Methane, sulfinylbis-: Human health tier II assessment

18 September 2014

CAS Number: 67-68-5

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.

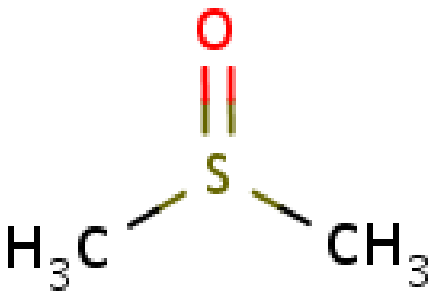
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	DMSO dimethyl sulfoxide methane, 1,1'-sulfinylbis- methyl sulfoxide sulfinylbis(methane)
Structural Formula	
Molecular Formula	C2H6OS
Molecular Weight (g/mol)	78.13
Appearance and Odour (where available)	Odourless and colourless liquid
SMILES	CS(C)=O

Import, Manufacture and Use

Australian

No specific industrial use, import, or manufacturing information has been identified.

The following non-industrial uses have been identified (Australian Pesticides and Veterinary Medicines Authority—APVMA):

- in pesticides and fungicides; and
- in veterinary medicines (anti-arthritic and anti-inflammatory agents).

International

The following international uses have been identified through the 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); Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances

(CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use:

- as a solvent.

The chemical has reported domestic use including in:

- coatings, paints, lacquers and varnishes;
- paint and varnish removers;
- washing and cleaning products;
- ink and toners;
- fillers, putties, plasters and modelling clay; and
- polishes and wax blends.

The chemical has reported commercial use including:

- as a solvent;
- in anti-freeze and de-icing products;
- in adhesives and sealants;
- in hydraulic fluids; and
- in construction materials.

The chemical has reported site-limited use including as a:

- solvent; and
- chemical intermediate.

Restrictions

Australian

The chemical (dimethyl sulfoxide) is listed in the *Poisons Standard* (the Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP) in Schedules 4 and 6:

- Schedule 4—Prescription Only Medicine, or Prescription Animal Remedy (excluding dimethyl sulfone) for therapeutic uses except:

(a) when included in Schedule 6; or

(b) in *in vitro* test kits.

- Schedule 6—Poison (excluding dimethylsulfone) except:

(a) when for therapeutic use; or

(b) for the treatment of animals:

(i) when combined with no other therapeutic substance(s);

(ii) in liquid preparations containing copper salicylate and 1 per cent or less of methyl

salicylate as the only other therapeutic substances; or

(iii) in clay poultices containing 2 per cent or less of dimethyl sulfoxide.

Schedule 6 chemicals are labelled with 'Poison'. These are 'Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'.

International

The chemical is listed on the following (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- EU Commission Regulation No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food—Annex I;
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist");
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain; and
- The Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1: List of substances which must not form part of the composition of cosmetic products.

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

The following exposure standards are identified (Galleria Chemica):

- time weighted average (TWA) of 50 ppm (150–160 mg/m^3) in Denmark, Estonia, Germany, Sweden and Switzerland; and
- a short term exposure limit (STEL) of 100 ppm (320 mg/m^3) in Switzerland and 150 ppm (500 mg/m^3) in Estonia and Sweden.

Health Hazard Information

Toxicokinetics

The chemical is rapidly absorbed following dermal and oral exposure. The in vitro dermal permeability rate of the chemical was calculated as 176 g/m^2/hour (compared with 24 g/m^2/hour for water), making it an excellent solvent for the dermal application of cosmetics and pharmaceuticals (OECD, 2008).

The exact mechanism by which the chemical enhances skin permeability is not known. It has been suggested that the chemical:

- removes the lipid matrix of the stratum corneum, making holes in the penetration barrier;
- produces reversible configurational changes in protein structure; and
- functions as a swelling agent (US EPA, 2006).

Once absorbed, the chemical is widely distributed in tissue and bodily fluid. After oral administration, the chemical is found in the kidneys, spleen, lung, heart and testes, with a smaller percentage being observed in the liver, fat, small intestine, brain, skeletal muscle and heart. Dermal administration resulted in a similar distribution profile to that from oral administration, although at lower concentrations (OECD, 2008).

The chemical is rapidly biotransformed in mammalian species into either dimethyl sulfone (CAS No. 67-71-0) or dimethylsulfide (CAS No. 75-18-3). Approximately 85 % of the chemical was excreted in either urine or faeces. Only 1 % was excreted in exhaled air, with dimethyl sulfide accounting for the characteristic ‘garlic odour’ in the breath (US EPA, 2006; OECD 2008).

