Stannane, dimethylbis[(1-oxoneodecyl)oxy]-: Human health tier II assessment

12 December 2019

CAS Number: 68928-76-7

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.

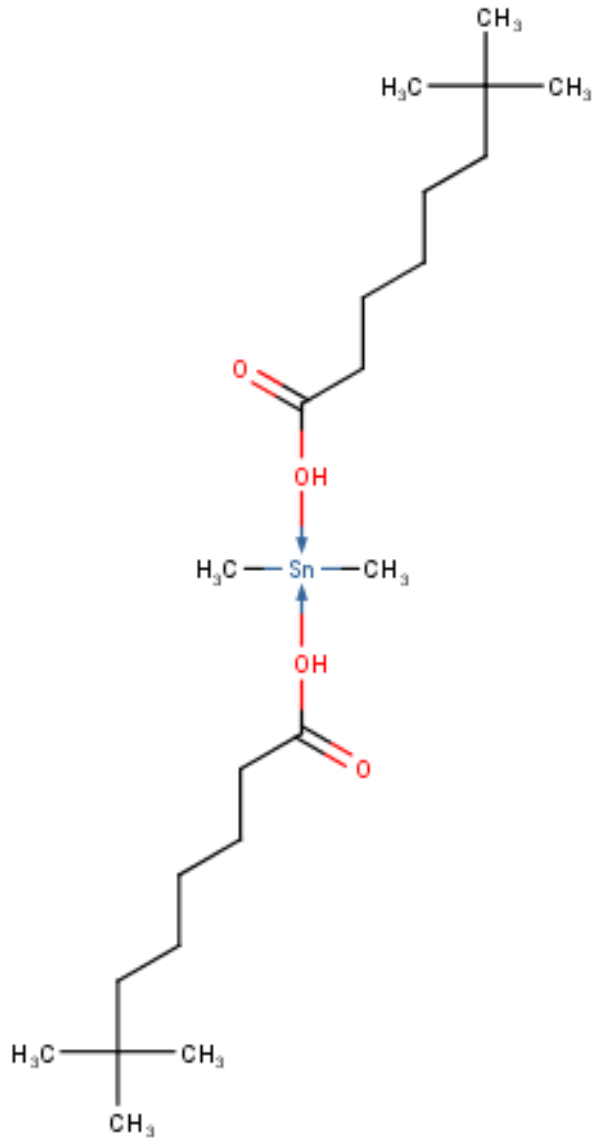
For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	dimethyltin dineodecanoate neodecanoic acid, 1,1'-(dimethylstannylene) ester
Structural Formula	

	
Molecular Formula	C22H44O4Sn
Molecular Weight (g/mol)	491.2
Appearance and Odour (where available)	clear to colourless viscous liquid
SMILES	C(=O)(CCCCCC(C)(C)C)O[Sn](C)(C)OC(=O)CCCCCC(C)(C)C

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified for the chemical.

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 uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers; the Organisation for Economic Co-operation and Development (OECD) Screening information data set International Assessment Report (OECD, 2006); Galleria Chemica; the OECD High Production Volume chemical program (OECD HPV); World Health Organization (WHO) Concise International Chemical Assessment Document (CICAD) 73 (WHO, 2006); Classification, Labelling and Harmonisation (CLH) report; the Agency for Toxic Substances and Disease Registry (ATSDR, 2005) report and Health Canada Priority Substances List Assessment Report (Health Canada, 1993).

Stannane, dimethylbis[(1-oxoneodecyl)oxy]- (CAS No. 68928-76-7), hereafter referred to as the chemical has reported commercial use in articles for food contact applications.

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

- an intermediate in the production of heat stabilisers in PVC;
- an intermediate in manufacturing other organotin compounds, or other chemical and mineral products; and
- a coating on glass.

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, 2019). 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 % or less of the dialkyl, trialkyl or triphenyl tin component; or

d) in paint containing 1 % 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).

