Annex 15 report

Proposal for identification of a substance of very high concern (SVHC) under UK REACH

Substance Name(s): Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs, and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety

EC Number(s): -

CAS Number(s): -

March 2026

Contents

1. Proposal

Substance name(s): Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety

EC number(s): -

CAS number(s): -

This report covers a group of substances that are defined by the name above. Examples of substances covered include the mono-constituent substance dioctyltin dilaurate (EC No. 222-883-3), and the UVCB substance (substance of Unknown or Variable composition, Complex reaction products or Biological material)[1], stannane, dioctyl-, bis(coco acyloxy) derivs. (EC No. 293-901-5). The conclusions of this report apply to all substances that fall under this name. The group of substances are referred to as DOTL for convenience.

The substances are proposed to be identified as substances meeting the criteria of Article 57 (c) of UK REACH owing to their classification in the hazard class toxic for reproduction category 1B[2].

Summary of how the substance meets the criteria set out in Article 57 of UK REACH

Dioctyltin dilaurate (EC No. 222-883-3), and stannane, dioctyl-, bis(coco acyloxy) derivs. (EC No. 293-901-5) are included in the GB Mandatory Classification and Labelling (MCL) list. They are covered by the entry with index number 050-031-00-9 and classified in the hazard class toxic for reproduction category 1B (H360D; May damage the unborn child).

[1] UVCB (Unknown or Variable composition, Complex reaction products or Biological materials): Substances with unknown or variable constituents, often from complex reactions or biological sources, so no single precise structure applies. Under UK REACH they are identified by source and manufacturing process, with typical constituent ranges rather than exact compositions.

[2] Classification in accordance with section 3.7 of Annex I to the retained Regulation (EC) No 1272/2008 as amended for Great Britain (hereinafter referred to as GB CLP).

2. Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

This Annex 15 report covers dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety.

Examples of substances covered include dioctyltin dilaurate (EC No 222-883- 3) and stannane, dioctyl-, bis(coco acyloxy) derivs. (EC No 293-901-5).

Table 1: Substance identity for dioctyltin dilaurate

EC number:	222-883-3
EC name:	Dioctyltin dilaurate
CAS number (in the EC inventory):	3648-18-8
CAS name:	Stannane, dioctylbis[(1-oxododecyl)oxy]-
Deleted CAS number:	1245942-04-4
IUPAC name:	[dodecanoyloxy(dioctyl)stannyl] dodecanoate
Index number in GB MCL List	050-031-00-9
Molecular formula:	$C_{40}H_{80}O_4Sn$
Molecular weight range:	743.7708 g/mol
Synonyms:	Bis(lauroyloxy)dioctylstannane Di-n-octyl-zinn dilaurate Di-n-octyltin dilaurate Stannane, bis(dodecanoyloxy)dioctyl- Stannane, bis(lauroyloxy)dioctyl-Stannane,

	didodecanoyloxydioctyl-Stannane, dioctylbis((1-oxododecyl)oxy)- Stannane, dioctylbis(lauroyloxy)- Stannane, dioctyldi(lauroyloxy)- Stannane, dioctyldidodecanoyloxy- Tin, dioctyl-, dilaurate dioctylstannanebis(ylium) didodecanoate Dioctyltin laurate diottil dilaurato Stannane, dioctylbis[(1-oxododecyl) oxy] - Stannane, dioctylbis[(1-oxododecyl)oxy] DOTL
Structural formula:	
Substance type:	Mono-constituent

Table 2: Substance identity for stannane, dioctyl-, bis(coco acyloxy) derivs.

EC number:	293-901-5
EC name:	Stannane, dioctyl-, bis(coco acyloxy) derivs.
CAS number (in the EC inventory):	91648-39-4
CAS name:	Stannane, dioctyl-, bis(coco acyloxy) derivs.
IUPAC name:	-
Index number in GB MCL List:	050-031-00-9
Molecular formula:	n.a. (UVCB)

Molecular weight range:	n.a. (UVCB)
Synonyms:	-
Structural formula:	n.a. (UVCB)
Substance type:	UVCB

Data source: EU Annex 15 report ECHA (2020a). Also refer to HSE's Technical Report for DOTL (HSE 2025)

2.1.2 Composition of the substance

Impurities and/or additives are not relevant for SVHC identification of the substance.

2.1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as a SVHC in accordance with Article 57 (c) of UK REACH.

2.1.4 Identity and composition of structurally related substances (used in grouping or read-across approach)

Not relevant for the identification of the substance as a SVHC in accordance with Article 57 (c) of UK REACH.

2.1.5 Physicochemical properties

Not relevant for the identification of the substance as a SVHC in accordance with Article 57 (c) of UK REACH.

2.2 Mandatory classification and labelling

Table 3: Mandatory classification in the GB MCL list

Index No	International Chemical Identification	EC No	CAS No	GB MCL list Classification		Aligned with EU CLH[a]
				Hazard Class and Category Code(s)	Hazard statement code(s)	Y/N
050-031-00-9	dioctyltin dilaurate [1]; stannane, dioctyl-, bis(coco acyloxy) derivs. [2]	222-883-3 [1]; 293-901-5 [2]	3648-18-8 [1]; 91648-39-4 [2]	Repr. 1B STOT RE 1	H360D H372 (immune system)	Y

[a] EU CLH is harmonised classification and labelling in accordance with Regulation (EC) 1272/2008

2.3 Human health hazard assessment

Please see Section 2.2 (mandatory classification and labelling).

