

Decanedioic acid, bis(1,2,2,6,6-pentamethyl-4-piperidinyI) ester: Human health tier II assessment

10 March 2017

CAS Number: 41556-26-7



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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.

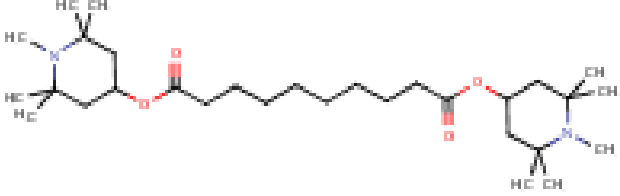
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Acronyms & Abbreviations

Chemical Identity

Synonyms	bis(1,2,2,6,6-pentamethyl-4-piperidyl) sebacate bis(1,2,2,6,6-pentamethyl-4-piperidyl) decandioate decanedioic acid, 1,10-bis(1,2,2,6,6-pentamethyl-4-piperidyl) ester decanedioic acid, bis(1,2,2,6,6-pentamethyl-4-piperidyl) ester pentamethyl piperidyl sesquisebacate
Structural Formula	
Molecular Formula	C ₃₀ H ₅₆ N ₂ O ₄
Molecular Weight (g/mol)	508.7824
Appearance and Odour (where available)	Light yellow liquid
SMILES	<chem>C1(C)(C)CC(OC(=O)CCCCCCCCC(=O)OC2CC(C)(C)N(C)C(C)(C)C2)CC(C)(C)N1C</chem>

Import, Manufacture and Use

Australian

The chemical has reported commercial use in printing inks.

There are several published Australian safety data sheets which identify commercial and domestic uses in adhesives, sealants, coatings and car refinishing products. The concentration listed was typically <1 %, although concentrations up to 10 % have been reported.

International

The chemical is listed on the Organisation of Economic Co-operation and Development (OECD) list of high production volume chemicals (Galleria Chemica).

The following international uses have been identified through:

- Galleria Chemica;
- the Substances and Preparations in Nordic countries (SPIN) database;
- the European Commission Cosmetic Ingredients and Substances (CosIng) database;
- the United States (US) Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and
- various assessments (Government of Canada, 2010; Danish EPA 2015).

The chemical functions as an antioxidant and an ultraviolet (UV) light stabiliser in products and provides protection against photodegradation.

The chemical has reported cosmetic use as a stabilising agent. However, there is no recent reported use of this chemical in cosmetics in the United States of America (INCI).

The chemical has reported domestic use, including in weatherproofing stains, adhesives, sealants, varnishes, auto-interior protectants, aerosol solvent-borne paints and window sealants. Reported concentrations were typically <1 % although concentrations up to 5 % have been reported in some products. Potential domestic use in car care products and printing inks has been identified.

The chemical has reported commercial uses, including:

- in automotive coatings;
- in antifouling agents;
- in colouring agents;
- in binding agents and adhesives; and
- as a corrosion inhibitor.

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

- the manufacture of rubber and plastic products; and
- the manufacture and maintenance of transport equipment.

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 Hazardous Substances Information System (HSIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Limited data are available for the chemical, decanedioic acid, bis(1,2,2,6,6-pentamethyl-4-piperidinyloxy)-ester (PEDA—CAS No. 41556-26-7). Bis(1-octyloxy-2,2,6,6-tetramethyl-4-piperidyl) sebacate (tradenname, Tinuvin 123—CAS No. 129757-67-1) and bis(2,2,6,6-tetramethyl-4-piperidyl) sebacate (bis-TMPS—CAS No. 52829-07-9) are structurally-related to PEDA and data will be read-across from these chemicals where appropriate.

Toxicokinetics

No toxicokinetics data are available for PEDA. Based on data for bis-TMPS (OECD, 2008), the chemical is assumed to undergo metabolic degradation by phase I hydrolysis to generate 3,3,4,4,5,5-pentamethylpiperidin-4-ol (CAS No. 2403-89-6) and decanedioic acid (CAS No. 693-23-2) as the main metabolites.

Acute Toxicity

Oral

The chemical PEDA has low acute oral toxicity based on results from animal tests following oral exposure. This is supported by results generated for structurally-related chemicals in animals.

The median lethal dose (LD50) for PEDA ranged from 2369 to 3920 mg/kg bodyweight (bw) in rats (Government of Canada, 2010).

The LD50s in rats for Tinuvin 123 and bis-TMPS were >2000 mg/kg bw/day and 3700 mg/kg bw/day, respectively (NICNAS, 1992; OECD, 2008). Reported signs of toxicity included raised hair, hunched posture, exophthalmos, rapid breathing, salivation and body weight gain.

Dermal

The chemical has low acute toxicity based on results from animal tests following dermal exposure and results from animal tests for structurally-related chemicals. The LD50 in rats for PEDA is >2000 mg/kg bw (Government of Canada, 2010).

