



# Hydrazine salts: Human health tier II assessment

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## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
<b>Hydrazine, dihydrochloride</b>	5341-61-7
<b>Hydrazine, sulfate (1:1)</b>	10034-93-2
<b>Hydrazine, sulfate (2:1)</b>	13464-80-7
<b>Hydrazine, monohydrobromide</b>	13775-80-9
<b>Hydrazine, dihydrobromide</b>	23268-00-0

## 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](http://www.nicnas.gov.au)

### Disclaimer

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### ACRONYMS & ABBREVIATIONS

## Grouping Rationale

The chemicals of this group involve the hydrazine salts (sulfates, bromides and dihydrochloride of hydrazine). These salts are formed by treating hydrazine with the respective mineral acid. Hydrazine salts dissociate in solution to form the hydrazinium cation (protonated hydrazine) and the respective anions (e.g. sulfates, bromides and chlorides). The sulfate, bromide and chloride anions are generally considered to be of low concern. Therefore, the toxicological properties of these salts are considered to be similar, as any toxicity is expected to result from the presence of the hydrazinium cation.

The hydrazine salts are expected to have similar systemic toxicity to hydrazine, but the lack of volatility and basicity will reduce the local toxicity, particularly by inhalation.

## Import, Manufacture and Use

### Australian

No specific Australian use, import or manufacturing information has been identified for any of the chemicals in this group.

### International

The following international uses have been identified through the European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the

## European Commission Cosmetic Ingredients and Substances (CosIng)

database; eChemPortal: OECD High Production Volume chemical program (OECD HPV), the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemicals have reported commercial use including:

- in metal plating on glass and plastics;
- in photographic developers;
- as commercial cleaning agents;
- in textile dyes; and
- as reducing agents.

The chemicals have reported site-limited use:

- in manufacturing organic compounds and hydrazine compounds;
- in separating rare earth metals; and
- as a catalyst in making fibres.

## Restrictions

### Australian

Hydrazine is listed in Schedule 6 of the Poisons Standard (the Australian Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP). The entry does not explicitly exclude salts and derivatives and therefore, the chemicals in this group are covered by this entry.

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 chemicals of this group are listed on the following (Galleria Chemica):

- European Union (EU) Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products: Hydrazine, its derivatives and their salts. However, many exceptions to this prohibition are listed, including hydrazine dihydrochloride (CAS No. 5341-61-7), hydrazine sulfate (1:1) (CAS No. 10034-93-2) and hydrazine sulfate (2:1) (CAS No. 13464-80-7) (CosIng);
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain—Table 1: Hydrazine, its derivatives and their salts;
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist"): Hydrazine, its derivatives and their salts; and
- The Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1—List of substances which must not form part of the composition of cosmetic products (Hydrazine, its derivatives and their salts).

## Existing Worker Health and Safety Controls

## Hazard Classification

Hydrazine salts are classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

T; R23/24/25 (acute toxicity)

Xi; R43 (sensitisation)

Carc. Cat. 2; R45 (carcinogenicity)

## Exposure Standards

### Australian

No specific exposure standards are available for the chemicals in this group.

### International

The following occupational exposure limit (OEL) or time weighted average (TWA) are identified (Galleria Chemica):

Hydrazine dihydrochloride (CAS No. 5341-61-7):

- 10 mg/m<sup>3</sup> (10 ppm) in Russia; and
- 0.13 mg/m<sup>3</sup> (0.1 ppm) in Finland.

Hydrazine sulfate (CAS No. 10034-93-2):

- 10 mg/m<sup>3</sup> in Russia; and
- 0.13 mg/m<sup>3</sup> (0.1 ppm) in Finland.

Hydrazine monohydrobromide (CAS No. 13775-80-9):

- 10 mg/m<sup>3</sup> in Russia; and
- 0.13 mg/m<sup>3</sup> (0.1 ppm) (8h) and 0.4 mg/m<sup>3</sup> (0.3 ppm) (15 min) in Finland.

Hydrazine dihydrobromide (CAS No. 23268-00-0):

- 10 mg/m<sup>3</sup> in Iceland and Russia; and
- 0.13 mg/m<sup>3</sup> (0.1 ppm) in Finland.

