# Draft recommendation of priority substances for inclusion in Annex 14 of UK REACH 2025

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

- EC: 239-622-4
- CAS: 15571-58-1

**October 2025**

# 1 Contents

# 1. Introduction

The Health and Safety Executive (HSE), as the Agency for UK REACH (with support from the Environment Agency on environmental matters), is required to recommend priority substances from the UK REACH Candidate List to be included in the Authorisation List (Annex 14) of UK REACH.

The criteria used by HSE are set out in the document entitled “Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH”[1].

The following document contains information to support the inclusion of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE) in HSE’s draft recommendation (2025) of priority substances for inclusion in the authorisation list of UK REACH.

Further information on the approach to this recommendation is provided in the document entitled “Technical rationale for the development of the recommendation”[2].

[1] “Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH”, available from here; https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx.

[2] “Technical rationale for the development of the recommendation”, available from here: https://www.hse.gov.uk/reach/assets/docs/recommendations.xlsx

# 2 Background information for prioritisation

## 2.1 Substance Identity

Identity of the substance in the UK REACH Candidate List

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

Available information indicates that DOTE is manufactured, imported and supplied as a reaction mass (multi-constituent substance) with the corresponding monooctyltin compound; 2-ethylhexyl 10-ethyl-4-[[2-[(2- ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE) (CAS number: 27107-89-7, EC number: 248-227-6). The typical ratio of DOTE:MOTE in the reaction mass is given as 70:30% by weight. As such, the substances are considered as a group and a background document for the reaction mass of DOTE and MOTE is also available.

HSE has prepared a Technical Report on DOTE and the reaction mass of DOTE and MOTE (HSE, 2025). Further information on the substance identity, hazards and use profile of these substances is provided in that document.

## 2.2 Intrinsic properties

DOTE is identified as a Substance of Very High Concern (SVHC) according to Article 57(c) of UK REACH owing to its classification in the GB Mandatory Classification and Labelling (MCL) list as toxic for reproduction, category 1B, Repr 1B; H360D (“May damage the unborn child”). The substance is covered by the GB MCL list entry with index number 050-027-00-7.

DOTE was included in the UK REACH Candidate List on 1st January 2021 in accordance with Article 59(1A).

## 2.3 Volume used in the scope of authorisation

No registrations for DOTE, MOTE or the reaction mass of DOTE and MOTE have been submitted under UK REACH and HSE assumes that these substances are not manufactured in GB.

However, the available information from Downstream User Import Notifications (DUINs)[3] suggests that DOTE, or the reaction mass of DOTE and MOTE, or mixtures containing these substances are imported into GB from the EU. Thirty DUINs have been submitted for DOTE and 20 for MOTE. No DUINs for the reaction mass of DOTE and MOTE were submitted, but this is likely because no registrations have been submitted for the reaction mass under EU REACH. Instead, the registration obligation for the reaction mass has been met in the EU by the registration of the individual constituents, DOTE and MOTE.

However, it is noted that there is uncertainty[4] in the DUIN database and HSE does not have accurate information on the actual tonnages of DOTE placed on the GB market.

## 2.4 Wide-dispersiveness of uses

As noted above, HSE has prepared a Technical Report on DOTE and the reaction mass of DOTE and MOTE (HSE, 2025). Whilst a call for evidence was held in 2023, HSE still does not have much GB-specific information about the use of these substances and has largely relied on EU information provided in the following European Chemicals Agency (ECHA) documents:

- the Annex 15 SVHC identification dossiers for DOTE (ECHA, 2014a) and the reaction mass of DOTE and MOTE (ECHA, 2014b);

[3] GB-based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a DUIN submitted to HSE.

[4] DUINs could be submitted for substances imported from the EU-27 into GB at any point within the two years prior to EU exit. They represent an approximate snapshot of substances on the GB market in the period before EU exit. As DUIN submission was a simple process and free of charge, companies may have under or over-reported substances (potentially erring on the side of caution to be compliant). Consequently, the DUIN data needs to be treated with caution. Many former DUs will not (currently) have full information on the identity of the substances they import from the EU. This is because most substances are placed on the market as mixtures and the full composition of those mixtures is not always given on a Safety Data Sheet (SDS) or a SDS may not be required. In addition, substances could be imported by multiple importers in lower volumes (i.e. below 1 tonne/year/importer); in these cases, the substances did not need to be included in a DUIN submission as there would be no registration duty under UK REACH for each importer.