Tin and its compounds are listed in Schedule 10 of 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)." (Safe Work Australia, 2019)

International

Organic Tin compounds—which includes the chemical in this assessment—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 to tin compounds organic.
- 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 sticky toy material, dry or brittle or powder like material, and scraped-off toy material, respectively.
- Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up —Table 3 Maximum allowed concentrations of impurities in products for tattoos and PMU; a limit of 50 ppm tin (Sn) applies.

Organotin compounds—which includes the chemical in this assessment—are listed in Annex XVII to the REACH regulations with restrictions relating to biocide and water treatment uses (ECHA).

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) (Safe Work Australia).

International

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

An exposure limit of 0.1 mg/m^3 TWA and 0.2–0.4 mg/m^3 STEL in different countries such as Bulgaria, Canada (Alberta, British Columbia, Ontario, Quebec, Saskatchewan, Yukon), Chile, Denmark, Egypt, Estonia, France, Greece, Hungary, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Spain, Sweden, Taiwan, the United Kingdom and the United States of America (California, Hawaii,

Minnesota, Tennessee, Vermont, Washington).

The American Conference of Government Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.1 mg/m TWA for Tin, organic compounds, as Sn 'to minimize the potential for adverse effects on immune function and the central nervous system.' and 0.2 mg/m STEL 'to minimize acute symptoms such as eye and upper respiratory tract irritation, headache, and nausea.' (ACGIH, 2011).

Health Hazard Information

Limited data are available for the chemical. The chemical contains a dimethyl (Me_2Sn^-) group and two labile ligands (X). Data available indicate that the chemical is hydrolysed to release neodecanoic acid (CAS No. 26896-20-8). Although there is limited evidence that the chemical is hydrolysed to dimethyltin dichloride (DMTC—CAS No.753-73-1), in general the toxicity of

organotin compounds depends largely on the organotin moiety (R group), with the anionic ligand (X) mostly influencing physico-chemical properties and local toxicity.

Therefore when data for the chemical being assessed are not available, health hazard information for dimethyltin compounds, DMTC and dimethyl alkyl mercaptoacetates (NICNASa; NICNASb), has been included in this report for read across for systemic toxicity endpoints. Available data for the metabolite, neodecanoic acid indicate a low order of systemic toxicity (OECD, 2008; NICNASc).

The Tier II Human Health assessment reports for DMTC and dimethyl alkyl mercaptoacetates are available at https://www.nicnas.gov.au. These reports should be read in conjunction with this Tier II assessment.

Toxicokinetics

In a hydrolysis study (OECD Test Guideline (TG) 111), using $^{119-}$Sn NMR, the chemical was hydrolytically stable at pH 4 and 7. Under simulated gastric conditions, the chemical was hydrolysed to neodecanoic acid and an unidentified tin compound (REACH).

Acute Toxicity

Oral

No data are available for the chemical. Based on the molecular weight of the chemical, data for dimethyltin alkyl mercaptoacetates is considered more relevant than data for DMTC. Dimethyl alkyl mercaptoacetates have moderate oral acute toxicity with median lethal dose (LD50) values in the range 1000–1735 mg/kg bw (OECD, 2006; NICNASb). In the absence of available data for the chemical, hazard classification for acute toxicity is warranted.

Dermal

No data are available for the chemical. Based on the molecular weight of the chemical, data for dimethyltin alkyl mercaptoacetates is considered more relevant than data for DMTC. Based on the available data, for dimethyl alkyl mercaptoacetates (NICNASb), the chemical is likely to have low acute dermal toxicity.

Inhalation

No data are available for the chemical. Based on the molecular weight of the chemical, data for dimethyltin alkyl mercaptoacetates is considered more relevant than data for DMTC. Based on the available data, for dimethyl alkyl mercaptoacetates (NICNASb), the chemical is likely to have low acute inhalation toxicity.

Corrosion / Irritation

Skin Irritation

No data are available for the chemical. The corrosive effects observed for DMTC (NICNASa) are not expected for the chemical. Dimethyl alkyl mercaptoacetates are considered to be slight skin irritants (NICNASb).