Acute Toxicity

Oral

The chemical has low acute oral toxicity in rats.

The median lethal dose (LD50) in rats was greater than 2000 mg/kg bw (typically >15000 mg/kg bw). Observed sublethal effects included polyuria (excessive urination), hyperaemia (increased blood flow to tissues), polydipsia (excessive thirst) and decreased motor activity (OECD, 2008).

Dermal

The chemical is considered to have low acute dermal toxicity in rats and mice.

In a non-guideline study, rats (n = 14/sex at 100 % and n = 3/sex for all other concentrations) and mice (n = 6/sex for 40 and 60 %, n = 4/sex at 80 % and n = 5/sex at 100 %) were exposed (whole body immersion) to the chemical at 40, 60, 80 (aqueous solution) or 100 % (ca. 2, 13, 33 or 44 g/kg bw for rats and 22, 37, 49 or 91 g/kg bw for mice). The approximate LD50s of 40000 mg/kg bw and 50000 mg/kg bw were determined for rats and mice, respectively, with no clinical signs of toxicity being reported (OECD, 2008; REACH).

Inhalation

The chemical is considered to have low acute inhalation toxicity in rats.

The median lethal concentration (LC50) in rats is greater than 5.33 mg/L/4-hour (the highest concentration tested). No mortalities or clinical signs were observed at this concentration (OECD 2008; REACH).

Corrosion / Irritation

Respiratory Irritation

Based on the limited data available, the chemical is not expected to be a respiratory irritant.

No respiratory tract irritation was reported in rats during an acute inhalation toxicity study (see **Acute toxicity: Inhalation**).

Irritation of the nasal passage was reported in a repeated dose inhalation toxicity study (see **Repeated dose toxicity: Inhalation**). However, this was attributed to deposition of the non-respirable fraction of the aerosolised chemical at a high concentration of 2.783 mg/L/6-h/d (OECD, 2008).

Skin Irritation

The chemical is minimally irritating to the skin.

In a study conducted according to the OECD Test Guideline (TG) 404, New Zealand White rabbits (n = 3) were topically administered the chemical (0.5 mL on the posterior right flank) using a semi-occlusive dressing for four hours. The chemical caused no oedema (mean score from 24-, 48- and 72-hour readings was 0/3), but slight erythema (mean score from 24-, 48- and 72-hour readings was 0.33/3), which was fully reversible within 72 hours (OECD, 2008).

Eye Irritation

The chemical is a slight eye irritant.

Application of the chemical (0.1 mL) to the eyes of rabbits (n = 3) according to OECD TG 405 resulted in no iris lesions or corneal opacity (mean score 0/4 for the 24-, 48- and 72-hour readings for both effects). Slight conjunctival irritation (mean score 1.13/4 for the 24-, 48- and 72-hour readings) and slight chemosis (mean score 0.33/4 for the 24-, 48- and 72-hour readings) were observed. However, these effects were reversible within 96 hours; the chemical was reported to be a slight eye irritant (OECD, 2008).

Observation in humans

An extensive number of irritation studies have been carried out on humans using both dermal and ocular exposure routes. In most cases, symptoms included transient erythema, stinging, itching and burning, all of which disappeared soon after treatment (OECD, 2008).

The skin irritation effects of the chemical after dermal administration are largely dose-dependent. In one study, human volunteers were topically administered a drop of a solution containing the chemical at various concentrations (20–100 %). A significant number of subjects exposed to the neat chemical (100 %) experienced tiny follicular papules (with an erythematous ring) that appeared after 15 minutes, and persisted for one hour. Almost all

volunteers exposed to a single application of 80–90 % solution of the chemical reported erythema, but this was less frequent in those exposed to a 70 % solution of the chemical (OECD, 2008).

Solutions of the chemical at varying concentrations were instilled once into the lower conjunctival sacs of adult men. No effects were observed up to 50 % concentration, at which stage the subjects noted transient burning. A 90 % solution of the chemical caused temporary stinging and burning in human volunteers, although the eye was completely normal after 24 hours (OECD, 2008)

Sensitisation

Skin Sensitisation

The chemical is not a skin sensitiser.

In a skin sensitisation study using the maximisation method (OECD TG 406), Hartley guinea pigs (n = 10 females/dose) were induced with the undiluted chemical (volumes not given) on day one (intradermal application) and day eight (cutaneous application). A challenge was performed on day 22 with a cutaneous application of the undiluted chemical (0.1 mL). No positive skin reactions were observed in test animals (OECD, 2008; REACH).