No exposure standards have been identified for hydrazine sulfate (2:1) (CAS No. 13464-80-7).

## Health Hazard Information

Hydrazine and hydrazine monohydrate have been assessed separately (NICNAS). As there is limited data for the hydrazine salts, hydrazine and hydrazine monohydrate data have been used in this assessment for systemic toxicity end points where appropriate.

## Toxicokinetics

Hydrazine salts exist in pH-dependent equilibrium with hydrazine free base in the body, therefore, the chemicals of this group have similar distribution, metabolism and excretion. The metabolism of these chemicals is similar in all administration routes (CERI, 2007).

Animal studies indicated that the majority of the chemicals of this group, as for hydrazine, are rapidly absorbed into the blood through inhalation, oral and dermal routes and are readily distributed to tissues. After administration in rats, the chemicals are metabolised into monoacetylhydrazine, diacetylhydrazine, pyruvic acid hydrazone and urea. The metabolites are excreted in urine (CERI, 2007).

The chemicals can be metabolised by enzymatic and non enzymatic pathways to produce free radicals including acetyl, hydroxyl and hydrogen radicals. This metabolism is increased by cytochrome P450 inducers and is decreased by P450 inhibitors. The formation of free radicals during metabolism may contribute to the toxicity of the chemical (US Health, 1997).

In some humans with acetylase enzyme deficiency, hydrazine metabolism (acetylation) is extremely slow and any absorbed chemical could accumulate in the blood plasma (CERI, 2007; US Health, 1997).

## Acute Toxicity

### Oral

Hydrazine salts are classified as hazardous with the risk phrase 'Toxic if swallowed' (T; R25) in HSIS (Safe Work Australia). While the only available data on hydrazine sulfate (1:1) is in the harmful range of acute toxicity classification, hydrazine sulfate (2:1) and hydrazine (NICNAS) are in the toxic range, supporting the present classification. Given the pH-dependent equilibria, which lead to ready interconversion of hydrazine and its salts, an amendment of the present classification is not warranted for all the hydrazine salts in this assessment.

Hydrazine sulfate (1:1) (CAS No. 10034-93-2):

- The oral median lethal dose (LD50) is 601 mg/kg bw in rats and 434 mg/kg bw in mice (ChemIDplus).

Hydrazine sulfate (2:1) (CAS No. 13464-80-7):

- The oral LD50 is 200 mg/kg bw in rats with sublethal effects including convulsions and somnolence (ChemIDplus).

No acute oral toxicity data are available for hydrazine dihydrochloride (CAS No. 5341-61-7), hydrazine monohydrobromide (CAS No. 13775-80-9) and hydrazine dihydrobromide (CAS No. 23268-00-0).

Hydrazine:

- The oral LD50 is 60-90 mg/kg bw in rats; 59–83 mg/kg bw in mice; 55 mg/kg bw in rabbits; and 40 mg/kg bw in guinea pigs (ChemIDplus and IUCLID, 2000 cited in NICNAS report).

Hydrazine monohydrate:

- The oral LD50 is 129 mg/kg bw in rats, 83 mg/kg bw in mice, 40 mg/kg bw in guinea pigs and 55 mg/kg bw in rabbits with sublethal effects of excitation and muscle contraction (ChemIDplus cited in NICNAS report).

### Dermal

Hydrazine salts are classified as hazardous with the risk phrase 'Toxic in contact with skin' (T; R24) in HSIS (Safe Work Australia). There are no available data for hydrazine salts to support this classification. However, aqueous solutions of hydrazine salts will contain hydrazine in equilibrium, and hydrazine data (NICNAS) is used to support this classification for all hydrazine salts in this assessment.

The dermal LD50 for hydrazine is 91 mg/kg bw in rabbits and 190 mg/kg bw in guinea pigs (ChemIDplus cited in NICNAS report).

## Inhalation

Hydrazine salts are classified as hazardous with the risk phrase 'Toxic by inhalation' (T; R23) in HSIS (Safe Work Australia). There are no available data for hydrazine salts to support this classification. However, aqueous solutions of hydrazine salts will contain hydrazine in equilibrium, and hydrazine data (NICNAS) is used to support this classification for all hydrazine salts in this assessment.