- the Annex 14 recommendation support dossiers for DOTE (ECHA, 2019a) and the reaction mass of DOTE and MOTE (ECHA, 2019b);

- Comments submitted to ECHA during public consultations on these documents (ECHA, 2019c; ECHA, 2019d).

The UK was a member of the EU at the time these documents were prepared and the consultations were held, and in the absence of information suggesting otherwise coming to light during the development of the Technical Report (HSE, 2025) and this recommendation, this information is assumed to apply to GB.

The information from these documents has been supplemented with details submitted to ECHA in support of applications for authorisation for DOTE. This includes a chemical safety report (CSR), first published by ECHA in March 2024 (ECHA, 2024a) and an updated version published in April 2025 (ECHA, 2025a). Further details regarding the applications for authorisation are provided in Section 3.2 below.

The main use of DOTE appears to be as a heat stabiliser in plastics at industrial sites.

The above documents refer to formulation of liquid mixtures, formulation of dry polyvinyl chloride (PVC) mixtures and manufacture of PVC articles. From the available information, formulation of liquid mixtures containing DOTE only appears to take place at the two EU sites where it is manufactured. If formulation into liquid mixtures at the place of manufacture is typical, the absence of any registrations in GB would suggest that such liquid formulations are not made in GB. However, it remains a possibility. The remaining scenarios (formulation of dry PVC mixtures and manufacture of PVC articles) take place at multiple downstream user sites across the EU and HSE considers that these uses may also take place in GB.

There is uncertainty about the amount of residual DOTE that remains in articles after production. The CSR (ECHA, 2025a) notes that DOTE can be present in finished articles at concentrations above 0.1% w/w of the article. This is supported by the large number of Substance In Article Notifications (SIANs) submitted to ECHA where DOTE is listed. The CSR (ECHA, 2025a) concludes that final articles will contain a maximum concentration of 0.21% DOTE (although a worst-case approach of ≤ 0.3% was considered for modelling purposes).

EU registration information also suggests that DOTE is used as a reactive catalyst. However, very little information was available in ECHA's documents on this particular use and no information specific to GB has been provided.

Further information on the uses of DOTE is provided in HSE's Technical Report (HSE, 2025).

## 2.5 Further considerations for priority setting

As noted above, available information indicates that DOTE is manufactured, imported and supplied as a reaction mass (multi-constituent substance) with the corresponding monooctyltin compound MOTE. As such, DOTE and the reaction mass of DOTE and MOTE are considered as a group to prevent substitution of one for the other.

Alternatives to DOTE as a heat stabiliser may be available, but documents published by ECHA (see Sections 2.4 and 3.2 of this document) suggest that technical performance deficits may be a key barrier to substitution. Where substitution is straightforward, it would appear that in many cases this has already been achieved. In some instances, substitution may be achieved by accepting a lower technical performance for the end product, but this may not be possible where there are regulatory requirements to meet particular technical performance standards (for example for certain construction products).

# 3 Other factors and considerations

In addition to the above, HSE notes the 'Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026'[5], which states:

"The Appropriate Authorities will consider the criteria set out in the UK REACH Regulations, alongside a range of relevant factors including those identified in the '*New approach to ensure regulators and regulation support growth*'[6] UK Government Action Plan. In taking forward this strategic approach, the Appropriate Authorities will consider drawing from the regulatory decisions that the EU has made in this area (where appropriate)."

Recognising this, information is provided below to support the Appropriate Authorities consideration of regulatory consistency with decisions made by the EU.

## 3.1 EU prioritisation activity

DOTE was included in the EU Candidate List for authorisation on 17th December 2014, following ECHA's decision ED/108/2014.

