



Aziridines: Human health tier II assessment

27 November 2014

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Aziridine, 2-methyl-	75-55-8
Aziridine	151-56-4

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

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals are highly reactive and volatile. The chemicals are both known carcinogens due to the properties of the aziridine ring; they only differ in the substitution of a methyl group. The toxicological profile and use patterns are similar.

Import, Manufacture and Use

Australian

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

International

The following international uses have been identified through:

- the European Union (EU) Registration, Evaluation and Authorisation of Chemicals (REACH) dossiers;
- Galleria Chemica;
- the Substances and Preparations in the Nordic countries (SPIN) database;
- the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR),
- the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and
- various international assessments (IARC, 1999a; IARC, 1999b; ACGIH, 2011a; ACGIH, 2011b; NTP, 2014).

The chemicals have reported site-limited uses, including as chemical intermediates.

Derivatives of the chemicals are used in industries such as paper, textile, rubber, surface coating and petroleum refining.

The chemicals have reported domestic uses in the SPIN. However, it should be noted that the SPIN does not distinguish between direct use of the chemicals or use of the materials that are produced from chemical reactions involving the chemicals.

Restrictions

Australian

No known restrictions have been identified.

International

The chemicals are listed on the following (Galleria Chemica):

- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products;
- 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.

The chemicals are restricted under Annex XVII to REACH Regulations. The chemicals 'cannot be used in substances and preparations placed on the market for sale to the general public in individual concentrations $\geq 0.1\%$ ' (European Parliament and Council 1999; European Parliament and Council 2006; European Parliament and Council 2008).

Existing Worker Health and Safety Controls

Hazard Classification

2-Methylaziridine (CAS No. 75-55-8), is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- Carc. Cat. 2; R45 (carcinogenicity);
- T+; R26/27/28 (acute toxicity); and
- Xi; R41 (irritation).

Aziridine (CAS No. 151-56-4), is classified as hazardous, with the following risk phrases for human health in the HSIS (Safe Work Australia):

- Carc. Cat. 2; R45 (carcinogenicity);
- Muta. Cat. 2; R46 (genotoxicity);
- T+; R26/27/28 (acute toxicity); and
- C; R34 (corrosion).

Exposure Standards

Australian

2-Methylaziridine (CAS No. 75-55-8) has an exposure standard of 4.7 mg/m³ (2 ppm) time weighted average (TWA). Notices: Sk (absorption through the skin may be a significant source of exposure) (Safe Work Australia).

Aziridine (CAS No. 151-56-4), has an exposure standard of 0.88 mg/m³ (0.5 ppm) TWA. Notices: Sk (absorption through the skin may be a significant source of exposure) (Safe Work Australia).

The *Guidance on the interpretation of workplace exposure standards for airborne contaminants* advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2013).

International

The following exposure standards are identified (Galleria Chemica):

2-Methylaziridine (CAS No. 75-55-8)

An exposure limit (occupational exposure limit—OEL, threshold limit value—TLV) of 0.5–4.7 mg/m³ (0.2–2 ppm) (TWA) and 1–9.4 mg/m³ (0.4–4 ppm) short-term exposure limit (STEL) in different countries such as the USA (American Conference of Industrial Hygienists—ACGIH), Canada, Denmark, Indonesia, Ireland, Japan and Malaysia.

Aziridine (CAS No. 151-56-4)

An exposure limit (OEL, TLV) of 0.09–0.88 mg/m³ (0.05–0.5 ppm) (TWA) and 0.18–2.6 mg/m³ (0.1–1.5 ppm) (STEL) in different countries such as the USA (ACGIH), Canada, Denmark, Indonesia, Ireland, Japan and Malaysia.

Health Hazard Information

Toxicokinetics

Limited data are available for the chemicals. Based on the high acute toxicity observed in animals following oral, dermal and inhalation exposure (see **Acute toxicity**), the chemicals are considered to be readily absorbed by all routes of exposure.

