5 September 2018

Draft background document for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

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 DOTE on the Authorisation List or provided 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:	2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)
EC Number:	239-622-4
CAS Number:	15571-58-1

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-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it 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.

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.

2.2. Volume used in the scope of authorisation

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

[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

Only part of the tonnage reported in registration dossiers under EC number 239-622-4 has been considered relevant for the prioritisation of DOTE as identified in the Candidate List (mono-constituent substance). Indeed, registrants of reaction mass of DOTE and MOTE have made use of the option allowing the registration of their multi-constituents substances under individual constituents[3]. Part of the tonnage reported under EC number 239-622-4 (DOTE) refers to the reaction mass of DOTE and MOTE. The estimation of the volume of DOTE in the scope of authorisation has been derived by deducting from the total tonnage reported under EC 239-622-4 the tonnage clearly reported as related to reaction mass of DOTE and MOTE. Where no information was available, it has been assumed that the tonnage registered could refer to the mono-constituent substance (DOTE).

All uses appear to be in the scope of authorisation, apart from a possible use in food packaging (unconfirmed use, unknown tonnage). Therefore, in conclusion, the volume in the scope of authorisation is estimated to be in the range of 100 - 10,000 t/y.

More detailed information on uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

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

In earlier registrations and other sources of information the substance was reported to end up in articles (plastic articles) in volumes > 10 t/y. All registrations have been updated in 2016 and the references to the use in articles (service life) have been removed, however, the information provided does not allow to reliably conclude that the substance is not present in the final articles.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

DOTE is considered together with reaction mass of DOTE and MOTE as a group for the purpose of its prioritisation for inclusion in Annex XIV. 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)		
DOTE is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c) Score: 1	The amount of DOTE used in the scope of authorisation is estimated in the range of 100-10,000 t/y Score: 9-12	DOTE is used at industrial sites Initial score: 5 Furthermore, the substance is used in articles in volumes >10 t/y Refined score: 7	17-20 (19)	Grouping with reaction mass of DOTE and MOTE

Conclusion
On the basis of the prioritisation criteria further strengthened by grouping considerations, DOTE receives priority among the substances in the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise DOTE 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]. 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.

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

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 for the purpose of their inclusion in Annex XIV (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 DOTE.

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 DOTE 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:

- 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 DOTE for PPORD.

No PPORD notifications have been submitted for DOTE [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. 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE). Submitted by Austria, August 2014.

https://echa.europa.eu/documents/10162/21732369/annex_xv_svhc_ec_239-622-4_dote_en.pdf

ECHA (2018): 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE). 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 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1805908a5

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 uses

Based on registrations, DOTE appears to be used in two main sectors:

1. Use as **additive in plastics**

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

   In 2016 all the registrants have updated their registration, removing the service life in articles from the technical dossier (IUCLID) and the CSR. The lead registrant has provided additional information to support the statement that the substance mostly transforms into another substance when processed into articles. The information has been analysed and it is concluded that even though part of the substance may react on use (and form transformation products) the transformation seems not to be complete. During the SVHC public consultation (RCOM, 2014), companies had indicated that the substance ends up in articles.

   Tin stabilisers with tin-sulphur bonds are known to be highly efficient stabilisers allowing the production of crystal clear, rigid vinyl articles even under high-demanding processing conditions.

   It may be assumed that DOTE (as mono-constituent) is used in similar types of applications as the substance 'reaction mass of DOTE and MOTE' reported for use for packaging material (e.g. food and pharmaceutical packaging material), credit cards, and rigid construction sheets. The reaction mass is also applied 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 main uses appear to be in the production of rigid PVC, however there are also some niche applications where the substance is used in the production of plasticised PVCs (Annex XV SVHC report, 2014).

   Comments have been received during the public consultation on DOTE SVHC identification on the uses in food packaging and in immediate packaging of medicinal products (RCOM, 2014). This tends to confirm the use of DOTE as mono-constituent in these applications.

   Further information is provided in the Annex XV SVHC report (2014) on the use in food packaging. This use and the upstream uses are not discussed further in this document as they appear to fall outside the scope of authorisation (Food contact material 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

[9] ERPA (European Rigid PVC-film Association), IVK Europe, Klöckner Pentaplast Europe

(EC) No 726/2004 and indicated that this should be considered for a possible exemption under Art. 58 (2) of REACH[10].

2. Use as/in **reactive catalyst**

The use 'reactive catalyst' represents a minor share of the total tonnage of the substance for use in the EU. The use is limited at industrial sites (formulation and end use. No use by professional workers or consumers).

Information on the uses of DOTE and MOTE has also 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:
  - 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): DOTE 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 per use

1. Use as **additive in plastics**

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

[10] Reference was made by the comment submitters to the exemptions granted for DEHP, BBP and DBP for similar uses

[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)

progressive substitution by alternative stabiliser system was identified at that time. ECHA does not have more recent information.

2. Use as/in **reactive catalyst**

ECHA has no information about market trend for that use.

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.

DOTE is manufactured/imported by a limited numbers of suppliers. DOTE 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. DOTE is also used in one second sector, smaller in importance (use in catalyst) assumed to be limited to a small number of industrial sites.

The supply chain can be characterised[12] by the following actors: formulators and industrial users (including producers of articles). The articles produced can be 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, and catalyst (Relevant Product Categories: PC32, PC0).

A number of sectors are relying on the substance in some of their uses including the manufacturers of fine chemicals, the plastic product manufacturers, the building and construction sector, the health sector and the electricity, stream, gas, water supply sector (Relevant Sector of Uses: SU9, 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.

[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