

## **Annex XV dossier**

### **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name:** Dibutyltin dichloride  
**EC Number:** 211-670-0  
**CAS Number:** 683-18-1

**Submitted by:** Swedish Chemicals Agency  
**Version:** August 2012

**PUBLIC VERSION:** This version does not include the confidential annex referred to in the report.

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### ABBREVIATIONS AND ACRONYMS

The list includes abbreviations and acronyms used in this dossier and in the confidential annexes to the dossier.

AC	Article Category
CSR	Chemical Safety Report
DBTC	Dibutyltin dichloride
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
ERC	Environmental Release Category
ES	Exposure Scenarios
EU	European Union
NOAEL	No Observed Adverse Effect Level
OECD	Organisation for Economic Co-operation and Development
PROC	Process Category
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RPA	Risk & Policy Analysts Ltd.
SSL	Subsequent Service Life
SU	Sector of end Use
SVHC	Substances of Very High Concern

## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN**

**Substance Name: Dibutyltin dichloride**

**EC Number: 211-670-0**

**CAS Number: 683-18-1**

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B under Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 as well as its corresponding classification under Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 as toxic for reproduction category 2.

### **Summary of how the substance meets the CMR (Cat 1A or 1B) criteria**

Dibutyltin dichloride (DBTC) is listed as Index number 050-022-00-X of Regulation (EC) No 1272/2008<sup>1</sup> as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009<sup>2</sup> of 10 August 2009, and classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). The corresponding classification in Annex VI of this regulation, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Council Directive 67/548/EEC<sup>3</sup>) is Repr. Cat. 2; R60 (“May impair fertility”) - R61 (“May cause harm to the unborn child”). Therefore, this classification shows that DBTC meets the criteria for classification as toxic for reproduction in accordance with Article 57(c) of REACH<sup>4</sup>.

**Registration dossiers submitted for the substance: Yes**

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<sup>1</sup> 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.

<sup>2</sup> COMMISSION REGULATION (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

<sup>3</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

<sup>4</sup> 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.

## PART I

## JUSTIFICATION

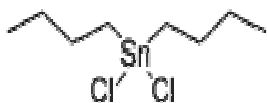
## 1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

## 1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	211-670-0
EC name:	dibutyltin dichloride
CAS number (in the EC inventory):	683-18-1
CAS number:	683-18-1
CAS name:	stannane, dibutyldichloro-
IUPAC name:	dibutyltin dichloride
Index number in Annex VI of the CLP Regulation	050-022-00-X
Molecular formula:	$C_8H_{18}Cl_2Sn$
Molecular weight range:	303.8445 g/mol
Synonyms:	Axion CS 2430 DBTCI Dibutyltindichloride; (DBTC) Dibutyldichlorostannane Tin dibutyl-dichloride

## Structural formula:



**1.2 Composition of the substance****Name:** Dibutyltin dichloride**Description:** Mono constituent substance**Degree of purity:** For REACH registration data *see Confidential Annex, Section 1.***Table 2: Constituents**

Constituents	Typical concentration	Concentration range	Remarks
Dibutyltin dichloride CAS No. 683-18-1	<i>See Confidential Annex, Section 2, Table 1</i>	<i>See Confidential Annex, Section 2, Table 1</i>	

**Table 3: Impurities**

Impurities	Typical concentration	Concentration range	Remarks
<i>See Confidential Annex, Section 3, Table 2</i>	<i>See Confidential Annex, Section 3, Table 2</i>	<i>See Confidential Annex, Section 3, Table 2</i>	

**Table 4: Additives**

Additives	Typical concentration	Concentration range	Remarks
None			According to registration information

### 1.3 Physico-chemical properties

**Table 5: Overview of physicochemical properties**

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	<i>Solid</i>	<i>From registration*</i>
Melting point	<i>37.2 - 38.2 °C</i>	<i>idem</i>
Boiling point	<i>135 °C at 10 mm Hg</i>	<i>idem</i>
Density	<i>1.40 x 10<sup>3</sup> kg/m<sup>3</sup> at 20.0 ± 0.5°C</i>	<i>idem</i>
Vapour pressure	<i>0.06 Pa at 20 °C</i>	<i>idem</i>
Water solubility	<i>320 mg/l at 20 °C and 2.53 pH</i>	<i>idem</i>
Partition coefficient n-octanol/water (log value)	<i>Log P<sub>ow</sub> 1.89 (QSAR estimate)<sup>5</sup></i>	<i>idem</i>
Flash point	<i>146 ± 2°C at 99.96 kPa</i>	<i>idem</i>

\*From dissemination database according to Regulation (EC) No. 1907/2006, article 119.