The LD50s in rats for Tinuvin 123 and bis-TMPS were >2000 mg/kg bw/day and 3170 mg/kg bw/day, respectively (NICNAS, 1992; OECD, 2008). Sub-lethal signs of toxicity included raised hair, abnormal posture, ventral recumbency and hyperventilation.

Inhalation

No data are available for the chemical. Based on data for bis-TMPS, classification is considered warranted (refer **Recommendation** section).

The chemical bis-TMPS has high acute toxicity based on results from animal tests following inhalation exposure. Male and female rats (nine animals/sex/dose) were exposed to the chemical at aerosol concentrations of 232, 394 and 887 mg/m³ bis-TMPS for four hours (nose-only exposure).

Mortalities in the 394 and 887 mg/m³ groups were 1/9 and 9/9, respectively. The median lethal concentration (LC50) in rats is 500 mg/m³. Observed sub-lethal effects included dyspnoea, salivation, trismus, tremor and sedation with a dose-dependent intensity noted in all rats on day one. Slight pulmonary oedema was observed in the rats that died (OECD, 2008).

Corrosion / Irritation

Skin Irritation

No conventional skin irritation studies have been conducted with PEDA. Based on available data (including for structurally-related chemicals), the chemical is considered to be a slight to moderate skin irritant. There are insufficient data to warrant hazard classification.

An inadequately characterised test article containing PEDA at an unknown concentration was reported to cause severe dermal irritation in New Zealand White (NZW) rabbits 24-72 hours following topical application with 0.5 mL. Signs included blanching, ulceration and oedema. No further information was available (Government of Canada, 2010).

Male and female hairless rabbits (three animals/sex) were exposed to undiluted bis-TMPS (unknown volume) under occlusive conditions for 24 hours and observed for seven days. Erythema was observed (maximum score 1) at 24 and 48 hours after patch removal and was reversed after 72 hours. Oedema was observed (maximum score 1) at 24 hours and was reversed within 48 hours (OECD, 2008).

In a phototoxicity test with bis-TMPS, no erythema or oedema was observed in male and female mice following exposure to the chemical at 0.3, 1 or 3 % (in acetone/ethanol), with or without UV-A irradiation (OECD, 2008).

The analogue Tinuvin 123 was assessed for skin irritation in three male NZW rabbits. Undiluted test substance (0.5 ml) was applied to the shaved, intact skin of animals and left under semi-occlusive conditions for four hours. Animals showed slight, reversible skin redness after one hour which persisted for more than 72 hours in one animal. The observed effects were insufficient to warrant hazard classification.

Eye Irritation

No conventional eye irritation studies have been conducted with PEDA. However, based on available data (including for structurally-related chemicals), it is considered to be a moderate to severe eye irritant. Given that the basicity of the chemical is considered to be more similar to bis-TMPS than Tinuvin 123, classification is recommended based on the irreversible eye damage observed in a study with bis-TMPS (refer **Recommendation section**).

In a non-guideline study, nine NZW rabbits had 0.1 mL of an inadequately characterised test material containing an unknown amount of PEDA, instilled into one eye each. Iritis, and to a lesser degree, corneal opacity and conjunctivitis were observed. No information on the grading or frequency of effects was reported (Government of Canada, 2010).

An eye irritation study with bis-TMPS was conducted, in which 0.1 g of undiluted bis-TMPS was applied to one eye of each of three rabbits, with observations made one, 24, 48 and 72 hours, seven and 21 days after instillation. Severe redness and conjunctival swelling was observed up to 72 hours in two animals and to a lesser extent in one animal. Conjunctival lesions were still present after seven days, but completely recovered within 21 days. Corneal opacity was observed in all animals up to 48 hours and in two animals at all timepoints. In two animals, corneal opacity was not reversible within 21 days. On the basis of these findings, bis-TMPS is considered to cause serious eye damage in rabbits (OECD, 2008).

Tinuvin 123 has also been assessed for ocular irritation. Three female NZW rabbits had 0.1 mL of the undiluted test chemical instilled into the conjunctival sac of one eye. Animals were assessed 1, 24, 48 and 72 hours following instillation. Slight conjunctival chemosis was observed in all three animals and was reversed within 48 hours of application. Slight conjunctival redness was also observed in all three animals after one hour and persisted for over 10 days in two of the animals before reversing fully. The chemical was found to be slightly irritating and did not warrant classification (NICNAS, 1992).

