1 October 2019

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[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present document.

Contents

[1] As of the last day of the public consultation, i.e. 5 December 2018
[2] Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

1. Identity of the substance

Identity of the substance as provided in the Candidate List[3]:

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[4]. 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.

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_en.pdf.

2.1. Intrinsic properties

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.

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).

ECHA has carefully considered the information on composition, uses and tonnage available in registrations under EC 239-622-4 (DOTE) to correlate it with Candidate List entry of DOTE. The estimation of the volume of DOTE (as defined in the Candidate List) in the scope of authorisation has been derived by deducting the tonnage clearly relating to the reaction mass of DOTE and MOTE from the total tonnage reported under EC 239-622-4. Where no explicit information was available, it has been assumed that the tonnage registered refers to DOTE.

Therefore, only part of the tonnage reported in registration dossiers under EC number 239-622-4 (DOTE) has been considered relevant for the prioritisation of DOTE as defined in the Candidate

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

List. Indeed, registrants of 'reaction mass of DOTE and MOTE' have made use of the provision that allows the registration of multi-constituent substances under individual constituents[5]. These registrants have thus submitted registration dossiers under EC 239-622-4 (DOTE) and EC 248-227-6 (MOTE).

The European Tin Stabilisers Association (ETINSA) representing most of the registrants of DOTE provided information to the authorities in 2013 that indicates that DOTE is not manufactured, imported or marketed as mono-constituent substance (Annex XV SVHC report, 2014) but only in reaction mass with MOTE. This could not be confirmed based on information in the registration dossiers.

In 2018 the Organotin REACH consortium indicated that DOTE is used as pure substance in low volume (ComRef, 2019).

All uses of DOTE appear to be in the scope of authorisation, apart from the possible use in food contact materials for which there is a generic exemption from the authorisation requirement as per Art. 56(5)(b) of REACH) (see Section 3.3.1).

During the Annex XIV public consultation, the Organotin REACH Consortium submitted information collected from their Downstream users indicating that DOTE is used in a volume band of 400-500 t/a in food contact films and immediate packaging for medication (ComRef, 2019). Considering that only this one estimation of the combined tonnage going to those two uses has been provided, it is not possible to conclude on the exact part of the tonnage falling outside the scope of authorisation. That tonnage should however represent no more than 500 t/y based on the information provided.

In conclusion, the volume in the scope of authorisation is estimated to be in the range of 1-10,000 t/y. This wide tonnage band reflects the various uncertainties associated to the information available.

More detailed information 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 previous registrations the substance was reported to be used in articles (plastic articles). All registrations have been updated in 2016 and the references to the use in articles have been removed, however, the information provided does not allow to reliably conclude that there is no use in articles anymore.

The extent to which the substance actually ends up in articles is uncertain. Contradicting information is available on the extent to which the stabiliser (being DOTE or reaction mass of DOTE and MOTE) transforms into another substance:

[5] Provision explained in Section 4.2.2 of the 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

- Based on information from registrants, the typical content for the mostly 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). Industry indicated 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 is stated to remain close to its initial concentration of around 1-2.5%.

- Comments received during the Annex XIV Public consultation (ComRef, 2019) by industry sector associations (Organotin REACH Consortium, EupC) indicated that the substance (referred to as DOTE) 'mostly' transforms into another substance when processed into articles. Industry noted that the purpose of a heat stabiliser like DOTE is to prevent the formation of HCl during manufacturing of PVC articles caused by heat and shear. DOTE reacts with any HCl generated to form the stable DOTEC, a reaction also found in the in-vitro metabolism of the substance). As a consequence the volume of DOTE, as such, in PVC gets reduced when a PVC article is produced. EuPC indicated that although some residues will be present it is the function of DOTE to react during processing (ComRef 2019). According to EuPC it is questionable whether the levels of DOTE in the finished article will exceed for all uses the 0.3% threshold depending on the original concentration of DOTE added.

- Background information (Frenkel, 2016) has been provided by DOTE lead registrant to justify that the substance does not end up in articles[6] (ECHA, 2018). DOTE is claimed to transform into the substance DOTEC during PVC processing. However the report states that the degree of transformation may vary from one process/processor to another, from one dry blend composition to another. ECHA notes that the NMR-spectrum provided by the registrant shows the presence of the transformation product. However it also shows the presence of a considerable amount of DOTE. This means that the degradation is not complete.

Based on information available it cannot be excluded that part of the Candidate List substance remains unreacted in the matrix.

The volume used in articles is unknown but might be < 10 t/y.

More detailed information on uses is provided in Annex I.

2.4. Further considerations for priority setting

DOTE is considered together with the reaction mass of DOTE and MOTE as a group for the purpose of its prioritisation for inclusion in Annex XIV. These 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.

[6] The service life has been removed from registrations under EC number 239-622-4 (DOTE)

2.5. Conclusion

Verbal descriptions and scores			Total score	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + 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 1-10,000 t/y Score: 3-12	DOTE is used at industrial sites Initial score: 5 Furthermore, the substance might be used in articles in volumes <10 t/y Refined score: 5-7	9-20 (15)	Grouping with the 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, DOTE is recommended for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[7] and as further specified in the practical implementation document[8]. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf .

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for DOTE:

Latest application date (LAD): Date of inclusion in Annex XIV plus 21 months

Sunset date: 18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

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

[8] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain.

