# Dibutyltin dicarboxylate salts: Human health tier II assessment

#### 27 October 2017

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# Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Stannane, dibutylbis[(1-oxooctadecyl)oxy]-	5847-55-2
Stannane, dibutylbis[(1-oxotetradecyl)oxy]-	28660-67-5
Stannane, dibutylbis[(1-oxo-9- octadecenyl)oxy]-, (Z,Z)-	13323-62-1
Stannane, dibutylbis[(1-oxohexadecyl)oxy]-	13323-63-2
Stannane, dibutylbis[(1-oxohexyl)oxy]-	19704-60-0
Stannane, dibutylbis[(1-oxoneodecyl)oxy]-	25168-22-3
Stannane, dibutylbis[(1-oxoisooctadecyl)oxy]-	59963-28-9
Stannane, dibutylbis[(1-oxononyl)oxy]-	25955-19-5
Stannane, dibutylbis[(1-oxononyl)oxy]-, branched	93686-50-1



Chemical Name in the Inventory	CAS Number
Stannane, dibutylbis[(1-oxooctyl)oxy]-, branched	93686-51-2
Stannane, dibutylbis[(1-oxo-9,12- octadecadienyl)oxy]-, (allZ)-	85391-79-3
Stannane, dibutylbis[(1-oxoisooctyl)oxy]-	85702-74-5
Stannane, dibutylbis[(1-oxoisodecyl)oxy]-	85702-75-6
Stannane, dibutylbis[(1-oxoisoundecyl)oxy]-	93893-96-0
Stannane, dibutylbis[(1-oxo-9,12,15- octadecatrienyl)oxy]-, (all Z)-	95873-60-2

# Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

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**ACRONYMS & ABBREVIATIONS** 

# **Grouping Rationale**

The chemicals in this group are di-substituted organotin compounds, specifically dibutyltin dicarboxylate salts with varying alkyl chain lengths (6–18 carbons). Di-substituted organotin compounds have the general formula R2SnX2. The toxicity of organotin compounds depends largely on the organotin moiety (R group), with the anionic ligand (X) mostly influencing physicochemical properties. These chemicals are grouped together for risk assessment due to their similar end uses and similar expected toxicity profiles (ATSDR, 2005).

## Import, Manufacture and Use

### Australian

No specific Australian use, import, or manufacture information has been identified. The National Pollutant Inventory (NPI) holds data for all sources of organotin compounds in Australia.

The following site-limited uses were identified for organotin compounds by the NPI in 2015–16:

- glass and glass product manufacturing; and
- polymer product manufacturing.

### International

No specific international use, importation, or manufacturing information has been identified for the chemicals. However, the structurally-related chemical dibutyltin dilaurate (DBTL) (CAS No. 77-58-7), has reported site-limited, commercial and domestic uses (NICNAS). Food related applications for the chemical DBTL have been phased out (European Parliament and Council, 2006).

Di-substituted organotin compounds are mainly used in the plastics industry as stabilisers in polyvinyl chloride (PVC). Dibutyl tins are also used as catalysts in the production of polyurethane foams and in the room temperature vulcanisation of silicones (ATSDR, 2005; RPA, 2007).

# Restrictions

### Australian

Tin organic compounds are listed in the Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) in Schedule 7 (SUSMP, 2017). This entry covers the chemicals in this group.

TIN ORGANIC COMPOUNDS, being dialkyl, trialkyl and triphenyl tin compounds where the alkyl group is methyl, ethyl, propyl or butyl **except**:

a) when separately specified in this Schedule;

b) in plastics;

c) in semi-solid sealants, adhesives or elastomers containing 1 per cent or less of the dialkyl, trialkyl or triphenyl tin component; or

d) in paint containing 1 per cent or less of such compounds calculated as tin in the non-volatile content of the paint.

Schedule 7 chemicals are described as: 'Dangerous poisons – Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.' (SUSMP 2017).

Tin and its compounds are listed in the Work Health and Safety Regulations (2016 revision) as restricted hazardous chemicals the restricted use is 'abrasive blasting at a concentration of greater than 0.1% as tin' (Galleria Chemica).

### International

Dibutyltin compounds are listed on the following:

- Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals—a severe restriction applies for the industrial chemical for public use (Galleria Chemica); and
- Annex XVII to the REACH Regulations—the chemicals cannot be used 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. Organostannic compounds are also restricted for biocide and water treatment uses (European Parliament and Council, 2006).

