Pyridine, alkyl derivatives: Human health tier II assessment

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CAS Number: 68391-11-7

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	alkyl pyridines pyridine bases paraldehyde and ammonia reaction products pyridines, polyalkylated, higher or lower boiling fractions crude tar bases
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight (g/mol)	Unspecified
Appearance and Odour (where available)	Yellow to brown liquid
SMILES	c1(CC)cc(C)ccn1

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, Authorisation and Restriction of Chemicals (REACH) dossiers; Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the Organisation for Economic Co-operation and Development (OECD) High Production Volume chemical program (HPV); the United States (US) Environmental Protection Agency's (EPA) Aggregated Computer Toxicology Resource (ACToR); and the Environment Canada (EC) report, Screening Assessment for the Challenge Pyridine, alkyl derivs. (EC, 2013).

The chemical has reported commercial uses as:

- a corrosion inhibitor in cleaning and de-scaling products for closed water heat transfer systems (boilers and cooling towers);
- an incidental ingredient in cleaning products for food contact surfaces;
- a component of construction materials; and
- a component of reprographic agents.

The chemical has reported site-limited uses as:

- a corrosion inhibitor in oil and gas wells and pipelines, and in iron and steel manufacturing;
- an industrial solvent;

- a chemical intermediate in manufacturing textiles, paints, dyes, pulp and paper products, rubber products and adhesives; and
- an ingredient in hydraulic fracturing fluids.

The following non-industrial uses have been identified internationally, including:

- in herbicide formulations; and
- as an active ingredient in pesticides.

Restrictions

Australian

No known restrictions have been identified.

International

The chemical is listed on the EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products. The entry lists 'Pyridine, alkyl derivs., if it contains > 0.1 % w/w benzene' (the European Commission Cosmetic Ingredients and Substances (CosIng) database).

Existing Work Health and Safety Controls

Hazard Classification

Pyridine, alkyl derivatives (crude tar bases) is classified as hazardous, with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

- R45 Carc. Cat 2 (carcinogenicity)
- R46 Muta. Cat 2 (mutagenicity)

These classifications are subject to notes H and J.

Note H states 'The classification and label shown for this substance applies to the dangerous property(ies) indicated by the Risk Phrase(s) in combination with the category(ies) of danger shown. The manufacturers, distributors and importers of this substance shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exists for all other properties to classify and label the substance. The final label shall follow the requirements of section 7 of Annex VI of directive 67/548/EEC.'

Note J states 'The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w benzene (EINECS no. 200-753-7). This note applies only to certain complex coal- and oil- derived substances in Annex I.'

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific international exposure standards are available.

Health Hazard Information

The chemical is a substance of unknown or variable composition, complex reaction product, or biological material (UVCB). It can be formed 'naturally through coal tar distillation or synthetically as the high-boiling distillates approximately above 150 °C from the reaction of ammonia with acetaldehyde,

formaldehyde or paraformaldehyde'. Approximately 5 % of the global volume of the chemical is derived from coal tar while 95 % is synthetically produced (EC, 2013).

The final composition of the chemical varies based on the reactants, additives, technology and reaction conditions used during manufacture, but is a combination of discrete polyalkylated pyridines with short alkyl side chains (i.e. mono-, di- or tri-methyl pyridines also known as picolines, lutidines and collidines; methyl-ethyl-pyridines; ethyl-pyridines; and propyl-pyridine). The chemicals 2-ethyl-4-methyl pyridine and its isomer, 2-methyl-5-ethyl pyridine (MEP), are considered as representative structures for polyalkylated pyridines comprising this UVCB. However, these major components are not considered to be 'highly hazardous', but the 'presence of by-products in commercial versions of the substance, such as nonalkylated derivatives of pyridine' (e.g. quinoline) most likely contribute to the hazard potential of the chemical. Quinoline is reported to account for ≤0.5 % by weight of the substance and other by-products, such as benzene, are not present above their detection limit of 0.01 % by weight in commercial versions of this UVCB in Canada (based on its low boiling point of 80 °C, it is expected that benzene would be removed in the distillation process) (EC, 2013).

