of concern. All reaction masses with concentrations of DOTE equal or above 10% are covered by the RMO analysis following the definition of a multi-constituent substance

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

An overview of current relevant legislation for DOTE is given in the Table below. Dioctyltin compounds (including DOTE) are listed in Annex XVII, group 20, No. 6 of REACH[2]. DOTE is also included in Annex XVII group 30. This provision means that DOTE shall not be placed on the market, or used for supply to the general public as substance or in mixtures. Under Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food DOTE is listed in the Union List (Annex I)[3]. The specific migration limit (SML) is 0.006 mg/kg (expressed as Sn), which must not be exceeded in food contact materials.

Legal instrument	EU/national	Status of DOTE
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registration of production and use. Tonnage band: 1,000 - 10,000 t/yr.
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Dioctyltin compounds are listed in Annex XVII in group 20 (organostannic compounds) No 6; they shall not be used after 1 January 2012 in the following articles for supply to, or use by, the general public, where the concentration in the article, or part thereof, is greater that the equivalent of 0.1 % by weight of tin: textile articles intended to come into contact with the skin, gloves, footwear or part of footwear intended to come into contact with the skin, wall and floor coverings, childcare articles, female hygiene products, nappies, two-component room temperature vulcanisation moulding kits (RTV-2 moulding kits)
REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	DOTE is included in Annex XVII, Group 30, resulting that DOTE is not allowed to be placed on the market, or used for supply to the general public as substance or in mixtures.
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	DOTE will be included in Annex VI with a harmonised classification as Repr. 1B, H360D following Regulation (EC) No 944/213 (5th ATP to CLP Regulation).
Food Contact Material - Regulation	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.	DOTE is listed in the Union list. The specific migration limit (SML) is 0.006 mg/kg expressed as tin.

[2] Commission Regulation (EU) No 276/2010of 31 March 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds)

[3] Commission Regulation (EU) No 10/2011of 14 January 2011 on plastic materials and articles intended to come into contact with food.

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 *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	x
Harmonised classification and labelling	
Identification as SVHC (authorisation)	x
Restrictions	
Other EU-wide measures	
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

The reaction mass of DOTE and MOTE (DOTE:MOTE) is used as heat stabiliser in the production of PVC. The concentration ratio between DOTE and MOTE in the reaction mass can differ depending on the manufacture of the mixture and depending on the technical needs. Typical DOTE contents are between 10 and 80%. DOTE has been fully registered in the EU in the tonnage range of 1.000-10.000 t/y. The registrants have made use of the option allowing the registration of individual constituents for multi-constituent substances and have submitted registration dossiers for DOTE and MOTE as individual substances[2]. DOTE is the toxicologically relevant substance of concern.

DOTE has adverse effects on the reproduction. It is classified as Reprotoxic 1B according to Reg. (EC) No 1272/2008. Pursuant to Annex III of Commission Regulation (EU) No 944/2013[4] as of 2 October 2013 (5th ATP) DOTE will be listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008[5] as toxic for reproduction Repr. 1B, H360D (May damage the unborn child).

The concern that triggers further considerations for risk management is the toxicity to reproduction of the reaction mass DOTE:MOTE. According to the registration dossiers there are significant sources of exposure of workers for the substance(s) during manufacture, formulation and processing. Concerning the workplace, mainly dermal and inhalation exposure may occur during industrial and professional uses and for severeal scenarios, risk characterization ratios are close to 1.

[4] Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

3.1.1 Harmonised classification and labelling

Not applicable.

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

In the frame of the SVHC Roadmap 2020 different criteria have been defined for selecting substances that are relevant for identification as SVHC. Table below demonstrates that DOTE:MOTE fulfils these criteria and thus it is in principle desirable to substitute this substance on a long term perspective.

SVHC Roadmap 2020 Criteria	**Yes**	**No**
a) Art 57 criteria fulfilled	✓	
b) Full registrations (Art. 10)	✓	
c) Registration includes uses within scope of authorisation	✓	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	✓	

The reaction mass of DOTE and MOTE is used predominantly as heat stabiliser in the PVC production leading to exposure of workers at industrial settings and of professionals. For several scenarios, such as certain mechanical manipulation of plastic articles, risk characterization ratios are close to 1.

Efforts to develop safer heat stabilisers for PVC production have been made during the last years, triggered for one part by the target of substitution of lead and cadmium based stabilisers. This led to the enhanced use of new groups of stabilisers, especially calcium-organic stabilisers. There seem to exist alternatives also for several applications of DOTE:MOTE. Furthermore, the use of alternative materials to PVC could be considered for certain product categories.

In view of the clear concern for human health and the fact that alternatives are increasingly available, authorisation is regarded as a particularly appropriate risk management measure. Insertion of the substance on the candidate list and subsequently in Annex XIV would build up a pressure for industry to substitute DOTE:MOTE where possible and to demonstrate that risk is adequately controlled until appropriate substitution becomes feasible.

In addition, in view of the wide range and complexity of PVC articles containing DOTE:MOTE candidate listing would enable consumers, downstream users and authorities to gain information on the presence of the substance in articles according to REACH article 33 and article 7.

All reaction masses with concentrations of DOTE equal or above 10% will be covered by the Annex XV SVHC dossier following the definition of a multi-constituent substance.

3.1.3 Restriction

Not applicable.

3.1.4 Other Union-wide regulatory risk management measures

Not applicable.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not applicable.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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

Follow-up action	Date for intention	Actor
Annex XV dossier for identification as SVHC	Submitted on August 4th, 2014	Austria