Groups of substances are considered together therefore DOTE and the reaction mass of DOTE and MOTE are allocated to the same slot (see Section 2.4).

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

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

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for DOTE.

During the public consultation ECHA did not receive comments requesting upfront review period for certain uses.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of DOTE.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

During the Annex XIV and SVHC public consultations (RCOM, 2014; ComRef, 2019), comments on the use of the substances[9] in packaging of medicinal products *[in some comments also referred to as packaging of pharmaceuticals, medication or medicines]* were received from several industry associations and one company.

Some 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 in their view the use falls outside the scope of authorisation as per Art.2(5)(a) of REACH.

ECHA notes that Article 2(5) of REACH excludes the use in medicinal products from the authorisation requirement, but not the use in the packaging of such products. The use in medicinal products packaging is not covered by any generic exemption from the authorisation requirement under REACH. Therefore such use can only be exempted under Article 58(2) of REACH.

Other comment submitters indicated that the use in packaging of medicinal products should benefit from a specific exemption. Reference was made by some comment submitters to the Art. 58(2) exemptions granted for DEHP, BBP and DBP for a similar use.

While ECHA does not recommend exemptions for any use of DOTE, ECHA invites the

[9] DOTE and/or the reaction mass of DOTE and MOTE

Commission to assess if a similar conclusion reached in the past for DEHP, BBP and DBP may apply to the specific case of DOTE and the reaction mass of DOTE and MOTE. Such assessment should also be done in accordance with the considerations on the application of Article 58(2) set out by the General Court and the European Court of Justice in their judgments in Cases T-360/13 and C-651/15 P Vecco and others v. European Commission[10].

MSC is of the opinion that there is currently not a sufficiently clear basis for recommending exemptions in Annex XIV for the prioritised substances under Article 58(2) of REACH[11]. MSC notes that ECHA intends to invite the European Commission to assess if a similar conclusion in relation to Article 58(2) exemptions which were granted in the past for DEHP, BBP and DBP for use in immediate packaging of pharmaceuticals may apply for the same uses of DOTE and the reaction mass of DOTE and MOTE and supports this invitation to the European Commission. However, MSC also notes the MSC Opinion on the first amendment of existing Annex XIV entries of DEHP, BBP, DBP and DIBP as agreed on 26 June 2019[12]. MSC is of the opinion that similar considerations by the European Commission as outlined in that opinion should also apply to DOTE and the reaction mass DOTE and MOTE.

During the Annex XIV and SVHC public consultations (RCOM, 2014; ComRef, 2019), comments on the uses of the substance in food contact applications *[in some comments also referred to as food packaging, or food contact]* have also been received. The comment submitters emphasised that these uses are covered within the scope of Regulation 1935/2004/EC and Regulation 10/2011/EC and should therefore be considered as falling outside the scope of authorisation (generic exemption as per Art. 56(5)(b) of REACH).

ECHA agrees with such assessment and notes that if a use falls under the generic exemptions from authorisation, there is no need to propose an additional specific exemption.

It is the responsibility of companies to assess whether their uses comply with the requirements relevant for the exempted uses.

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

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of DOTE for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications have been submitted for DOTE by the end of public consultation.

ECHA therefore does not recommend exempting any use of DOTE for PPORD from authorisation.

[10] http://curia.europa.eu/juris/liste.jsf?num=T-360/13&language=EN and http://curia.europa.eu/juris/liste.jsf?language=en&num=C-651/15%20P

[11] https://www.echa.europa.eu/documents/10162/13576/msc_opinion_and_supdoc_9th_draft_rec_annex_xiv_26062019_adopted.pdf/449547a9-9f43-2355-2195-084378139111

[12] https://www.echa.europa.eu/documents/10162/13576/msc_opinion_draft_amendment_dehp_bbp_dbp_dibp_26062019_en.pdf

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

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_comref_dote_en.rtf

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 5 December 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

RCOM (2019) "Responses to comments" document. Document compiling the responses to comments from the commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_dote_dotemote_en.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.

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 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)

- 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 seemed to be an evolution in the classes of tin stabilisers used[13]). No clear indication of progressive substitution by alternative stabiliser systems was identified at that time. ECHA does not have more recent information. 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).

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 were made to allocate the substance to a specific LAD slot. For the purpose of LAD assignment groups of substances are considered together. Therefore the information summarised below refers to the group DOTE' and the reaction mass of DOTE and MOTE.

DOTE and reaction mass of DOTE and MOTE are manufactured/imported by a limited number of registrants. The substances are 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 according to industry information > 100. DOTE is also used in one further sector, for smaller part of tonnage (use in catalyst) assumed to be limited to a small number of industrial sites.

The supply chain can be characterised[14] by the following actors: formulators and industrial users (including producers of articles). (Relevant life cycle stages: F, IS, SL).

The substances end up in the following product types: polymer preparation and compounds; catalysts (Relevant Product Categories: PC32, PC0 (catalysts)).

A number of sectors are relying on the substances in some of their uses including the manufacturers of fine chemicals, plastic product manufacturers, the general manufacturing sector (e.g. vehicles), the building and construction sector, the health sector and the electricity, stream, gas, water supply sector (Relevant Sector of Uses: SU9, SU12, SU17, SU19, SU20, SU23).

The substances are used in the production of the following types of articles: plastic articles (Relevant Article categories: AC13).

[13] 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)
[14] 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

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