In a radiolabelled study with aziridine in rats (with administration by intraperitoneal injection (i.p.)), the chemical was demonstrated to be widely distributed throughout the body. Approximately 50 % of the administered dose was excreted in the urine with the majority as metabolites (unidentified). Some accumulation in the liver, intestines, caecum, spleen and kidneys was observed (ACGIH, 2011a; REACH).

The opening of the aziridine ring appears to be an important metabolic step in the chemicals' mutagenic action (IARC, 1999a).

Acute Toxicity

Oral

The chemicals are classified as hazardous with the risk phrase 'Very toxic if swallowed' (T+; R28) in HSIS (Safe Work Australia). The available data (median lethal dose—LD50) support this classification. These are:

- 5–15 mg/kg bw in rats for aziridine; and
- 19 mg/kg bw in rats for 2-methylaziridine (ACGIH, 2011a; ACGIH, 2011b; REACH).

Reported signs of toxicity for aziridine include apathy, abdominal pain, increased urine secretion and histopathological changes in the kidneys (REACH).

The target organ for toxicity is the kidney. Renal papillary necrosis has been observed in rats and rabbits in subacute toxicity studies with aziridine, and in rats following a single i.p. injection of 2-methylaziridine (IARC, 1999a; IARC 1999b, ACGIH, 2011a; ACGIH, 2011b; REACH).

Dermal

The chemicals are classified as hazardous with the risk phrase 'Very toxic in contact with skin' (T+; R27) in HSIS (Safe Work Australia). The available data (LD50 values) support this classification. These are:

- approximately 13 mg/kg bw in rats and rabbits for aziridine; and
- 34 mg/kg bw in rats for 2-methylaziridine (ACGIH, 2011a; ACGIH, 2011b; REACH).

Reported signs of toxicity for aziridine include apathy, abdominal pain, increased urine secretion and histopathological changes in the kidneys (REACH). In a subacute toxicity study repeated (3–4 times) dermal application of 8.3 mg/kg led to mortality and renal papillary necrosis in all three rabbits tested. Repeated dermal exposure (10 times) to doses of 4.15 mg/kg bw was survived by all three rabbits with renal papillary necrosis observed in one (REACH).

Inhalation

The chemicals are classified as hazardous with the risk phrase 'Very toxic by inhalation' (T+; R26) in HSIS (Safe Work Australia). The available data support this classification.

The chemical aziridine has a reported median lethal concentration (LC50) of 15 ppm (0.03 mg/L) in rats following an eight-hour exposure (ACGIH 2011a). In a separate series of acute inhalation studies in guinea pigs and rats, the eight-hour LC50 in guinea pigs was established as 25 ppm (0.04 mg/L). One out of six rats died at this concentration. Extreme respiratory difficulty was observed in both species at concentrations higher than 10 ppm. Clinical signs of toxicity include irritation, vomiting and central nervous system (CNS) effects (ACGIH, 2011a).

Limited data are available for 2-methylaziridine. Exposure to 500 ppm (1.2 mg/L) for four hours produced mortality in 5/6 rats tested, with exposure for two hours producing no lethality. Exposure to 500 ppm (1.2 mg/L) for two hours produced mortality in 3/5 guinea pigs tested, with exposure for 30 minutes producing no lethality (ACGIH, 2011b).

Observation in humans

Acute exposure (inhalation or dermal) to the chemical aziridine has been reported to cause irritation of the eyes and respiratory tract, CNS effects, damage to the liver and kidneys and in some cases, death. In one case, death was caused by destruction of the tracheobronchial cartilage over a period of two months following a five minute exposure (ACGIH, 2011a).

Corrosion / Irritation

Corrosivity

Aziridine is classified with the risk phrase 'Causes burns' (R34) in Australia. The data available support this classification. The Globally Harmonized System of Classification (GHS) classification 'Corrosive to the respiratory tract' (AUH071) should also apply (refer to **Recommendation** section).

In non-guideline studies in rabbits, aziridine caused necrosis of the skin within 1.5 hours after application and corrosion of the cornea (REACH). The chemical has been reported to corrode the skin and mucous membranes and cause severe corneal

damage (ACGIH, 2011a). Destruction of the tracheobronchial cartilage as been observed in humans (refer **Acute toxicity** section).

