

## Annex XV report

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

Substance Name(s):

Diocetyl tin 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): -

Submitted by: Sweden

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## PROPOSAL FOR 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 proposed to be 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 1B<sup>1</sup>.

Summary of how the substance meets 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 (H360D<sup>2</sup>).

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.)

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

<sup>2</sup> H360D: 'May damage the unborn child'.

## PART I

### Justification

#### 1. Identity of the substance and physical and chemical properties

This Annex XV 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.

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 manufacturing process consists in 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 report 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.

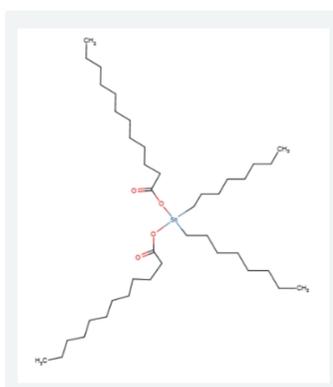
ANNEX XV – IDENTIFICATION OF DIOCTYL TIN DILAURATE, STANNANE, DIOCTYL-, BIS(COCO ACYLOXY) DERIVS., AND ANY OTHER STANNANE, DIOCTYL-, BIS(FATTY ACYLOXY) DERIVS. WHEREIN C12 IS THE PREDOMINANT CARBON NUMBER OF THE FATTY ACYLOXY MOIETY AS SVHC

## 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 <sub>40</sub> H <sub>80</sub> O <sub>4</sub> Sn
Molecular weight range:	743.7708
Synonyms:	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, dioctyldi(lauroyloxy)- Stannane, dioctyldidodecanoyloxy- Tin, dioctyl-, dilaurate dioctylstannanebis(ylum) didodecanoate Diocetyl tin laurate diottil dilaurato Stannane, dioctylbis[(1-oxododecyl)oxy] - Stannane, dioctylbis[(1-oxododecyl)oxy] DOTL

Structural formula:



ANNEX XV – IDENTIFICATION OF DIOCTYL TIN 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 SVHC

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]: UVCB<sup>3</sup>

## 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.

<sup>3</sup> 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 follows<sup>4</sup>:

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).

<sup>4</sup> 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 (H360D<sup>5</sup>).

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.

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<sup>5</sup> H360D: 'May damage the unborn child'.

## Part II

Diocetyl tin dilaurate has one full registration in REACH, whereas there is no registration for stannane, dioctyl-, bis(coco acyloxy) derivs. According to the REACH lead registrant of diocetyl tin 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 diocetyl tin dilaurate (personal communication, January 2016).

Thus, the information in Part II refers only to the registration for diocetyl tin dilaurate.

## 7. Registration and C&L notification status

### 7.1 Registration status

Table 4: Registration status of diocetyl tin dilaurate.

From the ECHA dissemination site <sup>6</sup>	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

### 7.2 CLP notification status

Table 5: CLP notifications for diocetyl tin dilaurate.

	CLP Notifications <sup>7</sup>
Number of aggregated notifications	21
Total number of notifiers	1021

## 8. Total tonnage of the substance

Table 6: Tonnage status for diocetyl tin dilaurate.

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) <sup>8</sup>	100-1000 t/pa
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<sup>6</sup> <https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/13131> (accessed 2020-05-05)

<sup>7</sup> C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 2020-05-05)

<sup>8</sup> <https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/13131> (accessed 2020-05-05)

## 9. Information on uses of the substance

Diocetyl tin dilaurate has one joint submission supported by 9 companies. The total tonnage band is 100-1000 tonnes per year and the substance has widespread use (i.e. used by formulators, industrial workers, professional workers, consumers and users of articles). According to the registered uses, there is high potential for exposure of workers through, for example, PROC 7 (industrial spraying), PROC 10 (roller application or brushing) and PROC 11 (non-industrial spraying).

Generally, mono- and diorganotin compounds are used as stabilisers and catalysts in the production of e.g. plastics and rubber. Diocetyl tin dilaurate is used in a wide variety of product categories including: adhesives and sealants, coatings and paints, thinners, paint removers, fillers, putties, plasters, modelling clay, metal surface treatment products, non-metal-surface treatment products, ink and toners, products such as pH-regulators, flocculants, precipitants, neutralisation agents, leather treatment products, paper and board treatment products, polishes and wax blends, polymer preparations and compounds, textile dyes and impregnating products as well as washing and cleaning products.

