5 September 2018

Draft background 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)

Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of reaction mass of DOTE and MOTE on the Authorisation List or in the registration dossiers (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

Name:	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)
EC Number:	-
CAS Number:	-

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[2]. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation is available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

2.1. Intrinsic properties

SVHC identification
2-ethylhexyl10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360D ("May damage the unborn child") and was included in the Candidate List for authorisation on 17/12/2014, following ECHA's decision ED/108/2014.

DOTE is together with MOTE the main constituent of the reaction mass of DOTE and MOTE.

The reaction mass of DOTE and MOTE was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) based on DOTE's classification and was included in the Candidate List for authorisation on 17/12/2014, following ECHA's decision ED/108/2014.

Ongoing CLH proposal
In October 2017 Germany submitted a CLH dossier for DOTE, proposing to revise the current harmonised classification in Annex VI of the CLP Regulation related to the reproductive toxicity properties. The public consultation on the CLH proposal ended on 2 February 2018. The substance is scheduled for discussion at ECHA's Risk Assessment Committee (RAC) in November 2018. The final outcome of the ongoing harmonised classification process and its possible impact on the Candidate Listing of the substance will be considered by ECHA when finalising its recommendation for inclusion of the substance in Annex XIV.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table
[2] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

2.2. Volume used in the scope of authorisation

The amount of reaction mass of DOTE and MOTE manufactured and/or imported in the EU is, based on registration data, estimated to be > 1,000 t/y (ECHA, 2018).

Registrants of the reaction mass of DOTE and MOTE have made use of the option allowing the registration of individual constituents for multi-constituent substances[3] and have submitted registration dossiers for DOTE and MOTE as individual substances. Therefore registration dossiers submitted for both individual substances have been considered for the priority assessment. However, only part of the tonnage reported has been considered relevant for the prioritisation of the reaction mass of DOTE and MOTE. The estimation of the volume of the reaction mass of DOTE and MOTE for use in the EU has been derived by deducting from the total tonnage reported under DOTE and MOTE the tonnage clearly related to the mono-constituents substances. Where no information was available, it has been assumed that the tonnage registered may refer to the reaction mass and has therefore been considered relevant.

All uses of the substance appear to be in the scope of authorisation, apart from the use in food packaging (tonnage confidential). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y.

More detailed information on uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of the reaction mass of DOTE and MOTE in the scope of authorisation include uses at industrial sites (production of dry-blend of DOTE; production of dry-blend of MOTE; processing of polymers containing DOTE as a stabiliser through calendering, extrusion, injection and low energy manipulation of plastic articles; processing of polymers containing MOTE as a stabiliser through calendering, extrusion, injection and low energy manipulation of plastic articles) (ECHA, 2018).

Furthermore according to some registrations the substance is used in articles (plastic articles) in volumes > 10 t/y.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

The reaction mass of DOTE and MOTE is considered together with DOTE as a group for the purpose of its prioritisation for inclusion in Annex XIV. DOTE is one of the main constituents of the reaction mass of DOTE and MOTE. The two candidate list substances have commonalities in terms of composition and can be used as stabilisers in similar types of applications (e.g. rigid PVCs) (Annex XV SVHC report, 2014) indicating the potential to substitute each other in (some of) their uses.

3 Section 4.2.2. of ECHA Guidance for identification and naming of substances under REACH and CLP https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Reaction mass of DOTE and MOTE is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c) Score: 1	The amount of Reaction mass of DOTE and MOTE used in the scope of authorisation is estimated in the range of 1,000 - 10,000 t/y Score: 12	Reaction mass of DOTE and MOTE is used at industrial sites Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 7	20	Grouping with DOTE

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, the reaction mass of DOTE and MOTE receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise the reaction mass of DOTE and MOTE for inclusion in Annex XIV.

The final outcome of the ongoing CLH process (see section 2.1) and its possible impact on the Candidate Listing of the substance will be considered by ECHA when finalising its recommendation for inclusion of the substance in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA suggests the following transitional arrangements:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **18, 21 or 24 months**
Sunset date:	18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach[4] and the criteria described in the implementation document[5].

[4] General approach can be accessed at http://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

[5] Practical implementation document can be accessed at

According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

A summary of the information currently available to ECHA is provided in Annex I (section 3).

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

ECHA will allocate to the same slot substances considered as a group (see Section 2.4), i.e. DOTE and reaction mass of DOTE and MOTE will be allocated to the same slot.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for any use of reaction mass of DOTE and MOTE.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to recommend exemptions for uses of reaction mass of DOTE and MOTE on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses *'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'*.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

https://www.echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[6]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[7], there is no need to propose an additional specific exemption.

3.3.2 Exemption of product and process oriented research and development (PPORD)

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of reaction mass of DOTE and MOTE for PPORD.

No PPORD notifications have been submitted for reaction mass of DOTE and MOTE[8].

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

[6] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15, or in section C.2 in https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375

[7] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc

[8] As of 1 February 2018.

4. References

Annex XV SVHC report (2014): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH article 57. 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). Submitted by Austria, August 2014.

https://echa.europa.eu/documents/10162/21732369/annex_xv_svhc_dote_mote_reaction_mass_en.pdf

ECHA (2018): 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE). 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE). ECHA's dissemination website on registered substances. Accessed on 1 February 2018.

https://echa.europa.eu/search-for-chemicals

RCOM (2014): "*Responses to comments*" document. Document compiled by Austria from the commenting period 1/09/2014-16/10/2014 on the proposal to identify 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) as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1805908e3

Vinylplus (2017): Vinylplus progress report 2017 (reporting on 2016 activities)

https://vinylplus.eu/uploads/downloads/VinylPlus_Progress_Report_2017.pdf

Annex I: Further information on uses

1. Detailed information on use

Reaction mass of DOTE and MOTE appears to be used for one main application, the use as stabiliser in plastics (Annex XV SVHC report, 2014; ECHA, 2018).