2-Methylaziridine is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). A 5 % solution of the chemical produced corneal damage in rabbits (ACGIH, 2011b).

Whilst the available data for a 5 % solution support the existing classification, given the structural similarity to aziridine, corrosive effects to the skin and respiratory tract are also expected at higher concentrations. An amendment of classification is recommended (refer to **Recommendation** section). The existing eye damage classification is implicit within the proposed corrosivity classification.

Sensitisation

Skin Sensitisation

No data are available.

Repeated Dose Toxicity

Oral

Due to the scope of studies conducted, limited data are available regarding non-cancer effects following repeated oral exposure. Given the reported effects from acute toxicity studies (see **Acute toxicity**) the kidneys are likely to be the target organ.

Dermal

Due to the scope of studies conducted, limited data are available regarding non-cancer effects following repeated dermal exposure. Given reported effects from acute toxicity studies (see **Acute toxicity**) the kidneys are likely to be the target organ.

Inhalation

In a repeated dose inhalation study Sprague Dawley (SD) rats were exposed to aziridine at a nominal concentration of 5 ppm (8.8 mg/m³) for 27 weeks or until death (approx. 66 weeks). A reduced lifespan, histopathological changes in the kidneys and trachea and an increased incidence of tumours in trachea, lung, skin and breast were observed (REACH).

Daily inhalation of 5 ppm (8.8 mg/m³) of aziridine, four hours a day, for 1.5 months caused bronchitis and degenerative changes in the kidneys and liver in rats (ACGIH, 2011a).

Genotoxicity

Aziridine, is classified as hazardous—Category 2 mutagenic substance—with the risk phrase 'May cause heritable genetic damage' (T; R46) in HSIS (Safe Work Australia). The available data support this classification.

Aziridine was mutagenic in bacteria (*Salmonella typhimurium* strains TA100 and TA 1535) and produced gene mutations and chromosomal aberrations in mammalian cells in vitro. The formation of DNA adducts has been demonstrated in vitro. The chemical was positive in a rat micronucleus test in vivo. The chemical produced sex-linked recessive lethal mutations in *Drosophila melanogaster* and caused dominant lethal effects in mice (IARC, 1999a, ACGIH, 2011a, REACH).

Limited data are available for 2-methylaziridine. The chemical was mutagenic in bacteria (*S. typhimurium* strains TA100 and TA 1535) and induced mitotic recombination in *Saccharomyces cerevisiae*. The chemical produced somatic mutations in *D. melanogaster* and sex-linked recessive lethal mutations in an inhalation experiment using a repair-deficient genotype of *D. melanogaster* (IARC, 1999b; ACGIH 2011b). The chemical significantly induced micronucleated reticulocytes, in the bone marrow and peripheral blood, in an in vivo rat micronucleus test (HSDB).

Given the structural similarity to aziridine, and similarity of observed effects in genotoxicity studies where comparison is possible, classification of both chemicals for genotoxic effects is considered warranted (refer **Recommendation** section).

Carcinogenicity

The chemicals are currently classified as hazardous as a Category 2 carcinogen with the risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia). The available data support this classification.

The chemicals have produced tumours at several different tumour sites (lung, liver, mammary gland) in rats and/or mice following oral and inhalation exposure and administration by subcutaneous injection (IARC, 1999a; IARC, 1999b; ACGIH 2011a; ACGIH 2011b; NTP, 2014). Whilst the tumour data provide evidence for carcinogenicity in animals, due to differences in species and routes of administration it is difficult to compare the relative potency and mechanisms associated with the carcinogenicity of the chemicals.

No epidemiological data relevant to the carcinogenicity of the chemicals were available.

The International Agency for Research on Cancer (IARC) overall evaluation is that the chemicals are 'possibly carcinogenic to humans' (Group 2B) based on 'sufficient evidence in experimental animals' (IARC, 1999a; IARC, 1999b). The United States National Toxicology Program's *Report on carcinogens* listed the chemical, 2-methylaziridine as 'Reasonably anticipated to be a human carcinogen' (NTP, 2014).

Reproductive and Developmental Toxicity

Limited data are available.