<sup>5</sup> This (Q)SAR study gets a Klimisch reliability score of 4 (not assignable). The estimated value is derived from the EPIWIN model, developed by Syracuse Research Corporation, which has not been validated for chemicals that contain metals and thus the value should be used with caution.



## 2 HARMONISED CLASSIFICATION AND LABELLING

**Table 6: Classification according to part 3 of 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		Specific Conc. Limits, M-factors
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram Signal Word Code(s)	Hazard statement code(s)	
050-022-00-X	dibutyltin dichloride; (DBTC)	211-670-0	683-18-1	Muta. 2	H341	GHS06	H341	Skin Corr. 1B; H314: C ≥ 5 % Skin Irrit. 2; H315: 0,01 % ≤ C < 5 % Eye Dam. 1; H318: 3 % ≤ C < 5 % Eye Irrit. 2; H319: 0,01 % ≤ C < 3 % M=10
				Repr. 1B	H360FD	GHS05	H360FD	
				Acute Tox. 2 *	H330	GHS08	H330	
				Acute Tox. 3 *	H301	GHS09	H301	
				Acute Tox. 4 *	H312	Dgr	H312	
					H372**		H372**	
					H314	H314		
				STOT RE 1	H400	H410		
				Skin Corr. 1B	H410			
				Aquatic Acute 1				
Aquatic Chronic 1								

\* Indicates that the classification corresponds to the minimum classification for a category.

\*\*For certain hazard classes, e.g. STOT, the route of exposure should be indicated in the hazard statement only if it is conclusively proven that no other route of exposure can cause the hazard in accordance to the criteria in Annex I. Under Directive 67/548/EEC the route of exposure is indicated for classifications with R48 when there was data justifying the classification for this route of exposure. The classification under 67/548/EEC indicating the route of exposure has been translated into the corresponding class and category according to this Regulation, but with a general hazard statement not specifying the route of exposure as the necessary information is not available.

**Table 7: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008.**

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
050-022-00-X	dibutyltin dichloride; (DBTC)	211-670-0	683-18-1	Mut. Cat. 3; R68 Repr. Cat. 2; R60-61 T+; R26	T+; C; N R: 60-61-21-25-26-34-48/25-68-50/53	C; R34: C ≥ 10 % Xi; R36/38: 0,01 % ≤ C < 10 % N; R50-53: C ≥ 2,5 % N; R51-53: 0,25 % ≤	E

				T; R25-48/25 C; R34 Xn; R21 N; R50-53	S: 53-45-60-61	C < 2,5 % R52-53: 0,025 % ≤ C < 0,25 %	
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*Note E: Substances with specific effects on human health (see Chapter 4 of Annex VI to Directive 67/548/EEC) that are classified as carcinogenic, mutagenic and/or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are also classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances, the risk phrases R20, R21, R22, R23, R24, R25, R26, R27, R28, R39, R68 (harmful), R48 and R65 and all combinations of these risk phrases shall be preceded by the word 'Also'.*

### **3 ENVIRONMENTAL FATE PROPERTIES**

Not relevant for this dossier.

### **4 HUMAN HEALTH HAZARD ASSESSMENT**

See section 2 on Harmonised Classification and Labelling.

### **5 ENVIRONMENTAL HAZARD ASSESSMENT**

Not relevant for this dossier.

### **6 CONCLUSIONS ON THE SVHC PROPERTIES**

#### **6.1 CMR assessment**

DBTC is listed as Index number 050-022-00-X of Regulation (EC) No 1272/2008 as amended and adapted to technical and scientific progress by Regulation (EC) No 790/2009 of 10 August 2009, and classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360FD: “May damage fertility. May damage the unborn child.”). The corresponding classification in Annex VI of this regulation, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Council Directive 67/548/EEC) is Repr. Cat. 2; R60 (“May impair fertility”) - R61 (“May cause harm to the unborn child”). Therefore, this classification shows that DBTC meets the criteria for classification as toxic for reproduction in accordance with Article 57(c) of REACH.

