

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: Dibutylbis(pentane-2,4-dionato-O,O')tin

EC Number: 245-152-0

CAS Number: 22673-19-4

Submitted by: Swedish Chemicals Agency (KemI)

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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: Dibutylbis(pentane-2,4-dionato-O,O')tin

EC Number: 245-152-0

CAS Number: 22673-19-4

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B¹.

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

ECHA's Risk Assessment Committee (RAC) has adopted an opinion on a proposed harmonised classification and labelling of dibutylbis(pentane-2,4-dionato-O,O')tin as Repr. 1B (H360DF) and STOT RE 1 (H372, immune system)². Dibutylbis(pentane-2,4-dionato-O,O')tin is included in the 14th ATP to Regulation (EC) 1272/2008, Annex VI (CLP).

Dibutylbis(pentane-2,4-dionato-O,O')tin is covered by index number 650-056-00-0 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 it is classified in the hazard class toxic for reproduction category 1B (H360FD³).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

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

Registration dossiers submitted for the substance: Yes

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

² RAC opinion, adopted 5th of December 2017, [CLH-O-0000001412-86-184/F](#).

³ H360FD: 'May damage fertility. May damage the unborn child'.

PART I

Justification

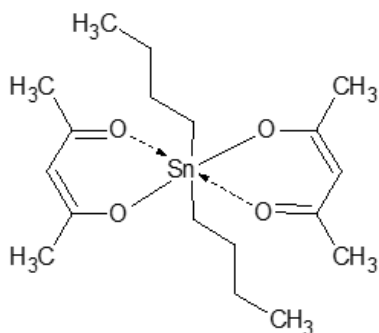
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	245-152-0
EC name:	Dibutylbis(pentane-2,4-dionato-O,O')tin
CAS number (in the EC inventory):	22673-19-4
Other CAS number:	50701-16-1
CAS name:	Tin, dibutylbis(2,4-pentanedionato.kappa.O2, .kappa.O4)-, (OC-6-11)-
IUPAC name:	<ul style="list-style-type: none"> • (3Z,3'Z)-4,4'-[(Dibutylstannandiyl)bis(oxy)]bis(3-penten-2-on) • (Z)-4-oxopent-2-en-2-olate; pentane; tin(4 +) • 6,6-dibutyl-2,4,8,10-tetramethyl-1λ³,5,7λ³,11-tetraoxa-6-stannaspiro[5.5]undeca-1,3,7,9-tetraene • Tin, dibutylbis(2,4-pentanedionato-kO2,kO4)-,
Index number in Annex VI of the CLP Regulation	650-056-00-0
Molecular formula:	C ₁₈ H ₃₂ O ₄ Sn
Molecular weight range:	431.15
Synonyms:	<ul style="list-style-type: none"> • DBTP • Dibutyltin bis(2,4-pentanedionate) • Di-n-butylbis(2,4-pentanedionate)tin • Dibutyltin bis(acetylacetonate) • ZINC170157078 • 3-Penten-2-one, 4,4'-[(dibutylstannylene)bis(oxy)]bis-, (3Z,3'Z) • (Z)-4-[dibutyl-[(Z)-1-methyl-3-oxo-but-1-enoxy]stannyl]oxypent-3-en-2-one • Dibutyltin ketonate • Dibutyltin diketonate

Structural formula:



1.2 Composition of the substance

Name: Dibutylbis(pentane-2,4-dionato-O,O')tin

Description: organotin compound

Substance type: Mono-constituent

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.

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

ECHA's Risk Assessment Committee (RAC) has adopted an opinion on a proposed harmonised classification and labelling of dibutylbis(pentane-2,4-dionato-O,O')tin as Repr. 1B (H360FD) and STOT RE 1 (H372, immune system). Dibutylbis(pentane-2,4-dionato-O,O')tin is included in the 14th ATP to Regulation (EC) 1272/2008, Annex VI (CLP).

