Decanedioic acid, bis(2,2,6,6-tetramethyl-4-piperidinyl) ester: Human health tier II assessment

26 October 2018

CAS Number: 52829-07-9

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.

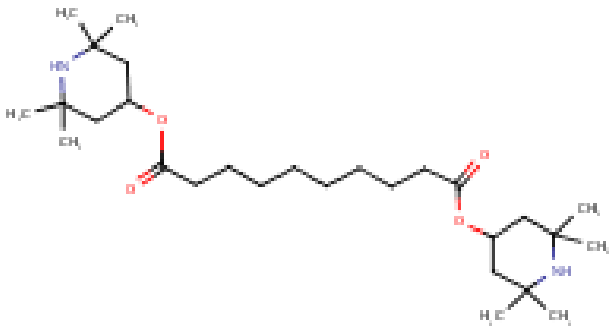
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	bis(2,2,6,6-tetramethyl-4-piperidinyl) sebacate decanedioic acid, 1,10-bis(2,2,6,6-tetramethyl-4-piperidinyl) ester 1,10-bis(2,2,6,6-tetremethyl-4-piperidinyl) ester Antioxidant 770
Structural Formula	
Molecular Formula	C28H52N2O4
Molecular Weight (g/mol)	480.728
Appearance and Odour (where available)	White to off-white odourless granular solid
SMILES	C1(C)(C)CC(OC(=O)CCCCCCCCC(=O)OC2CC(C)

	(C)NC(C)(C)C2)CC(C)(C)N1

Import, Manufacture and Use

Australian

The following Australian domestic uses were reported from safety data sheets (SDS) from various Australian companies:

- as a sealant (concentration < 1 %);
- as a stabiliser (concentration 0.2–0.5 %); and
- in adhesives (concentration 0.25–2.5 %).

International

The following international uses have been identified through European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening Information Dataset Initial Assessment Report (OECD SIAR, 2008); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; and eChemPortal: OECD High Production Volume chemical program (OECD HPV, 2008), the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported domestic uses including in:

- adhesives;
- paints, thinners and paint removers; and
- putties, plasters and modelling clay (REACH)

The chemical has reported commercial uses including:

- in plastic;
- in rubber;
- in construction materials; and
- as a UV stabiliser.

Restrictions

Australian

No known restrictions have been identified.

International

No known restrictions have been identified.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the HSIS (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available on the Hazardous Substances Information Systems (HSIS) (Safe Work Australia).

International

No specific exposure standards are available on Galleria Chemica.

Health Hazard Information

Toxicokinetics

There are no available data on the toxicokinetics of the chemical. However, based on the amphiphilic properties of the chemical it is expected to be well absorbed through oral exposure. Metabolic degradation by ester hydrolysis is assumed, giving rise to 2,2,6,6-tetramethylpiperidin-4-ol (HTMP) and decanedioic acid as the main metabolites. Based on the results of the reproductive toxicity study (see **Reproductive and Developmental Toxicity** section), the chemical or its metabolite(s) might be excreted in breast milk (OECD, 2008).

Acute Toxicity

Oral

The chemical had low acute toxicity in animal tests following oral exposure. The median lethal dose (LD50) in rats was 3700 mg/kg bw.

In an animal study similar to OECD Test Guideline (TG) 423, the chemical was administered to rats via gavage (five animals/sex/dose) at 0, 2500, 3200, 4000 and 5000 mg/kg bw for 14 days. Observed sub-lethal effects include salivation, diarrhoea and diuresis; the animals recovered within two days (REACH).

Dermal

Based on the available information, the chemical had low acute toxicity in animal tests following dermal exposure.

In a stated toxicity dermal study according to OECD TG 402, the chemical was administered to rats (strain not stated) (three/sex/dose) at 2150 and 3170 mg/kg bw/day. The animals displayed dyspnoea, exophthalmos, ruffled fur and hunched posture. The LD50 was reported to be higher than 3170 mg/kg bw (REACH).

Inhalation

Based on the available information, the chemical had high acute toxicity in animal tests following inhalation exposure.

In an inhalation study conducted similarly to OECD TG 403, rats (Tif. RAI) were exposed (nose only) to the chemical at concentrations of 232 ± 46, 394 ± 72 or 887 ± 138 mg/m^3 for four hours. All animals displayed dyspnoea, salivation, trismus, tremor and sedation with a dose-dependent intensity. The reported median lethal concentration (LC50) was 500 mg/m^3 (equivalent to 0.5 mg/L) (REACH).

Corrosion / Irritation

Skin Irritation

Based on the available information, the chemical is minimally irritating to skin.

In an in vivo study similar to OECD TG 404, 0.5 mL of the chemical was applied on a 2.5 × 2.5 cm area on New Zealand White rabbits (three animals/sex) with a 24-hour exposure duration, and observed for seven days. It was reported that under occlusive conditions minimal skin irritation was observed (REACH).

Eye Irritation

The chemical causes serious eye damage.

In New Zealand White rabbits, the chemical was found to be highly irritating with conjunctival redness and chemosis observed at 24, 48 and 72 hours post application. Effects on the iris and conjunctivae of all animals cleared within 21 days. However, in two animals corneal effects were not reversible within 21 days (REACH).

Observation in humans

No human data are available.

Sensitisation

Skin Sensitisation

Based on the available information, the chemical is not a skin sensitiser.