Tin compounds (organic) are listed on the following (Galleria Chemica):

- Council of Europe Resolution AP (92) 2 on control of aids to polymerisation for plastic materials and articles intended to come into contact with foodstuffs—Limits for finished articles; a limit of 0.05 mg/kg (as Sn) applies (Galleria Chemica); and
- Europe Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys—Maximum Migration Limits; limits of 0.2, 0.9 and 12 mg/kg of organic tin applies in liquid or sticky toy material, dry or brittle or powder-like or pliable toy material, and scraped-off toy material, respectfully.

# **Existing Worker Health and Safety Controls**

### **Hazard Classification**

The chemicals are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

### **Exposure Standards**

#### Australian

Tin organic compounds (as Sn) have an exposure standard of 0.1 mg/m<sup>3</sup> time weighted average (TWA) and 0.2 mg/m<sup>3</sup> short-term exposure limit (STEL).

### International

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The following exposure standards are identified for tin organic compounds (as Sn) (Galleria Chemica).

An exposure limit of 0.1 mg/m<sup>3</sup> TWA and 0.2 mg/m<sup>3</sup> STEL in different countries such as Bulgaria, Canada (Alberta, British Columbia, Ontario, Quebec, Saskatchewan, Yukon), Chile, Denmark, Egypt, Estonia, France, Greece, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Spain, Sweden, Taiwan, the United Kingdom and the United States of America (California, Hawaii, Minnesota, Tennessee, Vermont).

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.1 mg/m<sup>3</sup> TWA for 'Tin, organic compounds, as Sn'. 'This value is intended to minimize the potential for adverse effects on immune function and the central nervous system. A TLV–STEL of 0.2 mg Sn/m<sup>3</sup> is also recommended to minimize acute symptoms such as eye and upper respiratory tract irritation, headache, and nausea' (ACGIH, 2001).

# **Health Hazard Information**

Limited data are available for the chemicals. While median lethal dose (LD50) values indicate a high degree of acute oral toxicity (RTECSa; RTECSb), no study details are available to evaluate these values. The chemical DBTL (CAS No. 77-58-7) is a dibutyltin dicarboxylate salt that is more commonly used, for similar purposes, than the chemicals in this group. Therefore, its structural similarity and aligned uses make it a suitable analogue for the chemicals in this group. The health hazard information in the IMAP report for DBTL is considered relevant to the chemicals in this group (NICNAS).

The chemical DBTL was recommended for classification as hazardous through acute inhalation toxicity, corrosivity, repeated dose oral toxicity, genotoxicity, and reproductive and developmental toxicity. In repeated dose oral toxicity studies, DBTL caused immunotoxicity, hepatotoxicity and there was evidence of neurotoxicity (NICNAS). The chemical DBTL and its metabolite dibutyltin dichloride (DBTC—CAS No. 683-18-1), also cause adverse reproductive effects including an increased number of non-pregnant females, increased pre-implantation loss, increased early resorptions and foetal death (NICNAS). These data and recommendations are considered relevant to all dibutyltin dicarboxylate salts (see **Recommendation** section).

The Tier II assessment report for the chemical DBTL is available at: https://www.nicnas.gov.au/chemical-information/imapassessments/imap-assessment-details?assessment\_id=2033. The report should be read in conjunction with this Tier II assessment.

# **Risk Characterisation**

### **Critical Health Effects**

Based on information for the analogous chemical—DBTL (NICNAS), the critical health effects for risk characterisation of all dibutyltin dicarboxylate salts include systemic long-term effects (immunotoxicity, mutagenicity, neurotoxicity, reproductive toxicity and developmental toxicity), systemic acute effects (acute toxicity from inhalation exposure) and local effects (corrosivity).

### **Public Risk Characterisation**

Although use in domestic products in Australia is not known, based on information for DBTL the chemicals may be used in domestic products at concentrations up to 1 %. The general public could be exposed to the chemicals when using imported domestic products, specifically do-it-yourself sealants and adhesives containing the chemical. However, based on the low concentration of the chemicals in these products (<1 %), the minimal dermal contact expected and the low volatility of the chemicals, the risk to public health is not considered to be unreasonable. The chemicals are currently listed on Schedule 7 of the SUSMP for preparations containing >1 %, and these preparations are; therefore, not available for domestic use. Further risk management for these uses is not considered necessary for public safety.