Dibutylbis(pentane-2,4-dionato-O,O')tin is covered by Index number 650-056-00-0 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: 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	Chemical name	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)		
650-056-00-0	Dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	Repr. 1B STOT RE 1	H360FD H372 (immune system)	GHS08 Dgr	H360FD 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

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

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

Dibutylbis(pentane-2,4-dionato-O,O')tin is covered by index number 650-056-00-0 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 it is classified in the hazard class toxic for reproduction category 1B (H360FD⁴).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

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

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.

⁴ H360FD: 'May damage fertility. May damage the unborn child'.

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3: Registration status

From the ECHA dissemination site ⁵	
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 4: CLP notifications

	CLP Notifications ⁶
Number of aggregated notifications	13
Total number of notifiers	162

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁷	100-1,000 t/pa
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9. Information on uses of the substance

Dibutylbis(pentane-2,4-dionato-O,O')tin is manufactured and registered by one company, which can be regarded as a large-sized enterprise. The company handles several chemicals including other butyltin compounds. There are no PPORDs or downstream user reports available.

The functions of organotins, in general, within the different uses are:

- as biocides to prevent microbiological activities in wood preservatives, marine biocides, agricultural pesticides and in industrial wet processes in textile and shoe industry but also for the anti-odour treatment of final products,

⁵ <https://echa.europa.eu/registration-dossier/-/registered-dossier/11900> (accessed 18 September 2019)

⁶ C&L Inventory database, <http://echa.europa.eu/web/quest/information-on-chemicals/cl-inventory-database> (accessed 18 September 2019)

⁷ <https://echa.europa.eu/registration-dossier/-/registered-dossier/11900> (accessed 18 September 2019)

- as additives in plastic material,
 - as stabilisers in polymers or in plastisol prints,
- as catalysts and stabilisers in plastics, rubber, inks, paints, metallic glitter, and heat transfer material.

Dibutylbis(pentane-2,4-dionato-O,O')tin is manufactured for use in;

- adhesives, sealants, coatings and paints, thinners, paint removes, paper and board treatment products, dyes, finishing and impregnation products including bleaches and other processing aids, polymer preparations in production of resins and rubber, and textile dyes, and

for the manufacture of;

- textiles, leather, fur, wood and wood products, pulp, paper and paper products, rubber products, computer, electronic and optical products, electrical equipment, building and construction work and general manufacturing, e.g. machinery, equipment, vehicles, other transport equipment.

In summary, dibutylbis(pentane-2,4-dionato-O,O')tin has wide dispersive uses covering both:

- widespread use, i.e. industrial use, professional use, consumer use and articles service life.
- high potential for human exposure through, for example, PROC 10 (roller application or brushing), PROC 11 (non-industrial spraying), and PROC 13 (treatment of articles by dipping and pouring).

Table 6: Uses

	Use(s)	Registered use	Use possibly in the scope of Authorisation
Uses as intermediate	Manufacture of substance (PROC 4, 8b). Intermediate (PROC 2, 4, 5, 8b, 9, 14). ERC 1, 6a.	Yes	No
Formulation or repacking	Formulation of preparations (PROC 1-5, 8b, 9). ERC 2. PC 1, 9a, 26, 32, 34.	Yes	Yes
Uses at industrial sites	Research and development (PROC 7, 9, 10). ERC 8b. Catalyst and/or process regulator in a mixture (PROC 2-5, 8a, 8b, 9, 10, 13, 14). ERC 3, 5, 6b, 6d. PC 0 (P15500/15900), 1, 9a, 26, 32, 34.	Yes	Yes
Uses by	Catalyst and/or process regulator in a	Yes	Yes

professional workers	mixture (PROC 4, 5, 8a, 8b, 10, 11). ERC 8a, 8c, 8d, 8f. PC 0 (P15500/15900), 1, 9a.		
Consumer uses	Catalyst and/or process regulator in products with consumer applications. ERC 8a, 8c, 8d, 8f. PC 0 (P15500/15900), 1.	Yes	Yes
Article service life	Vehicles (AC 1), Machinery, mechanical appliances, electrical/electronic articles (AC 2), Electrical batteries (AC 3), Fabrics, textiles and apparel (AC 5), Leather articles (AC 6).	Yes	Yes