Toxicological data on the major components of the chemical, and the related chemical—pyridine (NICNAS, 2015), are used to complement the toxicity information for the chemical, where appropriate.

Acute Toxicity

Oral

The chemical is expected to have low acute oral toxicity based on the results from a rat study. The median lethal dose (LD50) in Sherman-Wistar rats was reported to be 2500 mg/kg bw (US EPA, 2009).

As some of the individual components of the chemical (i.e. picolines, lutidines, collidines and MEP) have oral LD50 values between 200–1600 mg/kg bw in rats and mice (EC, 2013), the oral LD50 of the chemical may vary depending on the concentration of each of the major components in the chemical and also the by-products.

Dermal

The chemical is expected to have low acute dermal toxicity based on the results from a rabbit study. The dermal LD50 in New Zealand White rabbits was reported to be >2 mL/kg bw (approximately >2000 mg/kg bw) (US EPA, 2009; EC, 2013).

As some of the individual components of the chemical (i.e. picolines, lutidines and MEP) have dermal LD50 values between 126–5000 mg/kg bw in rabbits and guinea pigs (EC, 2013), the dermal LD50 of the chemical may vary depending on the concentration of each of the major components in the chemical and also the by-products.

Inhalation

No data are available for the chemical. The acute inhalation toxicity of the chemical may vary depending on the concentration of each of the major components in the chemical and also the by-products.

Some of the individual components of the chemical (i.e. lutidines, ethyl-pyridines and MEP) have median lethal concentration (LC50) values between >650 ppm and <1000 ppm (approximately between >3000 mg/m^3 and <5000 mg/m^3) in rats (EC, 2013).

Corrosion / Irritation

Skin Irritation

Based on the available data, the chemical is considered to produce moderate skin irritation, warranting hazard classification (see **Recommendation** section). Although there are conflicting data for the chemical, individual components of the chemical (picolines and MEP) are reported to be severe skin irritants and/or corrosive (EC, 2013). The related chemical, pyridine, is classified as a corrosive chemical (NICNAS, 2015).

In eight dermal irritation studies (similar to OECD test guideline (TG) 404), rabbits were exposed (occlusively) to 0.5 mL of the chemical on intact and abraded skin for four or 24 hours, and observed up to 48 hours post-exposure. In three studies using New Zealand White rabbits (n = six females/study) exposed for four hours, moderate skin irritation was reported with mean primary dermal irritation indices (PDII) of 4.5/8, 4.1/8 and 3.9/8. Another study also reported moderate irritation in rabbits (n = 6, strain and sex not specified) exposed to the chemical for 24 hours, with a PDII of 4.6/8. However, in two studies using a four hour dermal exposure and in two studies using a 24 hour dermal exposure, rabbits (n = six/study, strain and sex not specified) were reported to show mild irritation only (PDII 0.4–1.9/8) (REACH).

Eye Irritation

No data are available for the chemical. Based on the information available on individual components of the chemical, this chemical may have potential to cause eye irritation. However, the available data are insufficient to warrant hazard classification.

Individual components of the chemical (i.e. picolines and MEP) are reported to be severe eye irritants (EC, 2013).

Sensitisation

Skin Sensitisation

No data are available for the chemical. Based on the information available for the components of the chemical, this chemical is not considered to be a skin sensitiser.

A component of the chemical, MEP, was reported to not cause skin sensitisation in guinea pigs (EC, 2013). The related chemical, pyridine, was not a skin sensitiser (NICNAS, 2015; US EPA, 2009).

Repeated Dose Toxicity

Oral

No data are available for the chemical. Data are available on some component chemicals. Treatment related systemic effects were seen in rats administered 3-picoline at doses >20 mg/kg bw/day and with MEP at 95 mg/kg bw/day. The available data are insufficient to make a conclusion on the repeated oral toxicity of the chemical.