The sensitising potential of the chemical was assessed in a local lymph node assay (LLNA; equivalent to OECD TG 429) using Balb/c mice (n = 3/dose). The chemical (in water) was tested at 20, 50 and 100 % concentrations and found to be non-sensitising (OECD, 2008; REACH).

The chemical also gave negative results using the Draize test, Buehler test and split adjuvant test for skin sensitisation (OECD, 2008).

Observation in humans

No skin sensitisation was observed in a patch test with 23 human subjects. The test was conducted using five inductions (for 48 hours each as an occlusive patch) with a 75 % aqueous solution of the chemical, and challenged with a 25 % solution of the chemical (OECD, 2008).

Repeated Dose Toxicity

Oral

The chemical is not considered to cause severe effects following repeated oral exposure.

In a chronic oral toxicity study (equivalent to OECD TG 452), Sprague Dawley (SD) rats (n = 50/sex/dose) and Pembrokeshire Corgi dogs (n = 5/sex/dose) were administered the chemical via oral gavage doses of 0, 1, 3 or 9 mL/kg bw/d (equivalent to 1100, 3300 and 9900 mg/kg bw/d) for five days a week for 18 months (rats) or 24 months (dogs). A no observed adverse effect level (NOAEL) of 3300 mg/kg bw/d was determined for rats based on ophthalmological and haematological effects observed at 9900 mg/kg bw/d, while a lowest observed adverse effect level (LOAEL) of 1100 mg/kg bw/d was determined for dogs based on ophthalmological changes. No deaths related to the treatment were observed up to the highest concentration tested (US EPA, 2006; OECD, 2008).

Dermal

The chemical is not considered to cause severe systemic effects following repeated dermal exposure. However, repeated dermal applications in animals induced irritation, dryness, scaling and thickening of the treated skin. Based on these effects, a hazard classification (R66—Repeated exposure may cause skin dryness or cracking) is recommended.

In a chronic toxicity study (equivalent to OECD TG 452), Rhesus monkeys were administered the chemical dermally at 0 (n = 2 males and 1 female), 990 (n = 2/sex/dose), 2970 (n = 2/sex/dose), or 8910 (n=3/sex/dose) mg/kg bw/d, daily for 18 months. No systemic toxic effects or mortalities were observed and thus the NOAEL for systemic toxicity was reported to be greater than the highest concentration tested (>8910 mg/kg bw/d) (OECD, 2008). All treated monkeys exhibited scaling and flaking of the skin at the site of application (US EPA, 2006; REACH).

Repeated dose dermal toxicity studies in rats, pigs, dogs and rabbits (both subchronic and subacute) also indicate LOAELs ranging from 5000–11000 mg/kg bw/d for ocular effects (OECD, 2008; REACH).

In a non-guideline study, guinea pigs (n = 10/sex/dose) exposed to the chemical (0.5 mL) daily for up to 63 consecutive days showed mild erythema or oedema initially, which developed into dryness, scaling and thickening by day 63 (US EPA, 2006; REACH).

Inhalation

The chemical is not considered to cause severe effects following repeated inhalation exposure.

In a 90-day study (OECD TG 413), SD rats (n = 10/sex/dose) were exposed to the chemical vapour at 0, 0.310, 0.964 or 2.783 mg/L for six hours per day. No significant differences were observed in ophthalmology, haematology, biochemistry, urinalysis or macroscopic pathology when compared with the control groups. The no observed adverse effect concentration (NOAEC) was determined to be greater than 2.783 mg/L/6-h/d for systemic toxicity. A lowest observed adverse effect concentration (LOAEC) for local effects was reported to be 2.783 mg/L/6-hour/day based on irritation in the nasal passage (lesions in the inferior ventral medial meatus, increased degree of eosinophilic inclusions of the olfactory epithelium) and pharynx (prominent goblet cells present) (OECD, 2008; REACH).

In a subacute study (OECD TG 412), SD rats (n = 32/sex/dose) were exposed to the chemical vapour at 0.2 mg/L for seven hours a day, five days a week over six weeks. There were no signs of systemic toxicity and the NOAEC was determined to be greater than 0.2 mg/L (US EPA, 2006).

Observation in humans

A number of repeated dose dermal toxicity studies have been conducted on humans volunteers. Some of these studies have shown transient or reversible local skin effects, supporting the hazard classification recommended in section **Repeat dose toxicity: Dermal**.