Diocetyl tin dilaurate is used for the manufacture of the following article categories: plastic products, fabrics, textiles, apparel, and leather.

Table 7: Uses of diocetyl tin dilaurate

	Uses	Registered use	Use likely in the scope of Authorisation
Uses as intermediate		No	-
Formulation or repacking	<p>Formulation of dry blend ERC: 3 PROC: 2, 4, 5, 8b, 9, 15, 21, 24 PC: 32</p> <p>Formulation of preparations ERC: 2 PROC: 2, 3, 4, 5, 7, 8a, 8b, 9, 15 PC: 1, 9a, 18, 26, 32, 34</p> <p>Manufacture of enamel ERC: 2 PROC: 1, 3, 5, 8a, 9, 15</p> <p>Manufacture of powder coatings and inks ERC: 2 PROC: 1, 2, 3, 5, 8a, 8b, 9, 15 PC: 9a, 18</p>	Yes	Yes
Uses at industrial sites	<p>Use of products containing substance as a catalyst process regulator ERC: 4, 5, 6b, 6d PROC: 1, 2, 3, 4, 5, 7, 8a, 9, 10, 13, 14, 16 PC: 1, 9a, 9b, 14, 15, 19, 20, 23, 26, 31, 32, 34, 35, 0 (K35000, P15500, P15900) SU 5, 6a, 6b, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 23, 24</p>	Yes	Yes

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	<p>Use in production of polymers, masterbatches and compounds  ERC: 5  PROC: 4, 5, 8a, 8b, 9, 14, 15  PC: 32  SU: 12</p> <p>Use of additive, plastic, masterbatch or compound in calendaring  ERC: 5  PROC: 4, 5, 6, 8a, 8b, 9, 10, 12, 21, 24  PC: 32  SU: 12</p> <p>Use of additives, plastic, masterbatch or compound in extrusion, injection and moulding applications  ERC: 5  PROC: 4, 5, 8a, 8b, 9, 14, 15, 21, 24  PC: 32  SU: 12</p> <p>Use of additives, plastic, masterbatch or compound in spread or dip coating  ERC: 5  PROC: 4, 5, 8a, 8b, 9, 10, 15, 21, 24  PC: 32  SU: 12</p> <p>Use of additives, masterbatch or compound in foam production by steaming  ERC: 5  PROC: 4, 5, 8a, 8b, 9, 12, 15  PC: 32  SU: 12</p> <p>Use as an additive to prevent reaction of polymer with reactive diluent  ERC: 6d  PROC: 4, 15  PC: 32</p> <p>Use as an additive for the production of rubber tyres  ERC: 5, 6d  PROC: 4, 5, 8b, 9, 14, 15  SU: 11</p> <p>Polymer industry  ERC: 6d  PROC: 8a, 8b, 14  PC: 32  SU: 12</p> <p>Electrical wire enamelling and coating  ERC: 4, 5  PROC: 1, 2, 3, 5, 7, 8a, 10, 13, 15</p>		
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	<p>Industrial application of coatings and inks ERC: 4 PROC: 1, 2, 3, 4, 5, 7, 8a, 8b, 10, 13, 15</p> <p>Use as a reactive catalyst, intermediate ERC: 4, 6a PROC: 1, 2, 4, 5, 8b, 9, 14, 15</p>		
Uses by professional workers	<p>Use of products containing substance as a catalyst process regulator ERC: 8c, 8f PROC: 10, 11, 19 PC: 1, 9a, 26, 32, 34, PC 0 (P15500; P15900; UCN D25000)</p> <p>Professional application of coatings and inks ERC: 8a, 8c, 8d, 8f PROC: 2, 3, 4, 5, 8a, 10, 11, 15</p>	Yes	Yes
Consumer uses	<p>Consumer use of products containing substance as a catalyst process regulator ERC: 8c, 8f PC: 1</p>	Yes	Yes
Article service life	<p>Service life (workers) ERC: 10a, 11a PROC: 21, 24 AC: 5, 6</p> <p>Service life (consumers) ERC: 10a, 10b, 11a AC: 5, 6, 13</p>	Yes	Yes

At the ECHA dissemination site, the reported uses are listed several times. Therefore, the aggregated sum-up of all descriptors for a specific use are listed in table.