The public could be exposed to the chemicals at low levels based on their use as PVC stabilisers and catalysts for various products. Internationally, tolerable daily intake (TDI) of 0.1 µg/kg bw (as Sn) for the group of tributyltins, triphenyltins, dibutyltins and dioctyltins has been established (EFSA, 2004). Based on an impact assessment report conducted in Europe (European Commission, 2009), the identified uses of the chemicals are not considered to significantly contribute to the overall TDI. The use

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of the chemicals in baking and cooking silicone moulds and silicone coated baking paper has been phased out and, therefore, this is no longer considered a significant source of exposure. In addition, the dominant contribution to human intake of organotins is via consumption of fish. Exposure levels are expected to reduce over time due to the 'ban' in the use of tributyltin in antifouling paints.

If data become available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment may be required.

### **Occupational Risk Characterisation**

During product formulation, dermal, ocular and inhalation (if aerosols are generated) exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemical at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term, acute and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support amendments to the hazard classifications in the HCIS (Safe Work Australia) (see **Recommendation** section).

# **NICNAS Recommendation**

Assessment of the chemicals is considered to be sufficient, provided that the recommended amendments to the classification are adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

If data become available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment may be required.

### **Regulatory Control**

### **Public Health**

Products containing the chemicals should be labelled in accordance with state and territory legislation (SUSMP, 2017).

### Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard Approved Criteria (HSIS) <sup>a</sup> GHS Classification (HCIS) <sup>b</sup>
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Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Not Applicable	Fatal if inhaled - Cat. 2 (H330)
Irritation / Corrosivity	Not Applicable	Causes severe skin burns and eye damage - Cat. 1B (H314)
Repeat Dose Toxicity	Not Applicable	Causes damage to the immune system through prolonged or repeated exposure - Cat. 1 (H372)
Genotoxicity	Not Applicable	Suspected of causing genetic defects - Cat. 2 (H341)
Reproductive and Developmental Toxicity	Not Applicable	May damage fertility. May damage the unborn child - Cat. 1B (H360FD)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

\* Existing Hazard Classification. No change recommended to this classification

### Advice for consumers

Products containing the chemicals should be used according to the instructions on the label.

### Advice for industry

#### **Control measures**

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemicals are is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemicals, if valid techniques are available to monitor the
  effect on the worker's health;
- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and

using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

#### Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemicals are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals*—Code of practice and Labelling of workplace hazardous chemicals—Code of practice, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of these chemicals has not been undertaken as part of this assessment.

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Safe Work Australia (SWA). Hazardous Chemicals Information System (HCIS). Accessed September 2017 at http://hcis.safeworkaustralia.gov.au/HazardousChemical

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Last Update 27 October 2017

# **Chemical Identities**

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxooctadecyl)oxy]- dibutylbis(stearoyloxy)stannane dibutyltin distearate stannane, dibutylbis((1-oxooctadecyl)oxy)-
CAS Number	5847-55-2
Structural Formula	

04/2020	IMAP Group Assessment Report
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Molecular Formula	C44H88O4Sn
Molecular Weight	799.89

Chemical Name in the Inventory and Synonyms	Stannane, dibutyIbis[(1-oxotetradecyI)oxy]- myristan di-n-butylcinicity stannane, bis(tetradecanoyloxy)dibutyl- dibutyItin dimyristate
CAS Number	28660-67-5
Structural Formula	



04/2020	IMAP Group Assessment Report
Molecular Formula	C36H72O4Sn
Molecular Weight	687.67

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxo-9-octadecenyl)oxy]-, (Z,Z)- dibutyltin dioleate stannane, dibutylbis(oleoyloxy)- 9-Octadecenoic acid (9Z)-, 1,1'-(dibutylstannylene) ester
CAS Number	13323-62-1
Structural Formula	

Molecular Formula	C44H84O4Sn
Molecular Weight	795.85

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxohexadecyl)oxy]- stannane, dibutylbis(palmitoyloxy)- dibutyltin dipalmitate dibutyl(hexadecanoyloxy)stannyl hexadecanoate
CAS Number	13323-63-2
Structural Formula	

21/04/2020	IMAP Group Assessment Report
Molecular Formula	C40H80O4Sn
Molecular Weight	743.78