DOTE was prioritised for addition to the authorisation list by ECHA and included in its 9th recommendation (ECHA, 2019e). The following information regarding tonnage and use was provided in the Annex 14 background document (ECHA, 2019a) at that time:

- The volume of DOTE estimated to be in scope of authorisation was in the range of 1 – 10,000 tonnes per year. This wide range reflected the uncertainty in the information available at that time, including the extent to which DOTE was supplied as a mono-constituent substance (as opposed to the reaction mass of DOTE and MOTE) and the tonnage used for applications outside the scope of authorisation (e.g., food contact material).

- Uses of DOTE in scope of authorisation included 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). It was also noted that there were uncertainties at that

[5] Defra rationale for prioritising substances in the UK REACH work programme; 2025-2026, available at: https://www.gov.uk/government/publications/uk-reach-rationale-for-priorities-2025-to-2026/rationale-for-prioritising-substances-in-the-uk-reach-work-programme-2025-to-2026

[6] '*New approach to ensure regulators and regulation support growth, available at* 'https://www.gov.uk/government/publications/a-new-approach-to-ensure-regulators-and-regulation-support-growth

time regarding the extent to which unreacted DOTE remained in finished articles. The volume used in articles was expected to be < 10 tonnes per year.

Grouping with the reaction mass of DOTE and MOTE was included as an additional consideration.

It is noted that the recent applications for authorisation of DOTE in the EU refer to a total of 2,000 to 5,000 tonnes of DOTE being used annually for the production of PVC products.

DOTE was added to Annex 14 of EU REACH on the 8th April 2022 (Commission Regulation (EU) 2022/586).

## 3.2 EU authorisations

Three applications for authorisation have been submitted to ECHA covering the following uses:

- Formulation of liquid mixtures containing DOTE
- Formulation of dry PVC mixtures (granules and pellets) containing DOTE
- Industrial manufacture of PVC articles containing DOTE as a stabiliser

ECHAs Committee for Risk Assessment (RAC) and Committee for Socioeconomic Analysis (SEAC) have adopted opinions on all 3 applications (ECHA, 2025b, ECHA, 2025c and ECHA, 2025d). At the time of drafting, the EU Commission has not yet provided regulatory decisions on these opinions. A broad summary of the 3 applications and the main conclusions of the ECHA (RAC and SEAC) opinions are provided below:

- As noted above, 2 applications covered formulation of mixtures containing DOTE only.
- Applications for points 2 and 3 covered use at multiple downstream user sites. RAC concluded that adequate control was demonstrated only for the sites confirming their compliance with the Operational Conditions (OCs) and Risk management Measures (RMMs) described in the CSR. Many of the downstream user sites did not provide site specific information or failed to provide sufficient information to demonstrate adequate control.
- Additional conditions to improve monitoring were proposed at those sites where it was agreed adequate control was demonstrated.
- Limited information on alternatives and substitution efforts was submitted.

- The review periods were linked to the final use as a stabiliser in the production of PVC articles (point 3 above). A shorter review period of 4-years was recommended (compared to the 7-year period requested by the applicants), with the opinion noting adequate justification for the longer period was not provided.

## 3.3 Consideration of regulatory decisions in the EU

Both DOTE and the reaction mass of DOTE and MOTE have been included in Annex 14 of EU REACH. Inclusion of both is to prevent substitution of one for the other.

As noted above, applications for authorisation covering the use of DOTE (or mixtures containing DOTE) in the production of PVC products have been submitted to ECHA. HSE notes that, at the time of this recommendation, no decision has been made by the EU Commission on the opinions of ECHA's committees regarding these applications. However, where sufficient information has been made available from the downstream users, RAC have concluded that the risks can be adequately controlled provided that the OCs and RMMs in the CSR are adhered to. There was limited evidence for adequate control as some downstream user sites and RAC concluded that for some sites, exposures could be above the DNEL.

RAC have specified additional conditions and monitoring measures to provide further information on the effectiveness of the OCs and RMMs.

A short review period of 4-years was also assigned, with the opinion noting the limited information on the technical feasibility of alternatives and substitution plans, with substitution already possible for some products and downstream users.