According to the Nordic database SPIN<sup>9</sup>, the total tonnages of dioctyltin dilaurate in 2017 were 2.6, 0.5, 0.2 and 0.7 tonnes in Sweden, Norway, Finland and Denmark, respectively. The number of preparations<sup>10</sup> containing dioctyltin dilaurate has increased in all Nordic countries. In addition, the total tonnage in 2010-2017 was higher than in 2000-2009, which indicates an overall increase. Also for other dioctyltin compounds (dioctyltin oxide, dioctylbis(pentane-2,4-dionato-O,O')tin and diisooctyl 2,2'-[(dioctylstannylene)bis(thio)]diacetate), the tonnage has increased. This could be an effect of the more rigid restriction of dibutyltin compounds, specified in entry 20 of Annex XVII to REACH and implemented in 2012, which may have shifted the use towards dioctyltin compounds. This is supported by a decreasing tonnage of dibutyltin compounds (dibutyl dilaurate and tin, dibutylbis(2,4-pentanedionato-O,O')-), reported in the SPIN database.

<sup>9</sup> <http://spin2000.net/> accessed on 2020-05-05

<sup>10</sup> The definition of a *preparation* in the SPIN database is equal to the definition of a *mixture* under REACH and CLP.

## 10. Information on structure of the supply chain

There is one joint submission for dioctyltin dilaurate supported by 9 companies located in 5 European countries. The substance is used at a high number of industrial sites. Also, a large number of companies (1021) have notified the substance in the C&L inventory. The substance is used in all life cycle stages and in a large number of product categories (15), article categories (3) and sectors of use (16). Taken together, the actors using the substance are diverse and the supply chain can be regarded as complex.

## 11. Additional information

### 11.1 Substances with similar hazard and use profiles on the Candidate List

Other dioctyltin compounds on the Candidate list:

- 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).
- Reaction mass of DOTE and MOTE, i.e. Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (MOTE, EC: 248-227-6, CAS: 27107-89-7).

### 11.2 Alternatives

Alternatives to organotin compounds used as PVC stabilisers or catalysts in the production of consumer articles have been evaluated in a consultant study from 2007, commissioned by the European Commission. The authors stated that there are suitable non-tin alternatives available on the market for most applications. Furthermore, a three-year phase-out period for dioctyltin compounds in consumer articles was deemed reasonable (RPA 2007).

It should be noted that the report is more than 10 years old and may not be fully applicable today as more feasible alternatives or technical solutions may have emerged since.

### 11.3 Existing EU legislation

- The use of dioctyltin compounds is restricted to 0.1% by weight of tin in certain article categories (textile articles or footwear intended to come into contact with the skin; gloves; wall and floor coverings; childcare articles; female hygiene products; nappies, and; two-component room temperature vulcanisation moulding kits) sold to the general public (Regulation (EC) 1907/2006, Annex XVII, entry 20:6, REACH).
- The use of organotin compounds is restricted for certain biocidal applications in aquatic environments and for treatment of industrial waters (Regulation (EC) 1907/2006, Annex XVII, entry 20:1-3, REACH).

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- Dioctyltin compounds are included in part 1 of Annex 1 to Regulation (EU) No 649/2012 concerning Prior Informed Consent (PIC).
- Dioctyltin dilaurate is included in a group restriction of 14 dioctyltin compounds in plastic materials and articles intended to come into contact with food (Regulation (EU) 10/2011). These compounds are covered by a total specific migration limit (SML(T)) of 0.006 mg/kg expressed as tin.
- Organotin compounds are included in the indicative list of the main pollutants in Annex VIII, entry 3, of the Water Framework Directive (WFD) (2000/60/EC), with related provisions (Directive 2008/105/EC, Directive 2006/11/EC, Directive 2010/75/EU, Regulation 166/2006/EC, Regulation 782/2003/EC).

## REFERENCES

### References for Part II

- EC (2000). Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, L 327/1.
- EC (2003). Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships, L 115/1.
- EC (2006). Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC.
- EC (2006). Directive 2006/11/EC of the European Parliament and of the Council of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, L 64/52.
- EC (2008). Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, L 348/84.
- EC (2010). Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control). L334/17.
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