## PART II

### INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

#### 1. INFORMATION ON MANUFACTURE, USE AND EXPOSURE

##### 1.1 Manufacture process and volumes

DBTC is produced by the reaction between tin tetrachloride (SnCl<sub>4</sub>) and a transalkylation agent. The final product is a mixture with monobutyltin trichloride (CAS No. 1118-46-3) and is distilled or recrystallized to purify (OECD, 2006). DBTC is manufactured in a closed system to prevent moisture and air from it (OECD, 2006). Tributyltin chloride (CAS No. 1461-22-9) is one among the impurities of the manufactured product (OECD, 2006).

No publicly available information for DBTC on annual EU import/export volumes could be identified. DBTC has been registered by the 2010 REACH registration deadline within the total tonnage band 1,000 – 10,000 t/y. It has been C&L notified to ECHA by 78 companies (*Source: C&L Inventory Database, available online at: <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>, accessed on 2012-08-20*).

*For more information on tonnage in the EU see Confidential Annex, Section 4.*

##### 1.2 Uses

Technical functions of DBTC are as an additive in rubber, stabiliser in PVC plastics, catalyser in the production of polyurethanes and silicones; use in insulations and coatings (*Source: SIN List Database, <http://w3.chemsec.org/chemical/275/>, accessed on 2012-08-20*). DBTC is used in food wraps and food packaging, T-shirts, polyurethane gloves, sanitary napkins, medical equipment, cellophane wrap and soft toys, PVC plastics (water pipes, packing materials, textile products), silicone rubber (sealants, dental products, paper coatings), polyurethanes (foam plastics, glue/sealants), glass (coatings), insulators in electronics and cables, deworming agent for poultry, polyurethanes, transparent plastic (*Source: SIN List Database <http://w3.chemsec.org/chemical/275/>, accessed on 2012-08-20*). Organotins (mono and di-substituted) use as PVC stabilisers is the largest of all of their uses (RPA, 2007). Of all the organotins, mercaptides (tin-sulphur bond) and carboxylates (tin-oxygen bond) have the best stabilising performance (Baerlocher, 2012). DBTC is mainly used as an intermediate in the production of other dibutyltin compounds (OECD, 2006).

The information presented in this Part II has been limited predominantly to that from the registration dossier as it is a primary source and existing previous information might not be relevant

as the below restrictions have/will have a significant impact on the market and uses. DBTC is restricted under the following two entries of Annex XVII of REACH.

➔ According to generic entry 30 for reprotoxic substances as follows

*“Shall not be placed on the market, or used,*

- as substances,*
- as constituents 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:*

*— either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,*

*— the relevant concentration specified in Directive 1999/45/EC.*

*Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: ‘Restricted to professional users’.”*

There is no specific concentration limit in part 3 of Annex VI to Regulation (EC) No 1272/2008 for DBTC for its reprotoxic properties. The 0.5% by weight cut-off value for reprotoxic substances specified in Directive 1999/45/EC<sup>6</sup> is therefore applicable for above restrictions (from 2015, for mixtures, the cut-off value will be 0.3% by weight as per Regulation (EC) No 1272/2008).

➔ According to specific entry 20 for organostannic compounds as follows

*“1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.*

*2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:*

*(a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes;*

*(b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming;*

*(c) any totally or partly submerged appliance or equipment.*

*3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.”*

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<sup>6</sup> DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

*“5. Dibutyltin (DBT) compounds:*

*(a) Dibutyltin (DBT) compounds shall not be used after 1 January 2012 in mixtures and articles for supply to the general public where the concentration in the mixture or the article, or part thereof, is greater than the equivalent of 0,1 % by weight of tin.*

*(b) Articles and mixtures not complying with point (a) shall not be placed on the market after 1 January 2012, except for articles that were already in use in the Community before that date.*

*(c) By way of derogation, points (a) and (b) shall not apply until 1 January 2015 to the following articles and mixtures for supply to the general public:*