The median lethal concentration (LC50) for hydrazine is 750 mg/m<sup>3</sup>/4 h (570 ppm) in rats and 330 mg/m<sup>3</sup>/4 h (252 ppm) in mice, with sublethal effects such as dyspnoea (shortness of breath) occurring in both rats and mice (ChemIDplus cited in NICNAS report).

## Corrosion / Irritation

### Skin Irritation

No animal data are available for hydrazine salts. Based on the limited data available in humans, and in the absence of information regarding skin irritation at higher concentrations for hydrazine sulfate, a hazard classification is not warranted for hydrazine sulfate or for any of the chemicals in this group. Hydrazine data for this local toxicity endpoint are not considered relevant for the hydrazine salts.

### Eye Irritation

No data are available for any of the chemicals in this group.

### Observation in humans

Hydrazine sulfate was not irritating at a 25 % concentration when applied to the skin of six volunteers for 24 hours (Bayer, 1954 cited in CERL, 2007).

## Sensitisation

### Skin Sensitisation

Hydrazine salts are classified as hazardous with the risk phrase 'May cause sensitisation by skin contact' (R43) in HSIS (Safe Work Australia). No animal data are available. The human case reports below support this classification for the chemicals in this group.

### Observation in humans

Hydrazine sulfate and some similar chemicals (hydrazine hydrochloride, hydrazine and hydrazine monohydrate (NICNAS)) have caused skin sensitisation reactions in humans.

#### Hydrazine sulfate

Hydrazine sulfate was reported as a skin sensitizer in the following tests conditions (patch testing) using a solution concentration of :

- 1 % applied to the skin of two gold-plating workers, three male workers and one female; and

- 0.05–5 % applied to the skin of three male workers for 48 and 96 hours (Health Canada, 2011).

Hydrazine hydrochloride (an analogue for hydrazine dihydrochloride) produced positive reactions at 0.1, 1 or 10 % concentration in five female patients suffering from contact dermatitis (IUCLID, 2000).

No skin sensitisation data are available for the other chemicals in this group.

#### Hydrazine

In a maximisation test, 23 volunteers were all sensitised at 0.5 % of the chemical applied epicutaneously for 48 hours (challenge phase). Pretreatment was conducted with a 5 % lauryl sulfate solution for 24 hours and then with a 5 % hydrazine solution for 48 hours (occlusive patches). This pretreatment was repeated four times (induction phase). The chemical was considered to be an extremely strong sensitiser (IUCLID, 2000 cited in NICNAS report).

Occupational exposure to hydrazine at concentrations of 0.15 % and 0.015 % for 24–72 hours resulted in clear sensitisation (IUCLID, 2000 cited in NICNAS report).

#### Hydrazine hydrate

A 36-year-old worker suffering from contact dermatitis showed a positive reaction at 0.005 % concentration of the chemical (occlusive patch) after one week of the test (IUCLID, 2000 cited in NICNAS report).

Occupational exposure to the chemical at 15 % concentration resulted in eczema on a worker's hands (IUCLID, 2000 cited in NICNAS report).

Hydrazine hydrate was a skin sensitiser at 1 % concentration in a patch test in one man (48 and 96 hours) (Health Canada, 2011 cited in NICNAS report).

## Repeated Dose Toxicity

### Oral

There were treatment-related adverse effects reported in mice and hamsters receiving hydrazine sulfate at low oral doses (i.e. doses within the hazard classification range for repeated dose oral toxicity). Similar to hydrazine and hydrazine monohydrate (NICNAS), the information available is sufficient to justify that the severity of the effects warrants a hazard classification for the chemicals in this group.

#### Hydrazine sulfate

In a repeated dose toxicity study, CBA mice and Syrian golden hamsters were administered the chemical orally at 0, 1.1, 2.3 or 4.9 mg/kg bw/d in drinking water for 15 to 25 weeks. The following effects were reported:

- increased mortality at 2.3 mg/kg bw/d and above respectively in both mice and hamsters;
- adrenal degeneration in female mice at 1.1 mg/kg bw/d and above;
- cirrhosis, bile duct hyperplasia, reticuloendothelial cell (cells of the immune system, primarily comprising macrophages and monocytes); and
- proliferation and degeneration of fibrous cells in the livers of hamsters at 4.9 mg/kg bw/d (Biancifiori et al., 1970 cited in CERI, 2007).