10. Information on structure of the supply chain

Dibutylbis(pentane-2,4-dionato-O,O')tin has one registrant affiliated in Mannheim Germany. In total, 162 companies have notified the substance in the C&L Inventory. The substance is used throughout the supply chain covering industrial use, professional use, consumer use and articles service life. It is manufactured in 100-1000 tpa and used in a large number of products within different sectors (see section 9).

In the latest version of the Report on exports and imports in 2017 of chemicals listed in Annex I to the Prior Informed Consent (PIC) Regulation, dibutyltin compounds including dibutylbis(pentane-2,4-dionato-O,O')tin was exported in total of 75 tonnes from the Netherlands, Germany and Spain to Brazil, Colombia, United States, China, Malaysia, Turkey and Switzerland.

11. Additional information

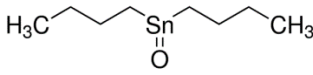
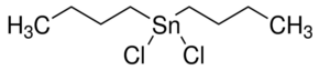
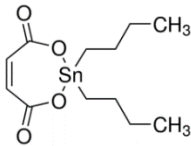
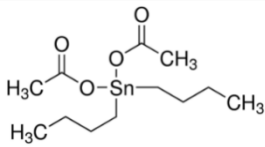
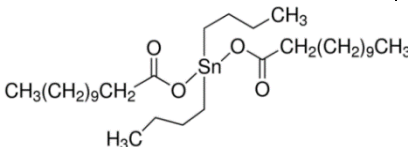
11.1 Substances with similar hazard and use profiles on the Candidate List

Dibutylbis(pentane-2,4-dionato-O,O')tin is considered to have similar properties and/or uses to dibutyltin dichloride (EC/CAS no. 211-670-0 / 683-18-1), which is already included in the Candidate List as toxic for reproduction (Article 57c) and was used as a source substance in the read-across approach for the harmonised classification and labelling of dibutylbis(pentane-2,4-dionato-O,O')tin as Repr. 1B (H360FD) and STOT RE 1 (H372 immune system) (Table 7).

11.2 Other similar substances

Also, other dibutyltin compounds were used as supportive data on reproductive effects on development in the read-across approach for the harmonised classification and labelling of dibutylbis(pentane-2,4-dionato-O,O')tin (Table 7).

Table 7: Example of structurally similar substances used in read-across

Substance	EC # / CAS #	Structure	Harmonised C&L
Dibutyltin oxide (DBTO)	212-449-1 / 818-08-6		
Dibutyltin dichloride (DBTC)	211-670-0 / 683-18-1		Muta. 2, Repr. 1B, Acute Tox. 2/3/4*, STOT RE 1, Skin Corr. 1B, Aquatic Acute and Chronic 1. Included in the Candidate List: Toxic for reproduction (Article 57c).
Dibutyltin maleate (DBTM)	201-077-5 / 78-04-6		
Dibutyltin (di)acetate (DBTA)	213-928-8 / 1067-33-0		
Dibutyltin dilaurate (DBTL)	201-039-8 / 77-58-7		Muta. 2, Repr. 1B, STOT RE 1

11.3 Alternatives

As a follow-up to a study on targeted risk assessment of organotins deemed to be of highest concern in consumer products namely dibutyltin, dioctyltin, tributyltin, and triphenyltin compounds, the European Commission contracted a study to collect information, among other things, on existing alternatives at Community level (RPA, 2007, SEC 2009). The study suggested several possible alternatives to these organotins, however this information is possibly outdated and needs to be overseen and complemented before any conclusion on available alternatives to current uses is made.

