# Stannane, dibutylbis[(2-ethyl-1-oxohexyl)oxy]-: Human health tier II assessment

**27 October 2017**

## CAS Number: 2781-10-4



## 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.

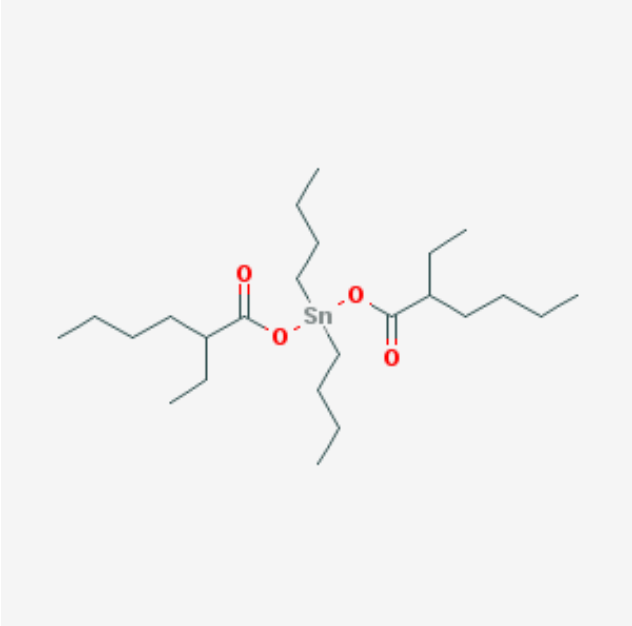
For more detail on this program please visit:www.nicnas.gov.au

**Disclaimer**



Acronyms & Abbreviations

## Chemical Identity

| | |
|---|---|
| Synonyms | dibutyltin bis(2-ethylhexanoate)<br>dibutyltin di(2-ethylhexanoate)<br>stannane, bis[(2-ethylhexanoyl)oxy]dibutyl-<br>dibutylstannanebis(ylium) bis(2-ethylhexanoate) |
| Structural Formula |  |
| Molecular Formula | C24H48O4Sn |
| Molecular Weight (g/mol) | 519.35 |
| Appearance and Odour (where available) | solid colourless pellets with slight odour |
| SMILES | C(=O)(C(CCCC)CC)O{-}.[Sn]{2+}(CCCC)(CCCC).O{-}C(=O)C(CCCC)CC |

# 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

The following international uses have been identified through: the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Agency for Toxic Substances and Disease Registry (ATSDR) assessment (ATSDR, 2005); and Galleria Chemica.

The chemical has reported site limited uses, including as a:

- catalyst in silicone and polyurethane foam manufacturing; and
- stabiliser in the formulation of polyvinyl chloride (PVC) matrices.

# 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 this chemical.

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 chemical 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; 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, respectively.

## Existing Work Health and Safety Controls

### Hazard Classification

The chemical is 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$^3$ time weighted average (TWA) and 0.2 mg/m$^3$ short-term exposure limit (STEL).

#### International

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

An exposure limit between 0.1 mg/m$^3$ TWA and 0.2 mg/m$^3$ 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$^3$ TWA for 'Tin, organic compounds, as Sn'. 'This value is intended to minimise the potential for adverse effects on immune function and the central nervous system. A TLV–STEL of 0.2 mg Sn/m$^3$ is also recommended to minimize acute symptoms such as eye and upper respiratory tract irritation, headache, and nausea' (ACGIH, 2001).

## Health Hazard Information

The chemical is a dibutyltin dicarboxylate salt, with 2-ethylhexanoic acid. Limited data are available for the chemical. While median lethal dose (LD50) values indicate moderate acute oral toxicity and high acute dermal toxicity (EHC, 1980; RTECS), study details are not available to evaluate these values. Toxicity data submitted as part of a REACH dossier for the chemical used dibutyltin dilaurate (DBTL—CAS No. 77-58-7), and other structurally similar chemicals as analogues for read-across. The chemical DBTL is a dibutyltin carboxylate salt that is more commonly used, for similar purposes, compared with the chemical. Its structural similarity and aligned uses make it analogous to the chemical and; therefore, health hazard information for DBTL is considered relevant to the chemical (NICNASa). Health hazard information derived from the 2-ethylhexanoic acid component of the chemical is also considered relevant for systemic toxicity (NICNASb), since this will be formed via dissociation of the chemical when metabolised.

The chemical DBTL was recommended for classification as hazardous through acute inhalation toxicity, corrosivity, repeated dose oral toxicity, genotoxicity, and reproductive and developmental toxicity (NICNASa). In repeated dose oral studies, DBTL caused immunotoxicity and hepatotoxicity and in addition, there was evidence of neurotoxicity (NICNASa). 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 (NICNASa). The metabolite 2-ethylhexanoic acid (CAS No. 149-57-5) is known to cause adverse developmental and reproductive effects, including dose dependent increases in foetal skeletal variations and malformations, reduced foetal body weights, early foetal deaths, impaired sperm motility and increased abnormal sperm, delays in mating, and complete infertility in some animals (NICNASb). These data and recommendations are considered relevant to the chemical (see **Recommendation** section).

The Tier II assessment report for DBTL is available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=2033. The Tier II assessment report for 2-ethylhexanoic acid is available at https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=787. These reports should be read in conjunction with this Tier II assessment.

# Risk Characterisation

## Critical Health Effects

Based on information for the analogue chemical—DBTL (NICNASa), and the anion—2-ethylhexanoate (NICNASb), the critical health effects for risk characterisation of the chemical include systemic long-term effects (immunogenicity, 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 is not known, it is a possibility based on information for other dibutyltin dicarboxylic acid esters (NICNASa). However, organotins 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 is not considered necessary for public safety.

The public could be exposed to the chemical at low levels based on its use as a PVC stabiliser and catalyst for various products. Internationally, a group tolerable daily intake (TDI) of 0.1 µg/kg bw (as Sn) for 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. In addition, the dominant contribution to human intake of organotins is via the consumption of fish. Exposure levels for organotins are expected to reduce over time due to the 'ban' in the use of tributyltin in antifouling paints.

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

## Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation (if aerosols are generated) exposure might 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 appropriate controls.

The data available support an amendment to the hazard classification in the HCIS (Safe Work Australia) (see **Recommendation** section).

# NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is 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 becomes available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment of this chemical may be required.

## Regulatory Control

### Public Health

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

### Work Health and Safety

The chemical is 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)[a] | GHS Classification (HCIS)[b] |
|---|---|---|
| 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) |

| Hazard | Approved Criteria (HSIS)[a] | GHS Classification (HCIS)[b] |
|---|---|---|
| Reproductive and Developmental Toxicity | Not Applicable | May damage fertility. May damage the unborn child - Cat. 1B (H360FD) |

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

[b] 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 chemical 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 chemical 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 chemical 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 chemical from entering the breathing zone of any worker;
- health monitoring for any worker who is at risk of exposure to the chemical, 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 chemical.

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 chemical 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 the chemical has not been undertaken as part of this assessment.

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