*— one-component and two-component room temperature vulcanisation sealants (RTV-1 and RTV-2 sealants) and adhesives,*

*— paints and coatings containing DBT compounds as catalysts when applied on articles,*

*— soft polyvinyl chloride (PVC) profiles whether by themselves or coextruded with hard PVC,*

*— fabrics coated with PVC containing DBT compounds as stabilisers when intended for outdoor applications,*

*— outdoor rainwater pipes, gutters and fittings, as well as covering material for roofing and façades,*

*(d) By way of derogation, points (a) and (b) shall not apply to materials and articles regulated under Regulation (EC) No 1935/2004.”<sup>7</sup>*

Risk & Policy Analysts Ltd. (RPA) was contracted by the Commission (DG Enterprise and Industry) “to study possible risks from the application of organostannic compounds in areas outside of their use as a biocide in anti-fouling systems, as well as describe the broad economic profile of the organotins industry”. Two reports by RPA on this in 2002 and 2003 were reviewed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) which raised some concerns that led to further study in this area by the RPA resulting in a final report in 2005 viz., “Risk assessment studies on targeted consumer applications of certain organotin compounds”. Upon identification of risks in the 2005 report, RPA was further contracted by the Commission to “assess the potential impacts of restrictions on the marketing and use of certain organotin compounds used in PVC stabilisers or catalysts in the production of consumer articles”. Subsequently, restrictions were introduced on tri-substituted, dibutyl and dioctyl organotins by amending Directive

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<sup>7</sup> REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

76/769/EEC in 2009 (2009/425/EC)<sup>8</sup> (since this directive was repealed by REACH these restrictions entered in its Annex XVII).

The uses for DBTC mentioned in the registration dossier are as an intermediate and as an additive in the production of tyre rubber (*Source: ECHA dissemination database, available at: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>, accessed on 2012-08-20*). The rubber used for the manufacture of tyre is a combination of natural and synthetic rubbers. Additives like DBTC are added to the synthetic rubber to modify them whereby the tin from DBTC forms a strong bond with carbon from the fillers such as carbon black that is used to improve the mechanical property of the synthetic rubber (Miyazaki, 2012). Typical composition of synthetic rubber in passenger tyres and in truck tyres is 27% and 14%, respectively (*Source: <http://r0.unctad.org/infocomm/anglais/rubber/uses.htm>, accessed on 2012-08-20*). The presence of DBTC at  $\geq 0.1\%$  by weight of tin in tyres for supply to and use by the general public is restricted from 1st of January 2012 according to the entry 20 of Annex XVII to REACH. Since there is no dossier update on the uses as of 2012-08-20 it is assumed that the tyre rubber with DBTC as an additive is used in the manufacture of off-the-road tyres and the tyres manufactured for export. Off-the-road tyres are used in vehicles such as dump trucks, articulated dump trucks, coal haulers, scrapers, trucks, shovels, loader, bulldozers, graders, mechanical handling equipment, cranes, log-skidders and tyre-rollers (see Table 9).

The statistics for European export of tyres in the last decade is as follows

**Table 8: European export of tyres.**

(*Source: European Tyre & Rubber Industry. Statistics 2010. Available at: [http://www.etrma.org/uploads/Modules/Documentsmanager/20101109-etrma\\_statistics\\_final.pdf](http://www.etrma.org/uploads/Modules/Documentsmanager/20101109-etrma_statistics_final.pdf), accessed on 2012-08-20*).

Year	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010 1 <sup>st</sup> half
Export of tyres in Million units	45.4	50.6	50.1	65.3	65.9	64.1	80.8	71.5	52.9	30.3

*See Confidential Annex, Section 5 for corresponding tonnage for the uses and other information.*

### 1.3 Potential Exposure

As there will be low consumer exposure owing to the Annex XVII restrictions, information has been only provided on worker and environmental exposure.

<sup>8</sup> COMMISSION DECISION of 28 May 2009 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of organostannic compounds for the purpose of adapting its Annex I to technical progress.

### 1.3.1 Workers

The following Use Descriptors were used in the registration dossier (as available on the ECHA public dissemination database of registered substances, <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>, accessed on 2012-08-20).