Eye Irritation

No data are available for the chemical. The corrosive effects observed for DMTC (NICNASa) are not expected for the chemical. Dimethyl alkyl mercaptoacetates are considered to be slight eye irritants (NICNASb).

Sensitisation

Skin Sensitisation

No data are available for the chemical. In general dialkytin compounds with the exception of dialkyltin alkylmercaptoacetates are not skin sensitisers.

Repeated Dose Toxicity

Oral

No data are available for the chemical. Based on the available data for the dimethyltin compound DMTC (NICNASa), the chemical is expected to cause serious health effects in the thymus and nervous system following repeated oral expsoure, warranting hazard classification (see **Recommendation** section).

Exposure to DMTC has been linked to decreased thymus weights and thymus atrophy in males; and increased kidney weights in females, accompanied by histopathological changes. Neurotoxic effects were noted across both sexes with signs including convulsions and tremors, and physiological changes including neuronal necrosis, ventricular dilation, and white matter vacuolisation in the brain and spinal cords (NICNASa).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

No data are available for the chemical. Based on the available data for DMTC (NICNASa) and DMT(EHMA) (NICNASb) the chemical is not considered to be genotoxic.

Carcinogenicity

No data are available for the chemical. Carcinogenicity was not observed in long-term studies using mixtures of mono- and dimethyltins (WHO, 2006).

Reproductive and Developmental Toxicity

No data are available for the chemical. Based on the available data for dimethyltin compounds, the chemical may cause developmental effects, warranting classification (see **Recommendation** section).

The chemicals DMTC is classified as hazardous with the hazard category 'Reproductive Toxicity - Category 2' and hazard statement 'Suspected of damaging the unborn child' (H361d) in HCIS (Safe Work Australia).

The available data for DMTC indicated the presence of variations and malformations, and developmental neurotoxicity at low doses in some of the animal studies (NICNASa).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long term effects (developmental toxicity, neurotoxicity and thymus effects) following oral exposure. The chemical can also cause systemic acute effects following oral exposure.

Public Risk Characterisation

Given the uses identified for the chemical, it is unlikely that the public will be exposed. Hence, the public risk from this chemical is not considered to be unreasonable.

The chemical is currently listed in Schedule 7 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP, 2019), precluding its use in consumer products in Australia at a concentration above 1 %.

The public could be exposed to the chemicals at low levels based on their use as PVC stabilisers and use in food contact applications. At these levels the acute and local effects are not expected. Internationally, a group tolerable daily intake (TDI) of (0.1 µg/kg bw as Sn) for organotins in foodstuff based on systemic effects has been established (European Commission, 2009). To reduce the identified risk of organotins transferred from food packaging to foodstuffs, the overall exposure should be lower than the TDI. The dominant contribution to human intake of organotins (mainly tributyltin) is via consumption of fish. Exposure to other organotins, including these chemicals is expected to be generally low both from food contact and handling PVC articles. Hence, the public risk from these chemicals is not considered to be unreasonable. If data becomes available indicating specific uses in Australia that could significantly contribute to the overall TDI for organotins, further assessment of these chemicals may be required.

Occupational Risk Characterisation

During product formulation, dermal, inhalation and ocular 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 acute health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise oral, dermal, inhalation and ocular 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. There is uncertainty regarding the risks to workers from repeated inhalation exposures. However, the control measures expected to be in place to protect workers from the risks of the known health effects (acute toxicity and corrosivity) should be adequate to minimise the risks of repeated inhalation exposure.

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.

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	Harmful if swallowed - Cat. 4 (H302)
Repeat Dose Toxicity	Not Applicable	Causes damage to the nervous system and immune system through prolonged or repeated exposure - Cat. 1 (H372)
Reproductive and Developmental Toxicity	Not Applicable	Suspected of damaging the unborn child - Cat. 2 (H361d)

[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 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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