In a non-guideline study in SD rats, dams were administered doses of approximately 2.57 and 1.03 mg/kg bw/day aziridine on days 6–15 of gestation. At the high dose, increased implantation loss and increased incidence of skeletal and organ malformations were observed in the presence of maternal toxicity (decreased bodyweight and vaginal bleeding). No significant maternal or foetal toxicity was observed at the low dose. The only effects noted were a decrease of the mean length of the fetuses and of the mean placental weight (REACH).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity), systemic acute effects (acute toxicity by all routes of exposure) and local effects (corrosivity). A genotoxic mode of action for carcinogenicity cannot be excluded.

Public Risk Characterisation

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

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemicals might occur, particularly where manual or open processes are used. These could 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 critical systemic long-term/systemic acute/local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal, ocular and inhalation exposure to the chemicals are implemented. The chemicals 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 *Guidance on the interpretation of workplace exposure standards for airborne contaminants* advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2013).

Based on the available data, the hazard classification in HSIS for aziridine is considered appropriate, although, the data available support an amendment to the hazard classification in HSIS for 2-methylaziridine (refer to **Recommendation** section).

Based on the available data, the current exposure standards may not be adequate to mitigate the risk of adverse effects. *Guidance on the interpretation of workplace exposure standards for airborne contaminants* advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2013). Given that lower exposure standards appear achievable (based on international exposure standards), Safe Work Australia should consider whether current controls adequately minimise the risk to workers.

NICNAS Recommendation

The data available support an amendment to the hazard classification in HSIS for 2-methylaziridine.

It is recommended that Safe Work Australia consider whether current controls for the chemicals adequately minimise the risk to workers. A Tier III assessment might be necessary to provide further information to determine whether the current exposure controls offer adequate protection to workers.

Regulatory Control

Work Health and Safety

The chemicals are 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.

The classifications for corrosivity and genotoxicity are the existing classification for the chemical aziridine.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Acute Toxicity	Very toxic if swallowed (T+; R28)* Very toxic in contact with skin (T+; R27)* Very toxic by inhalation (T+; R26)*	Fatal if swallowed - Cat. 2 (H300) Fatal in contact with skin - Cat. 1 (H310) Fatal if inhaled - Cat. 1 (H330)
Irritation / Corrosivity	Causes burns (C; R34)	Corrosive to the respiratory tract (AUH071) Causes severe skin burns and eye damage - Cat. 1C (H314)

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Genotoxicity	Muta. Cat 2 - May cause heritable genetic damage (T; R46)	May cause genetic defects - Cat. 1B (H340)
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)*	May cause cancer - Cat. 1B (H350)

^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 industry

Control measures

Control measures to minimise the risk from oral, dermal, ocular and inhalation exposure to the chemicals 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;
- 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 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 chemicals has not been undertaken as part of this assessment.

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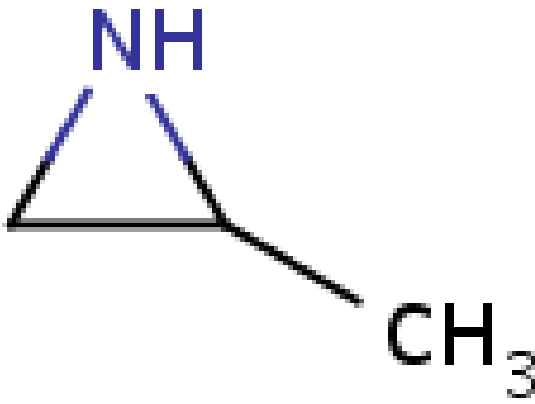
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Chemical Identities

Chemical Name in the Inventory and Synonyms	Aziridine, 2-methyl-propyleneimine 2-methylethylenimine
CAS Number	75-55-8
Structural Formula	
Molecular Formula	C ₃ H ₇ N
Molecular Weight	57.09

Chemical Name in the Inventory and Synonyms	Aziridine Ethyleneimine
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	Dihydroazirine Dimethyleneimine
CAS Number	151-56-4
Structural Formula	
Molecular Formula	C ₂ H ₅ N
Molecular Weight	43.07

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