- 78 volunteers were administered a gel containing the chemical at 80 % concentration (1 g/kg bw), daily for 14 days. Reported side effects included sedation (52 % of volunteers), headache (42 %), dizziness (18 %), and nausea (32 %). An NOAEL of 1000 mg/kg bw/d for systemic toxicity was reported (OECD, 2008).
- 20 subjects were administered the chemical (9 mL, at 90 % concentration) twice daily for three weeks. Treatment on one subject was discontinued after the 12th day when the subjects developed a diffuse erythematous and scaling rash accompanied by severe abdominal cramps. No other effects on haematological, biochemical or urine parameters were noted (OECD, 2008).
- male volunteers (aged 21–55, n = 38 in the treatment group and 18 in the control group) were treated with a single daily dermal application of 1 g/kg bw of chemical (80 % in a gel) for 90 days. Transient erythema was experienced by about one quarter of the subjects immediately following exposure during the first two weeks, with two subjects developing mild scaling diffuse erythematous dermatitis after two to three weeks (which disappeared despite continued treatment). Two thirds of the volunteers reported transient burning and stinging in the first few weeks of treatment. Transient eosinophilia was reported during the first few weeks in 51 % of the subjects (OECD, 2008).

Patients, (n = 500) treated for various types of chronic arthritis with the chemical (at 90 %, 6–8 mL) for up to 14 months, had transient skin irritation (due to liberation of histamine) but showed no effects on haematology, blood sugar or urine parameters (OECD, 2008).

Patients (n = 43) treated dermally with the chemical (1–45 mL/day) for up to 19 months did not exhibit any corneal, retinal or lenticular changes in the eye (OECD, 2008).

A study exposed 548 patients dermally to 60–90 % of the chemical for 30 minutes a day for seven days or up to 10 months. Erythema, itching and local urticaria were sometimes observed, but these local irritation effects were reversible within three days after treatment ceased (OECD, 2008).

Genotoxicity

Based on the available data, the chemical is not considered to be genotoxic.

The chemical gave negative results for genotoxicity in numerous in vitro studies:

- several gene mutation assays (OECD TG 471) with *Salmonella typhimurium* strains TA 97, TA98, TA100, TA1535 and TA1537, with or without metabolic activation, up to 10000 µg/plate (US EPA, 2006; OECD, 2008);
- a chromosome aberration assay using Chinese hamster ovary (CHO) cells (equivalent to OECD TG 474) up to 5 mg/mL (OECD, 2008); and
- a sister chromatid exchange assay (equivalent to OECD TG 479) conducted using CHO cells, with or without metabolic activation, up to 5 mg/mL (OECD, 2008).

The chemical gave negative results for genotoxicity in several in vivo assays:

- a micronucleus assay (equivalent to OECD TG 474) in rats up to 5000 mg/kg bw/d via intraperitoneal administration over five days (OECD, 2008);
- chromosome aberration and gene mutation studies in *Drosophila melanogaster* (EPA, 2006; OECD, 2008).

Carcinogenicity

No standard/guideline carcinogenicity studies have been conducted on the chemical alone. Based on the limited data available, the chemical is not expected to be carcinogenic.

The effect of the chemical on the tumorigenic activity of a known carcinogen, 7,12-dimethylbenz[a]anthracene (DMBA; CAS No. 57-97-6) was investigated in SD rats. Three groups of male rats (n = 50) were administered 20 mg of DMBA via oral gavage. In the first and second groups, DMBA treatment was followed by 50 ppm of the chemical in their drinking water three days before or after DMBA administration, respectively. The third group was a control that did not receive the chemical. After 18 months of treatment, the chemical had no observable effect on the latency or frequency of tumours induced by DMBA (OECD, 2008).

In a dermal carcinogenicity study, ICR/Ha Swiss mice (n = 20 females) received 0.1 mL of the chemical three times a week for 400 days after a primary treatment with DMBA (20 µg in 0.1 mL acetone, applied once). No skin tumours were induced in mice treated with the chemical after primary treatment with DMBA (OECD, 2008).

Another dermal carcinogenicity study (non-guideline) exposed SD rats (n = 40/dose) to 0.02 mL of a 1 % solution of DMBA dissolved in either the chemical or acetone (CAS No. 67-64-1), three times a week for 26 weeks. A third group of rats (n = 40) acting as a control group, received only the chemical (0.02 mL). No tumours (0/40) were observed in the rats receiving only the chemical, compared with rats (10/40) receiving DMBA in the chemical, and DMBA in acetone (34/40) (OECD, 2008).

Reproductive and Developmental Toxicity

Based on the available data, the chemical is not considered to have reproductive or developmental toxicity.