In another repeated dose toxicity study, Syrian golden hamsters were administered the chemical orally (as hydrazine) at 0, 4.6, 8.3 or 10.3 mg/kg bw/d in drinking water for two years. At 4.6 mg/kg bw/d and above (dose-dependent), no statistically significant changes were seen in water consumption, survival rate, or incidences of nodular hyperplasia, hypertrophy and necrosis in the hepatocytes at 18 months into the exposure period (Bosan et al. 1987 and Henschler, 1989 cited in CERI, 2007).

No oral repeated dose toxicity data are available for the other chemicals in this group.

## Dermal

No data are available for any of the chemicals in this group.

## Inhalation

No data are available for any of the chemicals in this group.

Although, hydrazine and hydrazine monohydrate (both liquids with vapour pressures 1300 Pa at 30.70 °C and 700 Pa at 25 °C respectively (Sigma-Aldrich)) caused inhalation toxicity in animals exposed at very low doses and were recommended for repeated inhalation dose toxicity classification (NICNAS).

The salts are all solids with expected low volatility; the information for hydrazine is not considered relevant for this endpoint. In the absence of repeated inhalation dose toxicity information, a hazard classification is not warranted.

## Genotoxicity

Based on the data available, hydrazine dihydrochloride and hydrazine sulfate are considered to be genotoxic and warrant a hazard classification. Considering the negative results reported for in vivo unscheduled DNA synthesis in mice, the ability of hydrazine salts to induce heritable mutations in germ cells of humans is uncertain. The classification for the other chemicals in this group is also warranted.

Hydrazine salts (hydrazine dihydrochloride and hydrazine sulfate) showed positive results in in vitro and in vivo genotoxicity tests. These include in vitro studies such as bacterial reverse mutation assays (Ames tests) and clastogenicity tests (mammalian chromosome aberration, mammalian gene mutation, unscheduled DNA synthesis, DNA damage test and *Saccharomyces cerevisiae* gene mutation tests). Positive in vivo genotoxicity was also reported in somatic cell mutagenicity assays (mouse spot tests and mammalian micronucleus in mice tests) (CERI, 2007; IUCLID, 2000).

Two nitrosamine-related DNA adducts (*N*7-methylguanine and *O*6-methylguanine) in the liver DNA were formed during in vivo treatment of male Syrian golden hamsters with hydrazine sulfate (Bosan et al. 1987 cited in Health Canada, 2011).

No genotoxicity data are available for the other chemicals in this group.

## Carcinogenicity

Hydrazine salts are currently classified as hazardous as a Category 2 carcinogens with the risk phrase 'May cause cancer' (T; R45) in HSIS (Safe Work Australia). The available data on hydrazine sulfate and similar chemicals (hydrazine, and hydrazine monohydrate (NICNAS) support this classification.

### Hydrazine sulfate

Oral exposure to hydrazine sulfate produced benign and malignant lung tumours (adenoma and adenocarcinoma) in mice and rats, liver tumours in mice (hepatocellular carcinoma) and spindle-cell sarcoma in male rats (NTP, 2011).

Oral exposure to hydrazine sulfate in drinking water at 8.3 or 10 mg/kg bw/d (calculated as hydrazine) for two years resulted in increased hepatocellular carcinomas in male Syrian hamsters compared with the control groups (Bosan et al., 1987 cited in Health Canada, 2011).

No carcinogenicity data are available for the other chemicals in this group.

The International Agency for Research on Cancer (IARC) classified hydrazine as a Group 2B carcinogen (possibly carcinogenic to humans) based on inadequate evidence in humans but sufficient evidence in experimental animals for the carcinogenicity of hydrazine (IARC, 1999 cited in NICNAS report).



## Reproductive and Developmental Toxicity

No data are available for hydrazine salts. However, in the absence of information and based on the limited data for similar chemicals, hydrazine hydrochloride, hydrazine and hydrazine monohydrate data (i.e. non-guideline studies with no details on experimental conditions or single dose studies) (NICNAS), no hazard classification is warranted for the hydrazine salts.