2.4 Conclusions on the SVHC properties

2.4.1 CMR assessment

Dioctyltin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. are covered by the entry with index number 050-031-00-9 in the GB MCL list and are classified in the hazard class toxic for reproduction category 1B (H360D; May damage the unborn child).

Therefore, the substances satisfy the criterion in Article 57 (c) of UK REACH.

This conclusion is extended to apply to all substances covered by the name dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety

3. Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

Dioctyltin dilaurate (EC: 222-883-3) is registered in the range of 10–100 tonnes per annum (tpa) under UK REACH. There are no UK REACH registrations for stannane, dioctyl-, bis(coco acyloxy) derivatives (EC: 293-901-5).

A total of 107 and 7 Downstream User Import Notifications (DUINs[3]) have been submitted under UK REACH for dioctyltin dilaurate and Stannane, dioctyl -,bis(coco acyloxy) derivatives, respectively.

Under EU REACH, dioctyltin dilaurate is registered in 100-1000 tpa[4] range. There are no EU REACH registrants for stannane, dioctyl-, bis(coco acyloxy) derivatives.

3.2 General description of uses and exposure

DOTL is generally used as a stabiliser and catalyst in the production of plastics and rubber. Products containing DOTL may be supplied to industrial and construction markets and the DIY consumer. Residual DOTL may remain in polymers and there is potential for this residual DOTL to migrate out of articles during service life or when they are discarded as waste (HSE 2025).

Further information is available in the TR on DOTL (HSE 2025).

3.3 Alternatives

ECHA (2020a) noted that alternatives to organotin compounds used as PVC stabilisers and catalysts were assessed in a study commissioned by the European Commission in 2007. The study concluded that suitable non-tin alternatives were available for most applications and that a three-year phase-out period for dioctyltin compounds in consumer

[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 Downstream User Import Notification (DUIN) submitted to the Agency.

[4] ECHA Chemicals database; ECHA CHEM https://chem.echa.europa.eu/

articles would be reasonable. ECHA (2020a) noted that the findings of the report might be outdated and that additional alternatives or technical solutions may now exist.

According to ECHA's Response to Comments (RCOM) (ECHA, 2020b) on the Annex 15 report ECHA (2020a), which compiles submissions from the public consultation, several industry contributors stated that no suitable alternatives were available for many uses because catalysts are typically process-specific and drop-in replacements are difficult to identify.

In the TR (HSE 2025), it was noted that the fast curing time for DOTL is a key advantage over alternatives when used as a catalyst in production of rubber and plastic. The TR also concluded that there are currently no viable alternatives to DOTL that could act as a suitable drop-in replacement across all applications.

Further information is available in the TR on DOTL (HSE 2025).

3.4 Additional information

No additional relevant information available.

References

ECHA (2018) Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of dioctyltin dilaurate; stannane, dioctyl-, bis(coco acyloxy) derivs.; CLH-O-0000001412-86-223/F; Date: 14/09/2018. Available at: https://echa.europa.eu/documents/10162/2d5e92f9-5e3f-dc37-e926-be5abeffc355 [Accessed: 09/2025]

ECHA (2020a) Annex XV report PROPOSAL FOR IDENTIFICATION OF SUBSTANCES OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57. Available at: https://echa.europa.eu/documents/10162/2e651995-b833-971c-3446-065d3b3900e0 [Accessed: 09/2025]

ECHA (2020b) COMMENTS ON AN ANNEX XV DOSSIER FOR IDENTIFICATION OF A SUBSTANCE AS SVHC AND RESPONSES TO THESE COMMENTS (RCOM) — Dioctyltin dilaurate; stannane, dioctyl-, bis(coco acyloxy) derivs.; and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety; Date: 16/11/2020. Available at: https://echa.europa.eu/documents/10162/2e651995-b833-971c-3446-065d3b3900e0 [Accessed: 10/2025]

ECHA Chemicals database; ECHA CHEM. Available at: https://chem.echa.europa.eu/ [Accessed: 10/2025]

HSE (2021b) Initial assessments of substances added to the EU Candidate List in 2021. Available at: https://www.hse.gov.uk/reach/assets/docs/svhc-assessment-summaries.pdf [Accessed: 09/2025]

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). Available at: https://www.legislation.gov.uk/eur/2008/1272/contents [Accessed 10/2025]

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA

relevance). Available at: https://www.legislation.gov.uk/eur/2006/1907/contents [Accessed 10/2025]

Glossary of terms used in Agency Annex 15 report

Agency, the	HSE
CLH	Harmonised Classification and Labelling
CLP	Classification, labelling and packaging
DOTL	Group name for dioctyltin dilaurate and stannane, dioctyl-, bis(fatty acyloxy) derivatives (UVCBs, incl. bis(coco acyloxy) derivs.), with C12 the predominant fatty-acyloxy chain.
DUIN	Downstream User Import Notifications
ECHA	European Chemicals Agency
EU	European Union
HSE	Health and Safety Executive
MCL	Mandatory Classification and Labelling
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals regulation
SVHC	Substance of very high concern

Further information

This publication is available on the HSE website here.

Published by the Health and Safety Executive 03/26.