11.4 Existing EU legislation

- Dibutyltin compounds are restricted in mixtures and articles where the concentration is greater than the equivalent of 0.1 % by weight of tin for supply to the general public (Regulation (EC) 1907/2006, Annex XVII, entry 20:5, REACH).
- Dibutyltins are also 'Severely restricted' concerning export and import of hazardous chemicals of certain uses (Regulation (EU) 649/2012, Annex I, Part I, PIC).
- Dibutylbis(pentane-2,4-dionato-O,O')tin has a harmonised classification as Repr. 1B (H360DF) and STOT RE 1 (H372) and included in the 14th ATP to Regulation (EC) 1272/2008, Annex VI (CLP).
- Due to the harmonised classification of dibutylbis(pentane-2,4-dionato-O,O')tin as Repr. 1B (H360FD) the substance will soon not be placed on the market, or used as a substance, as a constituent of other substances, or in mixtures for supply to the *general public* when the individual concentration in the substance or mixture is equal to or greater than the relevant specific or generic concentration limit specified in Part 3 of Annex VI, in the CLP Regulation (REACH Regulation, Annex XVII, entry 30).
- Organotin compounds have been selected amongst those which present a significant risk to or via the aquatic environment and therefore included in an indicative list in the Water Framework Directive (Directive 2000/60/EC, Annex VIII, entry 3) with related provisions (Directive 2008/105/EC, Directive 2006/11/EC, Directive 2010/75/EU, Regulation 166/2006/EC, Regulation 782/2003/EC).

References for Part I

RAC opinion, adopted 5th of December 2017, CLH-O-0000001412-86-184/F.

References for Part II

ECHA (2019): Dibutylbis(pentane-2,4-dionato-O,O')tin. Information on registered substances, published on ECHA's website <https://echa.europa.eu/sv/substance-information/-/substanceinfo/100.041.032> (accessed on 18 September 2019).

EC (98). Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), L 131/11.

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.

EU (2004). Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version). Official Journal of the European Union, L158: 50-76.

OECD (2006). SIDS INITIAL ASSESSMENT PROFILE, Dibutyltins <https://hvpchemicals.oecd.org/ui/handler.axd?id=cc85f5bb-0ccd-4713-9fa6-d7372acffa54>, accessed 2019-10-22.

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 (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, L 33/1.

EU (2006). 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. Official Journal of the European Union, L396: 1-849.

RPA (2007). Risk & Policy Analysts Limited, Impact Assessment of Potential Restrictions on the Marketing and Use of Certain Organotin Compounds, Final Report prepared for European Commission Directorate-General Enterprise and Industry, October 2007.

EU (2007). Corrigendum to 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. Official Journal of the European Union, L136: 3-280.
- 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.
- EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- EU (2009). Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 as regards of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII. Official Journal of the European Union, L164: 7-31.
- SEC (2009). COMMISSION OF THE EUROPEAN COMMUNITIES, Brussels, 28.5.2009, SEC(2009) 705 final, COMMISSION STAFF WORKING DOCUMENT Impact Assessment Report Proposal for a COMMISSION DECISION amending Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (Organostannic compounds).
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- PIC (2017). Report on exports and imports in 2017 of chemicals listed in Annex I to the Prior Informed Consent (PIC) Regulation (EU) 649/2012. https://echa.europa.eu/documents/10162/21728206/pic_article_10-2017_en.pdf/1d6f3191-00d3-7c03-996e-75ec86e1b44f
- OSHA (2019). Occupational Safety and Health Administration (OSHA), part of United States Department of Labor, <https://www.osha.gov/dsg/annotated-pels/tablez-1.html>.
- ACGIH (2019). American Conference of Governmental Industrial Hygienists (ACGIH). Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, <https://www.nsc.org/Portals/0/Documents/facultyportal/Documents/fih-6e-appendix-b.pdf>.