

Stannane, dibutyldimethoxy-: Human health tier II assessment

28 June 2019

CAS Number: 1067-55-6



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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

Chemical Identity

Synonyms	dibutyltin dimethoxide dibutyldimethoxytin
Structural Formula	
Molecular Formula	C ₁₀ H ₂₄ O ₂ Sn
Molecular Weight (g/mol)	295.01
Appearance and Odour (where available)	Liquid
SMILES	C(CCC)[Sn](CCCC)(OC)OC

Import, Manufacture and Use

Australian

No chemical-specific Australian use, import, or manufacturing 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 as sources of organotin compounds by the NPI in 2017-18:

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

International

The following international use has been identified through Galleria Chemica; the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; and various international assessments (EFSA, 2004; ATSDR, 2005; WHO, 2006).

Dibutyltin compounds are used as chemical intermediates, stabilisers for polyvinyl chloride (PVC) and as catalysts for various products including polyurethane, silicone, and polyester resin systems. Specifically the chemical has reported site-limited uses as an intermediate.

Restrictions

Australian

This chemical is listed in the *Poisons Standard—the Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) in Schedule 7 (SUSMP, 2019).

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, 2019).

International

Dibutyltin compounds—which includes the chemical in this assessment report—are listed on the following (Galleria Chemica):

- Annex I to Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals; 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)—which includes the chemical in this assessment report—are listed on:

- 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 material, and scraped-off toy material, respectively;
- The Council of Europe Resolution AP (92) 2 on the 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
- The Council of Europe Resolution ResAP (2008) 1 on requirements and criteria for the safety of tattoos and permanent make-up (PMU)—Table 3 Maximum allowed concentrations of impurities in products for tattoos and PMU; a limit of 50 ppm tin (Sn) applies (Galleria Chemica).

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/m³ time weighted average (TWA) and 0.2 mg/m³ short-term exposure limit (STEL).

International

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

- An exposure limit of 0.1 mg/m³ TWA and 0.2 mg/m³ STEL in different countries including Bulgaria, Canada (Alberta, British Columbia, Ontario, Quebec, Saskatchewan, Yukon), Chile, Denmark, Egypt, Estonia, France, Greece, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, the United Kingdom and the United States of America (California, Hawaii, Minnesota, Tennessee, Vermont).

Health Hazard Information

No data are currently available for dibutyldimethoxy stannane (CAS No. 1067-55-6). The health hazard information in the IMAP reports for other dibutyltin compounds, dibutyltin dichloride (DBTC—CAS No. 683-18-1), dibutyltin dilaurate (DBTL—CAS No. 77-58-7) and dibutyltin oxide (DBTO—CAS No. 818-08-6) are considered relevant to the chemical. Data for DBTC are considered relevant for systemic endpoints via repeated oral exposure, since the chemical is hydrolysed to dibutyltin dichloride under acidic conditions similar to the gastric environment. Data for DBTL and DBTO are also considered relevant for both acute oral and repeated oral dose toxicity as they are also converted in the stomach to DBTC. As the molecular weight of the chemical is similar to that of DBTC, results are likely to be quantitatively similar between the chemical and DBTC.

The chemicals DBTC, DBTL and DBTO were recommended for classification as hazardous for repeated oral dose toxicity, genotoxicity, and reproductive and developmental toxicity. DBTC and DBTO are also classified for acute oral toxicity. These classifications and classification recommendations are considered relevant to the chemical being assessed in this report (see **Recommendation** section).

In repeated dose oral toxicity studies, the chemicals caused immunotoxicity, hepatotoxicity and there was evidence of neurotoxicity. The chemicals also caused teratogenic effects and adverse reproductive effects including an increased number of non-pregnant females, increased pre-implantation loss, increased early resorptions and foetal death. DBTC produced evidence of mutagenic or clastogenic effects in several in vitro assays, and DBTC and DBTL were positive in other in vivo tests (NICNASa; NICNASb; NICNASc).

Limited data are available for effects following dermal or inhalation exposure. Other dibutyltin compounds cause fatality following inhalation (NICNASa, NICNASb). Effects after inhalation of vapours or mists cannot be ruled out. No data are available for local effects for the chemical and it is not possible to read across data from the other dibutyltin compounds.

No data are available for local effects (skin and eye irritation and sensitisation).

For specific toxicological data for these dibutyltin compounds, refer to the separate assessment reports listed below (NICNASa, NICNASb; NICNASc).

The Tier II assessment report for DBTC is available at <https://www.nicnas.gov.au>. This report should be read in conjunction with this Tier II assessment.

The Tier II assessment report for DBTL is available at <https://www.nicnas.gov.au>. This report should be read in conjunction with this Tier II assessment.

The Tier II assessment report for DBTO is available at <https://www.nicnas.gov.au>. This report should be read in conjunction with this Tier II assessment.

Risk Characterisation

Critical Health Effects

Based on information for dibutyltin compounds, the critical health effects for risk characterisation include systemic long-term effects (genotoxicity, reproductive and developmental toxicity) and systemic acute effects (acute toxicity from oral exposure). Local effects and effects after inhalation cannot be ruled out.

Public Risk Characterisation

Given the site-limited uses identified for the chemical, it is unlikely that the public will be directly exposed to significant amounts of the chemical. The chemical is currently listed in Schedule 7 of the SUSMP, restricting its use in domestic products in Australia (SUSMP, 2019). Hence, the public risk is not considered to be unreasonable.

The public could be exposed to the chemical at low levels based on its potential use as a 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 chemical are not considered to significantly contribute to the overall TDI. In addition, the dominant contribution to human intake of organotin is via consumption of fish. Exposure levels are expected to reduce over time due to the ban on the use of tributyltin in antifouling paints.

Occupational Risk Characterisation

During product formulation, oral, dermal, ocular and inhalation 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 and systemic acute health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, 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 at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The available data support an amendment to the hazard classification in the HCIS (Safe Work Australia) (refer to **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 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 chemical should be labelled in accordance with state and territory legislation (SUSMP, 2019).

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	Toxic if swallowed - Cat. 3 (H301)
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)

^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 oral, 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;
- 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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