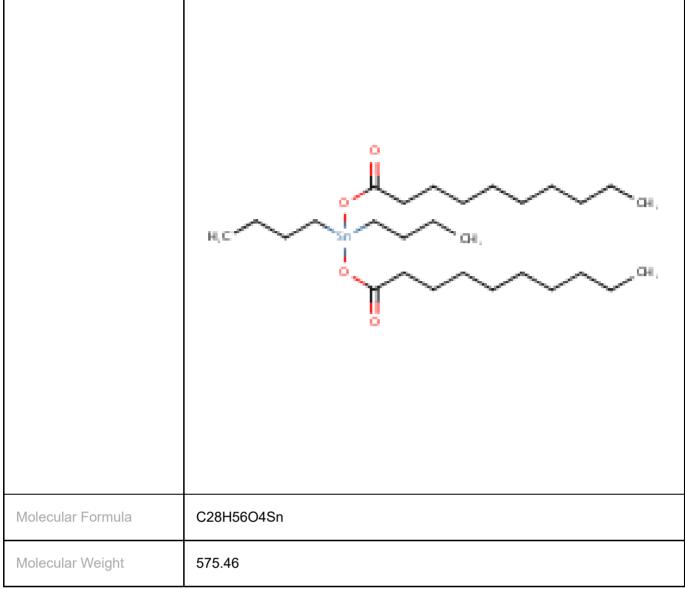
Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxohexyl)oxy]- bis(hexanoyloxy)di-n-butylstannane tin, bis(hexanoyloxy)di-n-butyl- dibutyltin dihexanoate dibutyltin dicaproate
CAS Number	19704-60-0
Structural Formula	



Molecular Formula	C20H40O4Sn
Molecular Weight	463.24

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxoneodecyl)oxy]- dibutyltin dineodecanoate stannane, dibutylbis(neodecanoyloxy)- dibutylbis[(1-oxoneodecyl)oxy]stannane
CAS Number	25168-22-3
Structural Formula	





Chemical Name in the Inventory and Synonyms	Stannane, dibutyIbis[(1-oxoisooctadecyI)oxy]- dibutyItin diisostearate isooctadecanoic acid, 1,1'-(dibutyIstannyIene) ester
CAS Number	59963-28-9
Structural Formula	

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Molecular Formula	C44H88O4Sn
Molecular Weight	799.89

Chemical Name in the Inventory and Synonyms	Stannane, dibutyIbis[(1-oxononyI)oxy]- dibutyIbis(nonanoyloxy)stannane dibutyI(nonanoyloxy)stannyI nonanoate
CAS Number	25955-19-5
Structural Formula	



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Molecular Formula	C26H52O4Sn
Molecular Weight	547.40

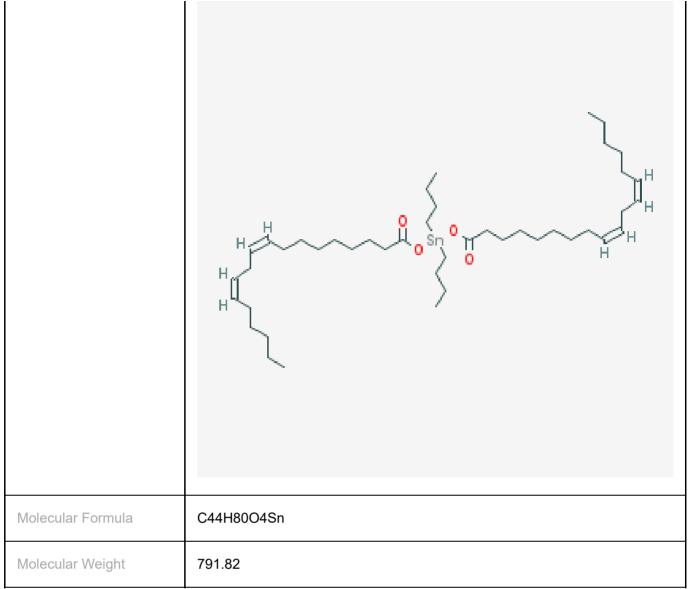
Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxononyl)oxy]-, branched
CAS Number	93686-50-1
Structural Formula	No Structural Diagram Available

https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment\_id=10310

Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxooctyl)oxy]-, branched
CAS Number	93686-51-2
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxo-9,12-octadecadienyl)oxy]-, (allZ)- dibutyltin dilinoleate dibutylbis(octadeca-9(Z),12(Z)-dienoyloxy) stannane
CAS Number	85391-79-3
Structural Formula	



Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxoisooctyl)oxy]-
CAS Number	85702-74-5
Structural Formula	

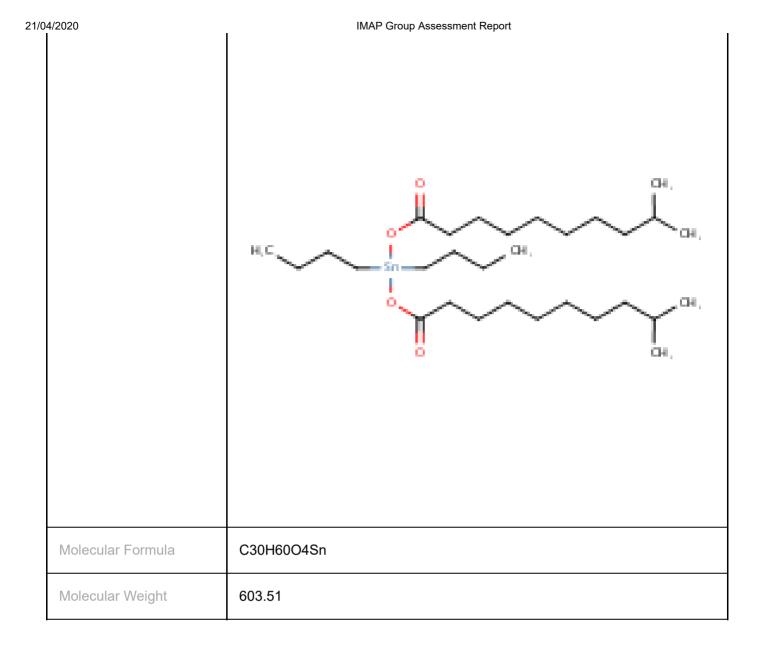


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Molecular Formula	C24H48O4Sn
Molecular Weight	519.35

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxoisodecyl)oxy]-
CAS Number	85702-75-6
Structural Formula	

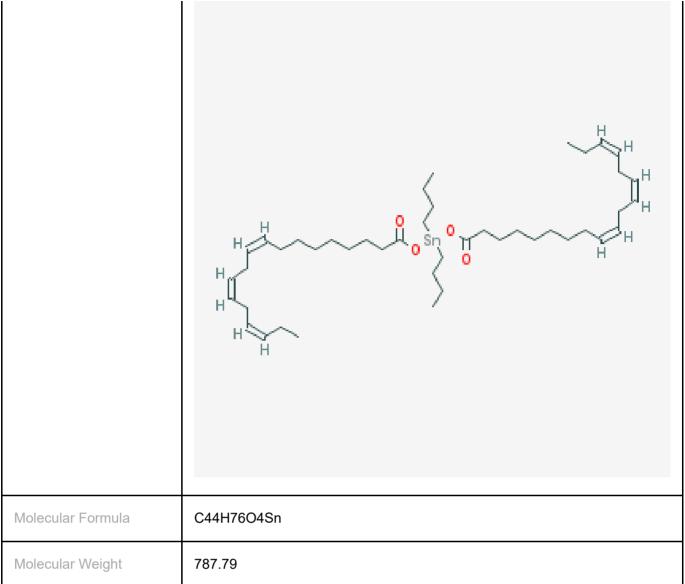
21/04/2020	IMAP Group Assessment Report
Molecular Formula	C28H56O4Sn
Molecular Weight	575.46

Chemical Name in the Inventory and Synonyms	Stannane, dibutylbis[(1-oxoisoundecyl)oxy]-
CAS Number	93893-96-0
Structural Formula	



Chemical Name in the Inventory and Synonyms	<b>Stannane, dibutylbis[(1-oxo-9,12,15-octadecatrienyl)oxy]-, (all Z)-</b> stannane, dibutylbis[(1-oxo-9,12,15-octadecatrienyl)oxy dibutyltin dilinolinate dibutylbis(octadeca-9(Z),12(Z),15(Z)-trienoyloxy) stannane
CAS Number	95873-60-2
Structural Formula	





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