Sensitisation

Skin Sensitisation

The chemical is considered to be a skin sensitizer based on positive results seen in a guinea pig maximisation test (GPMT) and in a closed patch sensitisation test in humans (see **Sensitisation—Observation in Humans** section). The OECD Toolbox (version 3.4) analysis indicated that there were functional alerts for sterically-hindered piperidine derivatives for protein binding for PEDA and structurally similar chemicals, suggesting a potential for skin sensitisation (OECD Toolbox). Although animal data for the structurally-related chemicals show no evidence of sensitisation, data for PEDA and the OECD toolbox alerts were considered sufficient to warrant classification (refer **Recommendation section**).

PEDA was assessed for skin sensitisation in a non-guideline study (limited experimental details are available). When exposed to a mixture containing 70–80 % PEDA and 15–25 % of a structurally related chemical, Tinuvin 765 (CAS No. 82919-37-7), guinea pigs showed strong positive reactions consistent with hypersensitivity, including erythema and oedema. Investigators determined that PEDA was a strong skin sensitizer under these conditions (Government of Canada, 2010). Sensitisation was reported for 75–85 % of animals, with dermal reactions becoming more severe with the second challenge (moderate to severe erythema and oedema). The chemical was reported to be a strong sensitizer at high concentrations in other studies submitted to the US EPA but limited study details were available (TSCATS).

Both of the structurally-related chemicals, Tinuvin 123 and bis-TMPS have been assessed for skin sensitisation in a GPMT conducted similarly to OECD Test Guideline (TG) 406 (skin sensitisation). No animals showed a sensitisation reaction and, under the test conditions, the chemicals were not skin sensitizers in guinea pigs (NICNAS, 1992; OECD 2008).

Observation in humans

Closed-patch sensitisation tests have been conducted in two male and eight female human volunteers using a mixed test material containing an unknown quantity of PEDA. Test material was applied to the right arm of test subjects, four days per week, for four weeks, followed by a challenge phase (four days per week for one week, with the patch removed two hours after application). Severe reactions were observed that were consistent with allergic contact dermatitis. Whilst the contribution to reactions from other components cannot be excluded, the positive results from guinea pig studies indicate that PEDA can have sensitising properties at high concentrations (Government of Canada, 2010).

Repeated Dose Toxicity

Oral

No repeat dose oral toxicity studies have been conducted using PEDA. Data for the structurally-related chemicals did not identify a consistent target organ. Based on the high doses at which toxicological significant effects were observed, classification is not considered warranted.

In a short-term repeat dose toxicity study, Tif:RAIf rats (four animals/sex/group) were administered Tinuvin 123 by oral gavage at 10, 100 or 1000 mg/kg bw, daily for 28 days. Mid and high dose males, and high dose females showed statistically significant dose-related increases in prothrombin time and total bilirubin levels when compared with controls. Hepatic extramedullary haematopoiesis was observed in all dose groups but significantly increased incidence and severity was only observed in high dose males. Based on clinical findings of increases in prothrombin times and bilirubin levels in males, a No Observed Effect Level (NOEL) of 10 mg/kg bw/day was determined (NICNAS, 1992).

Several repeat dose toxicity studies have also been conducted using bis-TMPS including:

- a 28 day oral gavage in Tif:RAIf rats (0, 600, 1000 or 2000 mg/kg bw/day);
- a 28 day oral gavage study in CFY rats (0, 50, 200 or 600 mg/kg bw);
- a 90 day diet study in Sprague Dawley rats (0, 400, 1300 or 4000 ppm (equivalent to 0, 26, 80 and 261 mg/kg bw, for males; and 0, 29, 90 and 277 mg/kg bw for females, respectively));
- a 90 day diet study in dogs (0, 800, 2600 or 8000 ppm (equivalent to 0, 27, 69 and 150 mg/kg bw for males and 0, 27, 78 and 155 mg/kg bw for females, respectively)); and
- a one-generation study (refer **Reproductive and Developmental Toxicity** section) (OECD, 2008; Government of Canada, 2010).

In all studies, reduced body weight gain was reported with the lowest observed effect levels ranging from ≤ 29 mg/kg bw/day to 300 mg/kg bw/day. Consistent effects on organ weights were not reported across studies. In general, histopathological findings were not reported, although reversible minimal hepatic periportal hypertrophy was observed in the high dose group in the 90 day study in dogs. In the 28 day oral gavage study in Tif:RAIf rats, neutrophil and eosinophil numbers were elevated in the spleen, within the blood vessels and in the perivascular lung tissue.

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemical is not considered to be genotoxic.

In vitro

The chemical PEDA was assessed in a bacterial reverse mutation assay in *Salmonella typhimurium* (strains not specified). Bacteria were incubated with the chemical (concentrations not reported), in the absence or presence of metabolic activation. The chemical did not cause mutations at a rate exceeding that observed in controls (Government of Canada, 2010).

Tinuvin 123 produced negative results in a bacterial reverse mutation assay. The chemical did not cause an increase in the incidence of mutations in *S. typhimurium* (TA98, TA100, TA1535 and TA1537 strains) or *Escherichia coli* (WP2uvrA strain), at concentrations up to 5 mg/mL with or without metabolic activation (NICNAS, 1992).