Fischer 344 (F344)/N rats and B6C3F1/N mice (n = 10/sex/dose) were exposed to 3-picoline (also known as 3-methylpyridine), at 0, 78, 156, 312, 625 or 1250 mg/L in drinking water for 14 weeks. Based on water intake in rats, the average daily doses were calculated as 6, 11, 22, 38 and 70 mg/kg bw/day for males and 6, 12, 23, 38 and 64 mg/kg bw/day for females. Based on water intake in mice, the average daily doses were calculated as 10, 20, 37, 77 and 148 mg/kg bw/day for males and 9, 18, 38, 72 and 134 mg/kg bw/day for females (NTP, 2014). In rats exposed to 3-picoline at the two highest doses, terminal body weights and liver weights were significantly decreased (by 7–17 % and 10–19 %, respectively) compared with controls. Hepatic enzymes were elevated in male and female rats exposed at ≥312 mg/L and ≥156 mg/L, respectively, compared with controls, when measured on day 23. In female rats exposed at 312 and 625 mg/L only, there was a significantly increased incidence of prolonged oestrus. In male rats, signs of nephropathy (microscopic lesions, hyaline accumulation) increased with increasing dose and renal a2u-globulin concentration was significantly increased at doses ≥312 mg/L. In mice, the only observation was significantly decreased lung weights in females exposed at the highest dose (NTP, 2014).

Another individual component of the chemical, MEP, was administered in Sprague-Dawley (SD) rats (n = five/sex/dose) by oral gavage at 0, 30, 95 or 300 mg/kg bw/day for 28 days. A lowest observed effect level (LOEL) of 95 mg/kg bw/day was reported based on hyaline droplets in the kidneys, increased liver weights and altered clinical chemistry parameters in males exposed at ≥95 mg/kg bw/day (EC, 2013).

Dermal

No data are available.

Inhalation

No data are available for the chemical. The data available on some component chemicals did not show severe adverse effects in rats following repeated inhalation exposure.

A component of the chemical, 2-picoline (also known as 2-methylpyridine), was administered in rats, rabbits and guinea pigs at 0, 25, 50 or 100 ppm (0, 95, 191 and 381 mg/m^3), seven hours per day for six months. The no observed adverse effect concentration (NOAEC) was reported to be 100 ppm, based on no adverse effects reported in rats and rabbits, and reversible hepatocyte changes in guinea pigs (dose details not available) (EC, 2013).

In rats exposed to 3-picoline (also known as 3-methylpyridine) at doses up to 290 ppm (1105 mg/m^3) for six hours per day, five days per week, for two weeks, the NOAEC was reported to be 290 ppm. Liver weight changes were observed in animals (dose details not available) at the end of the study, but these were reversible within 13 days from the last exposure (EC, 2013).

Genotoxicity

The chemical is classified as hazardous—Category 2 mutagenic substance—with the risk phrase ‘May cause heritable genetic damage’ (T; R46) in the HSIS (Safe Work Australia). However, this classification only applies if it contains >0.1 % w/w benzene (Safe Work Australia). As benzene is classified

as a Category 2 mutagenic substance—with the risk phrase ‘May cause heritable genetic damage’ (T; R46) in the HSIS (Safe Work Australia), this classification is supported for the chemical if the benzene level exceeds >0.1 % w/w. Benzene exposure is associated with chromosome lesions in peripheral blood cells. A threshold level for mutagenic effects has not been established, but genotoxicity is considered to be a mechanism of action of carcinogenicity (NICNAS, 2001).

It is not expected that benzene will be present at high concentrations in commercial preparations of this UVCB chemical. Based on its boiling point, benzene should be removed by the distillation process during manufacture (EC, 2013).

Individual components of the chemical such as picolines, lutidines, collidines, ethyl-pyridines and MEP have induced mostly negative results in various in vitro and in vivo genotoxicty tests (e.g. Ames test, gene mutation assays, DNA single-strand break assays and micronucleus tests) (EC, 2013; NTP, 2014).

Carcinogenicity

The chemical is currently classified as hazardous as a Category 2 carcinogen with the risk phrase ‘May cause cancer’ (T; R45) in the Hazardous Substances Information System HSIS (Safe Work Australia). However, this classification only applies if it contains >0.1 % w/w benzene (Safe Work Australia). Benzene is classified as a Category 1 carcinogenic substance—with the risk phrase ‘May cause cancer’ (T; R45). This classification is supported for the chemical if the benzene level exceeds >0.1 % w/w. One individual component of the chemical also showed carcinogenic effects (e.g. alveolar and bronchiolar adenoma or carcinoma in female rats). However, the concentration of individual components are expected to vary with the manufacturing process of this UVCB chemical (EC, 2013).