## 3.4 Summary of potential consequences of regulatory consistency with EU decisions

HSE does not have any information to indicate that DOTE or the reaction mass of DOTE and MOTE is manufactured in GB. However, it is likely that DOTE is imported (as part of a mixture or the reaction mass of DOTE and MOTE) and used at industrial sites in GB with a similar profile to the EU, with the possible exception of the formulation of liquid mixtures which may only happen at a limited number of sites outside of GB.

Applications to authorise the use of DOTE in the production of PVC articles have been submitted under EU REACH. Where appropriate and representative information has been made available, RAC have concluded that adequate control of the risk has been demonstrated so long as the OCs and RMMs described in the applications are adhered to. HSE has no reason to conclude that risks to workers in GB could not be adequately controlled should the same OCs and RMMs be applied. However, for some sites adequate

control could not be reliably demonstrated. This suggests that there could also be sites in GB in which improved exposure control could be achieved.

The additional conditions and monitoring measures proposed in the application for authorisation opinions could support further improvements to/adherence with workplace exposure controls as well as promoting consistency and stability in controls and measures applied.

Limited information is available regarding the technical feasibility of alternatives, particularly for certain uses where technical performance standards are established (e.g., in the construction industry). However, adding the substance to Annex 14 would require further consideration of substitution, given that it appears some alternatives are available and that in the EU it was found that information on consideration of substitution was scare.

Adding DOTE to Annex 14 of UK REACH would also provide regulatory consistency in decision making and could lead to clarity for users importing the substance from the EU.

# 4 Background information for the proposed Annex 14 entry

## 4.1 Latest application and sunset dates

HSE proposes the following transitional arrangements as referred to in Article 58(1)(c):

| | |
|---|---|
| Latest application date (LAD): | Date of inclusion in Annex 14 plus 18, 21 or 24 months |
| Sunset date: | 18 months after LAD |

HSE will set the LAD when finalising the recommendation and will use all available relevant information, including that received in the consultation. It has been estimated that a period of 18 months is required to prepare good quality applications for authorisation. When setting the LADs, HSE also considers its capacity to process authorisation applications. If a high workload is anticipated, a later LAD may be allocated.

## 4.2 Review period for certain uses

Review periods will be considered during the decision on whether to grant authorisation for specific applications submitted by manufacturers, importers or downstream users. All authorisation decisions will include specific review periods based on information provided in the application.

## 4.3 Uses or categories of uses exempted from authorisation requirement

### 4.3.1 Exemption under Article 58(2)

HSE proposes not to recommend exemptions for uses of DOTE based on Article 58(1)(e) in combination with Article 58(2) of UK REACH.

According to Article 58(2) of UK REACH it is possible to exempt from the authorisation requirement uses or categories of uses ‘provided that, on the basis of the existing specific 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’.

In deciding whether to recommend an exemption, HSE considers if:

- There is existing legislation addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing 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 14; generally, the legislation in question should specifically refer to the substance to be included in Annex 14 either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing 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) has to allow more stringent requirements than the specific minimum requirements set out in the legislation in question to be imposed. 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).

Requests for exemption from authorisation under Article 58(2) for a particular use will be assessed by HSE on a case-by-case basis.

### 4.3.2 Exemption of product and process-oriented research and development (PPORD)

HSE proposes not to recommend including in Annex 14 any exemption from authorisation for the use of DOTE for PPORD.

At the EU level, no exemptions for PPORD have been recommended for any substance. If an operator wishes to use a substance included in Annex 14 for a PPORD activity, it is possible for the operator to obtain authorisation for that use of the substance in accordance with Articles 60 to 64 of UK REACH.

ECHA noted in its background document that no PPORD notifications had been submitted to it for DOTE by the end of their consultation. As of October 2025, no PPORD notifications had been received by HSE.

# 5 References

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recommendation for the inclusion of substances in Annex XIV – October 2019. Available at: https://echa.europa.eu/documents/10162/f068d624-5e4d-1729-1fb7-3a9d2eb154e7

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# 6 Declarations

Within this document we have provided links to documents and information found on ECHA's website: https://echa.europa.eu/

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## Further information

This publication is available on the HSE website at;
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