In a reproductive/developmental toxicity study (OECD TG 421), SD rats (n = 12/sex/dose) were administered the chemical via oral gavage doses of 0, 100, 300 or 1000 mg/kg bw/d. Dosing occurred daily before and after mating, starting 15 days before mating, during mating (two weeks) for males and females, and until sacrifice for males and during pregnancy/lactation through to day 21 post-partum for females. There were no unscheduled deaths or treatment-related clinical signs observed during the study. No treatment-related effects were noted on mating and fertility parameters. The NOAEL for parental toxicity was considered to be 1000 mg/kg bw/d, based on marginally increased liver weights. The NOAEL for reproductive performance (mating and fertility) and progeny toxicity was 1000 mg/kg bw/d (OECD, 2008; REACH).

In a developmental toxicity study (OECD TG 414), pregnant SD rats (n = 25/dose) were administered the chemical via oral gavage doses of 200, 1000 or 5000 mg/kg bw/d on gestation days (GD) 6–15. The NOAEL for maternal toxicity was considered to be 1000 mg/kg bw/d based on decreased body weight at the highest dose. A NOAEL of 1000 mg/kg bw/d was determined for developmental toxicity, based on decreased foetal body weight and delayed rib ossification at the highest dose (US EPA, 2006; OECD, 2008).

In another study (OECD TG 414), New Zealand White female rabbits were administered the chemical via oral gavage doses of 100, 300 or 1000 mg/kg bw/d, on GD 7–28 . No signs of maternal toxicity or developmental toxicity were observed at the highest concentration tested. Therefore, the NOAEL for developmental toxicity was 1000 mg/kg bw/d (OECD, 2008).

Other Health Effects

Neurotoxicity

The neurotoxicological effects of the chemical were monitored during a subchronic inhalation toxicity study (OECD TG 413; see **Repeated dose toxicity: Inhalation**). A functional observation battery was conducted on all groups before exposure, during week 12 and during the recovery period, with a shortened battery of observation tests conducted during weeks 1–11. An NOAEC of 2.793 mg/L-air was established as there were no behavioural changes that indicated neurotoxicity observed at this highest dose tested (REACH).

Risk Characterisation

Critical Health Effects

The chemical can cause skin dryness or cracking on repeated dermal exposure, due to its defatting (dissolving dermal lipids) and drying characteristics. There are no other critical health effects expected from exposure to the chemical.

The chemical is an excellent solvent capable of dissolving a wide range of chemicals and carrying them across biological membranes (US EPA, 2006). Although no systemic toxicity effects are expected from penetration of the chemical alone (NOAELs for systemic toxicity are greater than 1000 mg/kg bw/d), the chemical's excellent solvating properties can enable other chemicals in product formulations enter the body.

Public Risk Characterisation

The chemical is listed on Schedule 4 (as a prescription only medicine or animal remedy) and Schedule 6 (Poison) of the *Poisons Standard* (SUSMP).

International uses indicate that the chemical could be present in cosmetics and domestic products (concentrations not available). However, the chemical is not listed in the Compilation of Ingredients Used in Cosmetics in the United States (CIUCUS, 2011). Any cosmetic use of the chemical in Australia is limited by Schedule 6 of the SUSMP.

Human volunteers (n = 38) treated with a gel containing the chemical at 80 % for 90 days, showed only transient erythema (~ 9/38) and mild scaling diffuse erythematous dermatitis (2/38) (see **Repeat dose toxicity: Observation in humans**). High concentrations of the chemical are not expected to be present in cosmetics or domestic products that are intended to be used repeatedly, so are not expected to cause dry, flaking and/or cracked skin. Therefore, the public risk from this chemical by itself is not considered to be unreasonable. Caution should be used in developing formulations containing the chemical to avoid ingredients that could cause systemic toxicity if carried through the skin.

Occupational Risk Characterisation

During product formulation, dermal and ocular exposure of workers to the chemical might occur, particularly where manual or open processes are used. These can include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations might 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 local skin effects from repeated exposure, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise dermal 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 a hazard classification for the chemical (refer to **Recommendation section**).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended 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 with non-therapeutic uses should be labelled in accordance with state and territory legislation (SUSMP).

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria as below. There is no comparable GHS hazard statement for this risk phrase. This assessment does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Repeat Dose Toxicity	Repeated exposure may cause skin dryness or cracking (R66)	Repeated exposure may cause skin dryness and cracking (AUH066)

[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

Caution should be used in developing formulations containing the chemical to avoid ingredients that could give rise to systemic toxicity if carried across the skin.

Control measures to minimise the risk from dermal 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:

- 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

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Last update 18 September 2014

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