It is not expected that benzene will be present at high concentrations in commercial preparations of this UVCB chemical. Based on its boiling point, benzene should be removed by the distillation process during manufacture (EC, 2013). Nonetheless, '...benzene is an established human carcinogen for which no safe level of exposure has been established' (NICNAS, 2001). Benzene exposure is associated with increased risk of blood and lymphatic system cancers (NICNAS, 2001).

No carcinogenicity studies are available for the chemical. There are carcinogenicity studies for some individual components of the chemical. The F344/N rats and B6C3F1/N mice (n = 50/sex/dose) were exposed to 3-picoline (also known as 3-methylpyridine) at 0, 156, 312 or 625 mg/L in drinking water for two years. Based on water intake in rats, the average daily doses were 6, 12 and 22 mg/kg bw/day for males and 7, 14 and 26 mg/kg bw/day for females. Based on water intake in mice, the average daily doses were 26, 50 and 92 mg/kg bw/day for males and 18, 37 and 68 mg/kg bw/day for females (NTP, 2014). In female F344/N rats exposed to 3-picoline at 625 mg/L (26 mg/kg bw/day), there was significantly increased incidence of alveolar/bronchiolar adenoma or carcinoma. Non-neoplastic lesions in all treated rats included alveolar epithelium metaplasia and hyperplasia. In all treated female B6C3F1/N mice there was significantly increased incidence of hepatocellular carcinoma. Alveolar/bronchiolar carcinoma were increased (not statistically significant) in all treated B6C3F1/N mice. Non-neoplastic lesions in B6C3F1/N mice included significantly increased incidence of olfactory epithelium atrophy in females exposed at 625 mg/L, and olfactory epithelium respiratory metaplasia in males exposed at ≥625 mg/L and in females exposed at 1250 mg/L (NTP, 2014).

Reproductive and Developmental Toxicity

No data are available for the chemical. Data are available for an individual component of the chemical. However, the available data are not sufficient to derive a conclusion on reproductive and developmental toxicity of the chemical.

An individual component of the chemical, MEP, was assessed in a one-generation study in SD rats (n = 10/sex/dose), where animals were exposed to MEP by gavage at 0, 30, 95 or 300 mg/kg bw/day for 15 days before mating and then throughout mating, gestation and lactation until postnatal day (PND) four. Parental toxicity was observed at doses ≥95 mg/kg bw/day, with reduced body weight gain in females during lactation. At 300 mg/kg bw/day, there was reduced body weight gain in all treated animals, inactive mammary tissues in three females and some organ toxicity (e.g. effects on the liver, kidney and spleen) in two males and three females. In two males at 300 mg/kg bw/day reduced testes, epididymides, prostate gland and seminal vesicle weights were reported. Although there were effects on male reproductive organs at the highest dose, an NOAEL of 300 mg/kg bw/day was reported for reproductive toxicity, based on no adverse effects on the general reproductive ability of the animals. For developmental toxicity, an NOAEL of 95 mg/kg bw/day was reported based on increased total litter loss, decreased offspring birth weights, decreased pup body weight gain and decreased pup viability at 300 mg/kg bw/day. Developmental toxicity was only seen at doses leading to maternal toxicity (EC, 2013).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- possible systemic long-term effects (carcinogenicity and mutagenicity) from potential impurities (e.g. benzene) in this UVCB chemical; and
- local effects (skin irritation and possible eye irritation).

Public Risk Characterisation

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

Occupational Risk Characterisation

Given the critical systemic long-term and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise exposure 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (see **Recommendation** section).

NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Regulatory Control

Work Health and Safety

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

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Irritation / Corrosivity	Irritating to skin (Xi; R38)	Causes skin irritation - Cat. 2 (H315)
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 exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using 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;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and

- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

References

Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. Third edition [NOHSC:1008 (2004)]. Accessed at http://www.safeworkaustralia.gov.au/sites/swa/about/publications/Documents/258/ApprovedCriteria_Classifying_Hazardous_Substances_NOHSC1008-2004_PDF.pdf

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