In an in vivo study, 1 % of the chemical in sesame oil was used for intradermal induction and 10 % in vaseline for topical induction on Pirbright-Hartley guinea pigs (10 animals/sex). Animals were challenged with 1 % chemical in vaseline and observed for seven days. It was reported that no skin sensitising effects were observed (REACH).

Repeated Dose Toxicity

Oral

The main effect seen in repeated dose toxicity studies was reduced body weight. However, this effect is transient and is not considered a severe effect that meets the criteria for hazard classification.

In a repeated dose toxicity study similar to OECD TG 408, male and female Sprague Dawley (SD) rats (20 animals/sex/dose; five animals/sex of controls and high dose for recovery) were exposed to the chemical at 0, 400, 1300 or 4000 ppm (males 0, 26, 80 or 261 mg/kg bw/day; females 0, 29, 90 or 277 mg/kg bw/day) in the diet for 90 days. The only treatment-related effect was a significantly reduced body weight in the high dose males, and mid and high dose females. No treatment-related abnormalities were noted after the recovery period. The lowest observed adverse effect level (LOAEL) was determined at 29 mg/kg bw/day based on the decreased body weight gain in females (REACH).

In a 90-day repeated dose toxicity study similar to OECD TG 408, male and female dogs (four animals/sex/dose) were exposed to the chemical at 0, 800, 2600 or 8000 ppm (equivalent to 0, 27, 69 or 150 mg/kg bw (males) and 0, 27, 78 or 155 mg/kg bw (females)). After 13 weeks, a significant reduction in body weight was observed in the both male and female high dose groups. Minimal hepatic periportal hypertrophy was noted in the high dose group. However, no treatment-related abnormalities were found after the recovery period. The LOAEL was determined at 69–78 mg/kg bw/day based on the decreased body weight and liver hypertrophy (REACH).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the available data, the chemical is not genotoxic.

The chemical tested negative for mutagenicity with and without metabolic activation in an in vitro Ames test (conducted similarly to OECD TG 471) with *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537. The chemical was not clastogenic in an in vitro chromosomal aberration test (OECD TG 473) in human lymphocytes with or without metabolic activation (OECD 2008; REACH).

Carcinogenicity

No data are available.

Reproductive and Developmental Toxicity

There is no evidence of reproductive toxicity and developmental effects were only observed secondary to maternal toxicity. The chemical does not show specific developmental toxicity.

In a one-generation reproduction toxicity study (OECD TG 415) male and female rats (24 animals/sex/dose) were administered the chemical (0, 3, 30 or 300 mg/kg bw/day) via gavage. Males were treated for 10 weeks including before mating, during mating and up to delivery of litters. Females were treated two weeks before mating, during mating, during gestation and up until weaning (20–22 days after birth). Treatment-related effects included decreased body weight gain and food consumption, and increased spleen (males only) and uterus weights in parental animals at 300 mg/kg bw/day.The no observed adverse effect level (NOAEL) for parental and developmental toxicity based on reduced pup weight was determined to be 30 mg/kg bw/day. No effects on fertility were observed. Slightly reduced pup weight during lactation was observed at 300 mg/kg bw/day, but was not associated with any other developmental adverse effects (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include a systemic acute effect (acute toxicity from inhalation exposure). The chemical can also cause serious eye damage.

Public Risk Characterisation

The concentrations used in products available to the public are low, generally 0.1–0.5 % (OECD 2008). Considering that the chemical is mostly retained in the polymer matrix, exposure to the general public is considered to be low. Therefore, the risk to public health is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may 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 acute and local health effects, the chemical might pose an unreasonable risk to workers unless adequate control measures to minimise ocular and inhalation exposure to the chemical 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 HSIS (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.

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Toxic by inhalation (T; R23)	Fatal if inhaled - Cat. 2 (H330)
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41)	Causes serious eye damage - Cat. 1 (H318)

[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 label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from 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 which may 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;
- 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 assist with meeting 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.

References

OECD (2008). SIDS Initial Assessment Profile (SIAP) on Decanedioic acid (52829-07-9) . Accessed at http://webnet.oecd.org/hpv/ui/handler.axd?id=a62e7888-04d7-4a47-b7fb-72a47e89e3a9

Aggregated Computational Toxicology Resource (ACToR). (Decanedioic acid 52829-07-9). Accessed October 2014 at http://actor.epa.gov/actor/GenericChemical?casrn=52829-07-9

ChemIDPlus Advanced, Accessed October 2014 at http://chem.sis.nlm.nih.gov/chemidplus/

ECHA (2012). REACH Dossier on Decanedioic acid (52829-07-9). http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ebfef41-5ef2-296e-e044-00144f67d031/AGGR-dbc8c4e0-e5c8-43f9-9287-20b9824c0f2f_DISS-9ebfef41-5ef2-296e-e044-00144f67d031.html#AGGR-dbc8c4e0-e5c8-43f9-9287-20b9824c0f2f

Galleria Chemica. Accessed October 2014. http://jr.chemwatch.net/galleria/

Hazardous Substances Data Bank (HSDB). National Library of Medicine. Accessed November 2014 at http://toxnet.nlm.nih.gov.

Safe Work Australia (SWA). Hazardous Substances Information System (HSIS). Accessed at http://hsis.safeworkaustralia.gov.au/HazardousSubstance in October 2014.

Substances in Preparations in Nordic Countries(SPIN). Accessed November 2014 at http://195.215.202.233/DotNetNuke/default.aspx

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