The substance is used by workers at industrial sites in the formulation of dry-blend batches and is then further processed within polymer matrix to produce plastic articles. Based on registrations, there seems to be no use of the substance (as such or in a mixture) by professional workers or by consumers (ECHA, 2018).

The substance ends up in articles. Reaction mass of DOTE and MOTE is reported to be used as heat stabiliser in the production of rigid and to a minor extent of plasticised PVC articles. The main applications identified are the following (Annex XV SVHC report, 2014): rigid PVC films and sheets used for packaging material (e.g. food and pharmaceutical packaging material), credit cards and rigid construction sheets. The reaction mass is also applied e.g. in PVCs used in the production of bottles (containing shampoos, shower gels and detergents rather than beverages), pipes (e.g. drinking water), fittings and profiles (e.g. window and furniture profiles).

The typical content for the most used reaction mass of DOTE and MOTE (70/30 % w/w) in the production of PVC is 1-2.5% (ETINSA, 2014 cited in Annex XV SVHC report, 2014). Based on information from registrants it seems that only a minor amount of the stabiliser present in the PVC compound reacts during the process of conversion in articles. Hence the concentration of the reaction mass of DOTE and MOTE in the articles remains close to its initial concentration of around 1-2.5% (Annex XV SVHC report, 2014).

Further information is provided in the Annex XV SVHC report (2014) on the use of the substance in food packaging: this use and the upstream use are not discussed further in this document as they appear to fall outside the scope of authorisation (Food contact materials are exempted from the authorisation requirement pursuant to Art. 56 (5) (b) (where the substance is identified as SVHC based on hazard to human health). The uses preceding an exempted end-use are also exempted (in the volumes ending up in the exempted end-use)).

During the SVHC public consultation (RCOM, 2014), comments on the use of the substance in pharmaceutical packaging were received from several industry associations and one company[9]. The comment submitters emphasised that aspects of safety of the immediate packaging of medicines are covered by Directive 2001/83/EC and Regulation (EC) No 726/2004 and indicated that this should be considered for a possible exemption under Art. 58 (2) of REACH[10].

Information on the uses of DOTE and MOTE has been extracted from the SPIN database. DOTE and MOTE have been registered in the SPIN database for the years 2005-2011 for the manufacture of rubber and plastic products, and the manufacture of chemicals and chemical products. DOTE is used according to information from SPIN database mainly as stabiliser, but also as colouring agent (Annex XV SVHC report, 2014).

Other uses of DOTE or reaction mass of DOTE and MOTE have been reported in the past which are now restricted (e.g. use in textiles). The substance is subject to the following restrictions:

- Annex XVII of the REACH regulation, entry 20:

[9] ERPA (European Rigid PVC-film Association), IVK Europe, Klöckner Pentaplast Europe
[10] Reference was made by the comment submitters to the exemptions granted for DEHP, BBP and DBP for similar uses

  - condition No 1: organostannic compounds shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint;
  - condition No 2: organostannic compounds shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of all craft […], cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, submerged appliance or equipment;
  - condition No 6: Dioctyltin (DOT) compounds 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 than the equivalent of 0.1 % weight of tin: textile articles intended to come into contact with the skin, gloves, footwear of 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)

- Annex XVII of the REACH regulation, entry 30 (Reprotoxic substances): reaction mass of DOTE and MOTE is classified as reprotoxic category 1B and is therefore not allowed to be placed on the market, or used for supply to the general public, as substance, as constituent of other substances or in mixtures, above the relevant concentration limit.

2. Market trend

In 2012 a tonnage of ~12,190 t/y of tin stabilisers was produced in the EU, representing a market share of 8% of the total stabiliser production for use in PVC (VinylPlus Report 2013 as cited in Annex XV SVHC report, 2014). Information collected in the context of the drafting of the Annex XV SVHC report (2014) indicated that the demand for tin stabilisers is constant (although there seems to be evolution in the classes of tin stabilisers used[11]). No clear indication of progressive substitution by alternative stabiliser system was identified at that time.

3. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate the substance group to a specific LAD slot in the final recommendation.

Reaction mass of DOTE and MOTE is manufactured and/or imported by a limited numbers of registrants. The substance is supplied to one main sector (plastic) involving PVC compounders and PVC converters. The number of industrial sites where organotin stabilisers (though not specifically DOTE) are used is assumed to be > 100.

The supply chain can be characterised[12] by the following actors: formulators and producers of articles. Articles produced are then used by workers and consumers (Relevant life cycle stages: F, IS, SL).

The substance ends up in the following product type: polymer preparation and compounds (Relevant Product Categories: PC35).

[11] According to ESPA (the European stabiliser producers association) since 2006/2007 the classes of organotins used as PVC stabilizers in Europe changed drastically. Butyltins have almost completely been replaced in most of the cases by a corresponding amount of octyltins (RCOM, 2014)
[12] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

A number of sectors are relying on the substance in some of their uses including the plastic manufacturer sector, the building and construction sector, the health sector and the electricity, stream, gas, water supply sector (Relevant Sectors of Uses: SU12, SU19, SU20, SU23).

The substance ends up in the following types of articles: plastic articles (Relevant Article Categories: AC13).

Some categories mentioned above may not be explicitly listed as use descriptors in registrations but could be derived from the information on uses available.