The chemical bis-TMPS produced negative results in a bacterial reverse mutation assay using *S. typhimurium* strains TA100, TA1535, TA98 and TA1537, in the presence or absence of metabolic activation (OECD, 2008; Government of Canada, 2010).

The chemical bis-TMPS was negative in a chromosomal aberration test using human lymphocytes, when tested in the presence or absence of metabolic activation (OECD, 2008; Government of Canada, 2010).

In vivo

In Tif:MAGf mice of both sexes, the analogue Tinuvin 123 did not produce an increase in the rate of micronuclei formation in bone marrow cells following intraperitoneal injection at 5000 mg/kg bw. Under these test conditions, the chemical was not clastogenic (NICNAS, 1992).

Carcinogenicity

No carcinogenicity studies are available for PEDA or the two structurally-related chemicals Tinuvin 123 and bis-TMPS.

Reproductive and Developmental Toxicity

No data are available for PEDA or Tinuvin 123. For the structurally-related chemical bis-TMPS, there is no evidence of reproductive toxicity and developmental effects were only observed secondary to maternal toxicity.

The chemical bis-TMPS has been assessed for developmental and reproductive toxicity. Rats of both sexes (strain not specified) were dosed with the chemical at 3, 30 or 300 mg/kg bw/day by gavage. Males were dosed for 10 weeks before mating, during mating and up to termination (after delivery of litters). Females were dosed for two weeks before mating, post-coitum and during 22 days of lactation. There was no treatment-related effect on fertility in this study. Male and female offspring exhibited statistically significant decreases in body weight when assessed on post-gestational days 14 and 21. No other treatment-related effects were observed in pups during this study. Parental effects have previously been reported (refer **Repeat dose toxicity** section). On the basis of these results, NOELs of 300 mg/kg bw/day and 30 mg/kg bw/day were determined for reproductive toxicity and developmental toxicity, respectively (Government of Canada, 2010).

Other Health Effects

Neurotoxicity

In the 28 day oral gavage study with bis-TMPS in Tif:RAIf rats (refer **Repeated Dose Toxicity** section), histochemical analysis of brain tissues from the animals dosed at 1000 mg/kg/bw/day showed reduced noradrenaline in the superior cervical ganglion. Clinical observations suggestive of neurological effects (eyelid ptosis, muscular hypertonia, sedation) were also observed in this study at doses ≥ 600 mg/kg bw/day (Government of Canada, 2010). Evidence of neurological effects were not observed in other repeated dose toxicity studies at lower doses.

Bis-TMPS was found to cause signs consistent with neurological effects in a short-term oral gavage study in rats (strain and number not specified) when dosed at 600 mg/kg bw/day. Effects included eyelid ptosis, muscular hypotonia and sedation. Neurohistochemical changes were also recorded at 1000 mg/kg bw/day (decreased levels of noradrenaline in the superior cervical ganglia) (Government of Canada, 2010).

In studies conducted using *Xenopus* oocytes, bis-TMPS was found to inhibit nicotinic acetylcholine receptors in a dose-dependent manner. Repeated intraperitoneal injections in rats has resulted in histological changes in myocardial cells and has also altered urinary noradrenaline levels (Government of Canada, 2010).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation are skin sensitisation, eye irritation and acute toxicity from inhalation exposure.

Public Risk Characterisation

The chemical has identified use in domestic products. Whilst the chemical has potential use in cosmetics, based on information on usage in the US, cosmetic use is not expected to be widespread.

Therefore, the general public would most likely be exposed to the chemical through skin and incidental eye contact or inhalation when using domestic products. The typical concentration of the chemical in such products is <1 %.

The margins of exposure estimated in a risk assessment conducted internationally for the chemical (Government of Canada, 2010) for uses in stains, aerosol paints, sealants and auto interior protectants (sprayed) indicate that the chemical does not pose an unreasonable risk to the public. The estimated margins of exposure are considered applicable in the Australian context. While there may still be a risk of sensitisation at the concentrations used in some of these products, the occasional use and lack of direct skin contact reduces this risk.

Taking normal precautions to avoid prolonged skin and eye contact should mitigate the risk of sensitisation and eye damage, given the low concentrations that are used in domestic products. A risk of contact dermatitis in susceptible individuals cannot be ruled out.

Further risk management is not considered necessary to protect public safety.

Occupational Risk Characterisation

During product formulation, dermal, ocular or inhalation 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 or inhalation exposure could occur if products are spray applied. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical 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 at a workplace (such as an employer) has adequate information to determine the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (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.

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 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)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)	May cause an allergic skin reaction - Cat. 1 (H317)

^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 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;
- 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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