Subcutaneous injection of a hydrazine salts analogue (hydrazine hydrochloride) at 8 mg/kg bw/d from gestation days (GD) 11–20 to Wistar rats (n = 26/group, doses = 0 or 8 mg/kg bw/d) showed some developmental effects including: reduced body weight gain, decreased survival and pale-looking foetuses. Reduced body weight gain and mortality of parent rats was also observed. A lowest observed adverse effect level (LOAEL) of 8 mg/kg bw/d for maternal toxicity was reported (Lee & Aleyassine, 1970 cited in Health Canada, 2011).

### Hydrazine and hydrazine monohydrate

No developmental anomalies were found in 293 albino rat fetuses treated with up to 0.016 mg/kg bw/d of hydrazine in drinking water for six months (non-guideline study). Lesions in the gonadal epithelial cells of male rats were observed at 0.0014 mg/kg bw/d and above. The no observed adverse effect level (NOAEL) is 0.00016 mg/kg bw/d (CERI, 2007 cited in NICNAS report).

In a developmental toxicity study, a group of pregnant F344 rats received a single dermal application of the chemical at 0, 5 or 50 mg/kg bw/d on GD nine and a caesarean section was performed on GD 20. There were no effects on implantation and resorption rates, foetal body weight, and external visceral or skeletal anomalies in the foetus. However, significant complete resorptions were noted in 10/12 maternal rats at 50 mg/kg bw/d. Suppression of maternal body weight gain in treated rats and epidermal necrosis in the application site 24 hours after treatment were observed (CERI, 2007; IUCLID, 2000 cited in NICNAS). A NOAEL of <5 mg/kg bw/d was reported based on reduced maternal body weight gain (IUCLID, 2000 cited in NICNAS report).

## Other Health Effects

### Neurotoxicity

Based on the data available, hydrazine salts are considered to have some neurotoxic effects. However, the reported neurotoxicity data in humans from accidental exposure to hydrazine and the reported data in rabbits are from exposure to large quantities (close to lethal dose for rabbits). As the chemicals are already classified as hazardous based on acute exposure routes, a separate classification for neurotoxicity is not recommended.

The effects of the hydrazine sulfate on the central nervous system, such as the focal necrosis in the visual cortex between white and grey matters, was reported after repeated intraperitoneal exposure to close to lethal dose of hydrazine sulfate in rabbits (exposure period not reported) (CERI, 2007).

Neurological effects have been reported in humans after inhalation, oral and dermal exposure to hydrazine and hydrazine hydrate (US Health, 1997 cited in NICNAS report).

Neurological effects with episodes of violent behaviour such as ataxia, coma, convulsions, hypaesthesia of the hands and paraesthesia (abnormal skin sensations such as tingling, tickling, itching or burning) of the arms and legs were the results of accidental ingestion of a large dose (up to a cupful of the chemical). Ingestion of a

mouthful of the chemical by a 24-year-old man led to confusion, lethargy, restlessness, paraesthesia and neurogenic atrophy (US Health, 1997).

No neurotoxicity data are available for the other chemicals in this group.

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation include:

- systemic long-term effects (carcinogenicity, mutagenicity and repeated dose toxicity);
- local effects (skin sensitisation); and
- systemic acute effects (acute toxicity from oral, dermal and inhalation exposure).

## Public Risk Characterisation

These chemicals have no identified domestic or cosmetic uses in Australia or overseas. However, Canada, New Zealand and the European Union (EU) have prohibited the use of hydrazine, its derivatives and their salts in cosmetic products, but with some exceptions such as hydrazine dihydrochloride (CAS No. 5341-61-7), hydrazine sulfate (1:1) (CAS No. 10034-93-2), and hydrazine sulfate (2:1) (CAS No. 13464-80-7) in the EU.

In Australia, hydrazine is listed in Schedule 6 of the SUSMP, including hydrazine salts. Schedule 6 chemicals require distinctive packaging with strong warnings and safety directions on the label if they are used in consumer products. This is considered appropriate, as the characterised critical health effects for these chemicals (skin sensitisation, carcinogenicity and mutagenicity) have the potential to pose an unreasonable risk if the chemicals are used in domestic or cosmetic products.

## Occupational Risk Characterisation

During manufacturing and product formulation, (dermal, ocular and inhalation) exposure of workers to the chemicals 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 chemicals at lower concentrations may also occur while using formulated products containing the chemicals. 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 may 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.

## NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks for workplace health and safety be managed through changes to classification and labelling.

Assessment of these chemicals is considered to be sufficient provided that risk management recommendations are implemented and all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

## Regulatory Control

### Public Health

The current regulatory controls are sufficient.

Hydrazine is on Schedule 6 of the SUSMP. Considering the serious health effects possible from exposure to these chemicals, any consumer/domestic products containing these chemicals should be labelled in accordance with the state and territory poisons scheduling.

## Work Health and Safety

These 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.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Toxic if swallowed (T; R25)* Toxic in contact with skin (T; R24)* Toxic by inhalation (T; R23)*	Toxic if swallowed - Cat. 3 (H301) Toxic in contact with skin - Cat. 3 (H311) Toxic if inhaled - Cat. 3 (H331)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (H317)
Repeat Dose Toxicity	Toxic: Danger of serious damage to health by prolonged exposure if swallowed (T; R48/25)	Causes damage to organs through prolonged or repeated exposure - Cat. 1 (H372)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 2 - May cause cancer (T; R45)*	May cause cancer - Cat. 1B (H350)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> 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 chemical(s) 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 chemical has not been undertaken as part of this assessment.

## **References**

Approved Criteria for Classifying Hazardous Substances [NOHSC: 1008(2004)] Third edition. Accessed October 2013 at <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/ns2004criteriaforclassifyinghazardous>

Chemicals Evaluation and Research Institute (CERI) 2007. Hazard assessment Report, Japan, 2007. Hydrazine (302-01-2) Accessed August 2013 at [http://www.cerij.or.jp/ceri\\_en/hazard\\_assessment\\_report/pdf/en\\_302\\_01\\_2.pdf](http://www.cerij.or.jp/ceri_en/hazard_assessment_report/pdf/en_302_01_2.pdf)

ChemIDPlus Advanced. Accessed August 2013 at <http://chem.sis.nlm.nih.gov/chemidplus/>

Cosmetics Directive (CosIng). Accessed August 2013. <http://ec.europa.eu/consumers/cosmetics/cosing/>

Environment Canada - Health Canada, 2011. Screening Assessment for the challenge - Hydrazine (302-01-2). Accessed November 2013 at <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=17647095-1>

Galleria Chemica. Accessed August 2013 at <http://jr.chemwatch.net/galleria/>

Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Accessed at [http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev03/03files\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html)

Hazardous Substances Data Bank (HSDB). US National Library of Medicine. Accessed August 2013 at <http://toxnet.nlm.nih.gov>.

International Agency for Research on Cancer (IARC), 1999. Re-evaluation of some organic chemicals,hydrazine and hydrogen peroxide - Catechol, IARC Monographs Volume 71. Accessed November 2013 at <http://monographs.iarc.fr/ENG/Monographs/vol71/mono71.pdf>

National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Human health assessment for Hydrazines. Australian Government Department of Health. Accessed November 2013 at <http://www.nicnas.gov.au>

National Toxicology Program (NTP) 2011. Report on Carcinogens, Twelfth Edition. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program.

REACH Dossier. Hydrazine (302-01-2). Accessed November 2013 at <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

Safe Work Australia (SWA). Hazardous Substances Information System (HSIS). Accessed November 2013, <http://hsis.safeworkaustralia.gov.au/HazardousSubstance>

Sigma-Aldrich Safety Data Sheet on Hydrazines. Accessed November 2013 at <http://www.sigmaaldrich.com/chemistry/chemistry-products.html?TablePage=16251510>

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) 2012. AustralianGovernment. Department of Health and Ageing. Therapeutic Goods Administration, (the SUSMP 3) No. 3, 2012. Accessed August 2013 at <http://www.comlaw.gov.au/Details/F2012L01200>

Substances in Preparations in Nordic Countries (SPIN). Accessed November 2013 at <http://188.183.47.4/dotnetnuke/Home/tabid/58/Default.aspx>

