

Substance 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

EC Number: -

CAS Number: -

**MEMBER STATE COMMITTEE SUPPORT DOCUMENT
FOR IDENTIFICATION OF**

**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**

**AS SUBSTANCES OF VERY HIGH CONCERN
BECAUSE OF THEIR TOXIC FOR REPRODUCTION
(ARTICLE 57C) PROPERTIES**

Adopted on 9 December 2020

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IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

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): -

- The substances are identified as substances meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to their classification in the hazard class toxic for reproduction category 1B¹.

Summary of how the substances meet the criteria set out in Article 57 of the REACH Regulation

The substances are exemplified by dioctyltin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. However, the conclusions apply to all substances covered by the substance name definition.

Dioctyltin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. are covered by index number 050-031-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class toxic for reproduction category 1B (H360D²).

Therefore, this classification of the substances in Regulation (EC) No 1272/2008 shows that they meet the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance?

Yes (dioctyltin dilaurate).

No (stannane, dioctyl-, bis(coco acyloxy) derivs.)

¹ Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

² H360D: 'May damage the unborn child'.

Justification

1. Identity of the substance and physical and chemical properties

This support document 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.

In this document, the substances are exemplified by dioctyltin dilaurate (EC No 222-883-3) and stannane, dioctyl-, bis(coco acyloxy) derivs. (EC No 293-901-5). According to the REACH lead registrant of dioctyltin dilaurate, the substance currently on the European market is the UVCB substance stannane, dioctyl-, bis(coco acyloxy) derivs. although registered under the mono-constituent substance dioctyltin dilaurate (personal communication, January 2016).

An example of the manufacturing process consists of the use of dioctyltin oxide and coconut fatty acids or commercial "lauric acid" as starting materials in the ratio 1:2. It should be noted that the composition of the substance manufactured using fatty acids obtained from coconut oil includes constituents having variable alkyl chain lengths. The composition of coconut fatty acids has been described as including C6, C8, C10, C12, C14, C16, C18, C20 saturated and C18 unsaturated alkyl chains at various concentration levels.

One example of carbon chain length distribution is (weight %):

- Caproic acid, C6: 0-0.8
- Caprylic acid, C8: 5.0-9.0
- Capric acid, C10: 6.0-10.0
- Lauric acid, C12: 44.0-52.0
- Myristic, C14: 13.0-19.0
- Palmitic acid, C16: 8.0-11.0
- Stearic acid, C18: 1.0-3.0
- Oleic acid, C18:1: 5.0-8.0
- Linoleic acid, C18:2: 0.0-1.0
- Arachidic acid, C20: 0.0-0.5

Substances having such variable alkyl chain lengths are UVCB substances that may have been described by a name reflecting the source e.g. stannane, dioctyl-, bis(coco acyloxy) derivs. or a name reflecting the variability of the alkyl chain length such as, but not limited to, "*Reaction product of dioctyltin oxide with fatty acids C12-16 even numbered*". Different actors may have for instance used different alkyl descriptors (e.g. C10-16 even numbered,...) to represent the carbon number distribution in the substance name.

Independently from the name used for describing such substances, the hazardous properties described in this document are correlated to the composition of these substances. Therefore the scope of the proposed entry covers all dioctyltin dialkyl substances that are represented by an alkyl descriptor that may also be considered for coconut fatty acids.

1.1 Name and other identifiers of the substance

Table 1: Substance identity [1]

EC number:	222-883-3
EC name:	Diocetyl tin dilaurate
CAS number (in the EC inventory):	3648-18-8
Deleted CAS numbers:	1245942-04-4
CAS name:	Stannane, dioctylbis[(1-oxododecyl)oxy]-
IUPAC name:	[dodecanoyloxy(dioctyl)stannyl] dodecanoate
Index number in Annex VI of the CLP Regulation:	050-031-00-9
Molecular formula:	C ₄₀ H ₈₀ O ₄ Sn
Molecular weight range:	743.7708
Synonyms:	<p>Bis(lauroyloxy)dioctylstannane Di-n-octyl-zinn dilaurat Di-n-octyltin dilaurate Stannane, bis(dodecanoyloxy)dioctyl- Stannane, bis(lauroyloxy)dioctyl- Stannane, didodecanoyloxydioctyl- Stannane, dioctylbis((1-oxododecyl)oxy)- Stannane, dioctylbis(lauroyloxy)- Stannane, dioctyl di(lauroyloxy)- Stannane, dioctyl didodecanoyloxy- Tin, dioctyl-, dilaurate dioctylstannanebis(ylum) didodecanoate Diocetyl tin laurate diottil dilaurato Stannane, dioctylbis[(1-oxododecyl)oxy] - Stannane, dioctylbis[(1-oxododecyl)oxy] DOTL</p>

Structural formula:

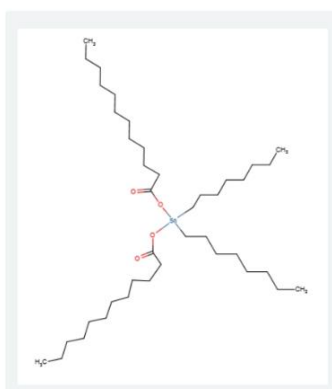


Table 2: Substance identity [2]

EC number:	293-901-5
EC name:	Stannane, dioctyl-, bis(coco acyloxy) derivs.
CAS number (in the EC inventory):	91648-39-4
Deleted CAS numbers:	-
CAS name:	-
IUPAC name:	-
Index number in Annex VI of the CLP Regulation:	050-031-00-9
Molecular formula:	n.a. (UVCB)
Molecular weight range:	-
Synonyms:	-

Structural formula: n.a. (UVCB)

1.2 Composition of the substance

Name [1]: Dioctyltin dilaurate

Description [1]: Organotin compound

Substance type [1]: Mono-constituent

Name [2]: Stannane, dioctyl-, bis(coco acyloxy) derivs.

Description [2]: Organotin compound

Substance type [2]: UVCB³

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

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

³ Substances of Unknown or Variable composition, Complex reaction products or Biological materials.

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

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

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

Diocetyl tin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. are covered by Index number 050-031-00-9 in part 3 of Annex VI to the CLP Regulation as follows⁴:

Table 3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
050-031-00-9	diocetyl tin 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)	GHS08 Dgr	H360D H372 (immune system)			

3. Environmental fate properties

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

4. Human health hazard assessment

Please see Chapter 2 (Harmonised classification and labelling).

⁴ COMMISSION DELEGATED REGULATION (EU) 2020/1182 of 19 May 2020 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures. Official Journal of the European Union, L261/2, 11.8.2020.

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

The substances are exemplified by dioctyltin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. However, the conclusions apply to all substances covered by the substance name definition (see section 1).

Dioctyltin dilaurate and stannane, dioctyl-, bis(coco acyloxy) derivs. are covered by index number 050-031-00-9 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and they are classified in the hazard class toxic for reproduction category 1B (H360D⁵).

Therefore, this classification of the substances in Regulation (EC) No 1272/2008 shows that they meet the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

6.2 PBT and vPvB assessment

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

6.3 Assessment under Article 57(f)

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

⁵ H360D: 'May damage the unborn child'.