#### Manufacture of Substance

PROC 1: Use in closed process, no likelihood of exposure

PROC 3: Use in closed batch process (synthesis or formulation)

ERC 1: Manufacture of substances

#### Use as an intermediate

PROC 1: Use in closed process, no likelihood of exposure

ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)

SU 9: Manufacture of fine chemicals

SSL: No

#### Industrial use as an additive for the production of rubber tyres

PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises

PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)

PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation

ERC 3: Formulation in materials

ERC 5: Industrial use resulting in inclusion into or onto a matrix

ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers

SU 11: Manufacture of rubber products

SSL: Yes

AC 10: Rubber articles

As interpreted from the description of above process categories (PROC 4, 5, 8b, 9, and 14), workers are at possible risk to DBTC exposure during its use as an additive.

The dermal and inhalational exposure levels to workers have been estimated since no measured exposure data are available. *See Confidential Annex, Section 6 for more information.*

### 1.3.2 Environment

The release of DBTC to different environmental compartments is minimal (*See Confidential Annex, Section 7 for information on environmental releases*). Moreover, provisions in the following legislations apply to DBTC.

DBTC is a member of organotin group of compounds which is included in the Annex VIII (Indicative List of the Main Pollutants) to the Water Framework Directive (WFD) (2000/60/EC)<sup>9</sup>. In the Annex X (List of Priority Substances in the Field of Water Policy) tributyltin compounds have been identified as priority hazardous substances. Pursuant to *Article 16*, for those pollutants measures shall be aimed at progressive reduction and, for priority hazardous substances, as defined in *Article 2(30)*, at the cessation or phasing-out of discharges, emissions and losses. Directive 2008/105/EC<sup>10</sup> implements this by laying down Environmental Quality Standards which for tributyltin compounds is 0.0002 µg/L as an annual average value for all surface waters (as documented in the registration dossier tributyltin chloride is found as an impurity in DBTC).

Directive 2006/11/EC<sup>11</sup> (Pollution caused by Dangerous Substances Directive) compliments the provisions in the WFD by preventing or limiting release of organotins into groundwater.

Annex I to directive 96/61/EC<sup>12</sup> (Integrated Pollution Prevention and Control - IPPC) includes the chemical installations for the production of organometallic compounds as one of the many industrial activities for which measures are laid down in the directive to prevent or, where that is not practicable, to reduce emissions in the air, water and land, including measures concerning waste. As of 7 January 2014 the IPPC directive will be replaced by directive 2010/75/EU<sup>13</sup> (Industrial Emissions Directive – IED).

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<sup>9</sup> 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.

<sup>10</sup> 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.

<sup>11</sup> 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.

<sup>12</sup> COUNCIL DIRECTIVE 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control.

<sup>13</sup> DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control).



In the Annex II to Regulation (EC) No 166/2006<sup>14</sup> (concerning the establishment of a European Pollutant Release and Transfer Register – E-PRTR) the reporting threshold for releases from the industries to both water and land for organotin compounds (as total Sn) is 50 kg/year.

## **2. CURRENT KNOWLEDGE ON ALTERNATIVES**

Information on alternatives has not been assessed.

## **3. RISK-RELATED INFORMATION**

There is a possible risk to workers during the use of DBTC as an additive in the manufacture of rubber tyres as the RCRs for some of the processes involved are close to 1.

*See Confidential Annex, Section 8 for risk characterisation for workers for long-term systemic effects.*

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<sup>14</sup> 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.

### REFERENCES

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**Table 9: Examples of vehicles with off-the-road tyres.**

(Source: [http://www.bridgestone.com/products/specialty\\_tires/off\\_the\\_road/products/index.html](http://www.bridgestone.com/products/specialty_tires/off_the_road/products/index.html), accessed on 2012-08-21)

Category	Vehicles
Earthmover	 <p>Dump Trucks</p>  <p>Articulated dump trucks</p>  <p>Coal haulers</p>  <p>Scrapers</p>  <p>Trucks</p>
Loader & Dozer	 <p>Shovels, Loaders, Bulldozers</p>
Grader	 <p>Graders</p>
Industrial	 <p>Mechanical handling Equipment</p>
Mobile Crane	 <p>Cranes</p>
Logging	 <p>Log-skidders</p>
Compactor	 <p>Tire-rollers</p>