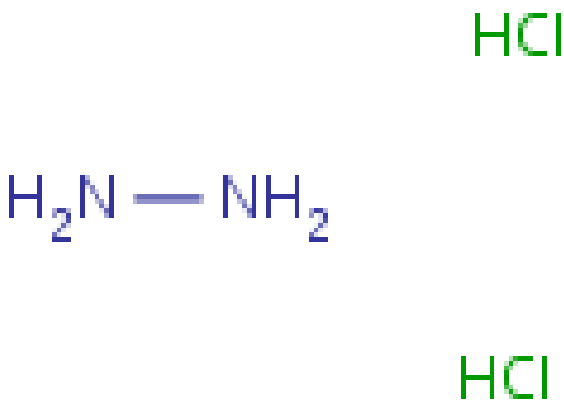
The International Uniform Chemical Information Database (IUCLID) 2000. Dataset on substance ID 302-01-2. Accessed November 2013 at [http://esis.jrc.ec.europa.eu/doc/IUCLID/data\\_sheets/302012.pdf](http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/302012.pdf)

US Department of Health and Human Services 1997. Toxicological profile for hydrazine. Accessed August 2013 at <http://www.atsdr.cdc.gov/toxprofiles/tp100.pdf>

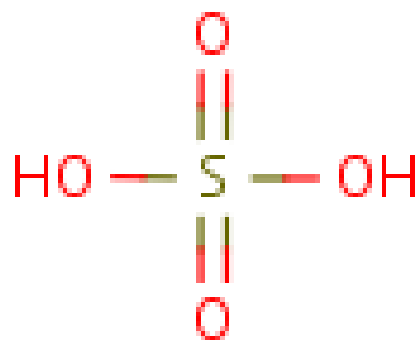
Last Update 04 July 2014

## Chemical Identities

Chemical Name in the Inventory and Synonyms	<b>Hydrazine, dihydrochloride</b> hydrazinium chloride hydrazine hydrochloride hydrazine HCl
CAS Number	5341-61-7
Structural Formula	

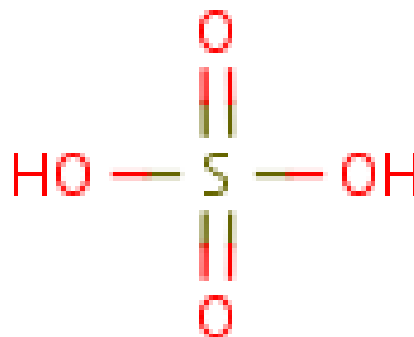
	
Molecular Formula	ClH.1/2H4N2
Molecular Weight	104.97

Chemical Name in the Inventory and Synonyms	<b>Hydrazine, sulfate (1:1)</b> hydrazinium sulfate hydrazine sulfate diamine sulfate hydrazine hydrogen sulfate hydrazine monosulfate
CAS Number	10034-93-2
Structural Formula	



Molecular Formula	H4N2.H2O4S
Molecular Weight	130.12

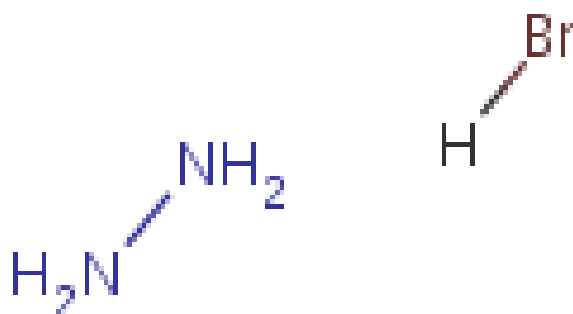
Chemical Name in the Inventory and Synonyms	<b>Hydrazine, sulfate (2:1)</b> dihydrazine sulfate dihydrazinium sulfate hydrazine hemisulfate
CAS Number	13464-80-7
Structural Formula	



Molecular Formula	H4N2.1/2H2O4S
Molecular Weight	162.17

Chemical Name in the Inventory and Synonyms	<b>Hydrazine, monohydrobromide</b> hydrazine, hydrobromide (1:1) hydrazinium bromide
CAS Number	13775-80-9
Structural Formula	





Molecular Formula	BrH.H4N2
Molecular Weight	112.96

Chemical Name in the Inventory and Synonyms	<b>Hydrazine, dihydrobromide</b> hydrazine hydrobromide (1:2) hydrazinium dibromide
CAS Number	23268-00-0
Structural Formula	



Molecular Formula	BrH.1/2H4N2
Molecular Weight	193.87

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