1,3-Benzenediamine, 4-methoxy-, sulfate: Human health tier II assessment

10 March 2017

CAS Number: 6219-67-6

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

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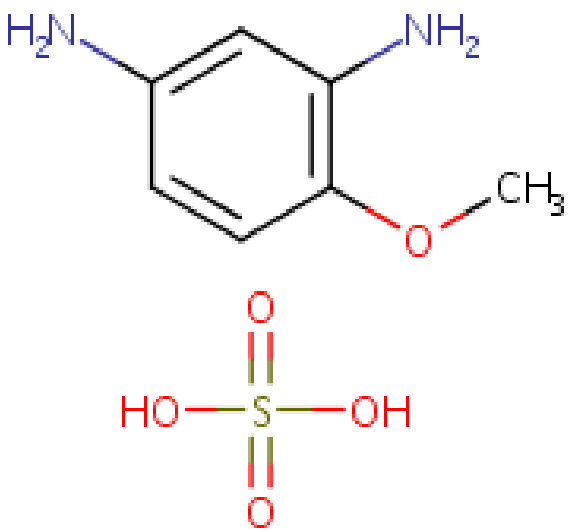
Acronyms & Abbreviations

Chemical Identity

Synonyms	m-phenylenediamine, 4-methoxy-, sulfate 2,4-diaminoanisole sulfate 1,3-benzenediamine, 4-methoxy-, sulfate (1:?)
Structural Formula	
Molecular Formula	C7H10N2O.xH2O4S
Molecular Weight (g/mol)	236.25
SMILES	c1(OC)c(N)cc(N)cc1_O=S(=O)(O)O

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified. The chemical is not listed on the 'List of chemicals used as dyes in permanent and semi-permanent hair dyes in Australia' (NICNAS, 2007).

International

The chemical is listed by several chemical supply companies, although no specific use information is available for CAS No. 6219-67-6. The CAS No. is not reported as being used in cosmetic products in the United States (US) (Personal Care Products Council, 2011), not listed in the European Commission Cosmetic Substances and Ingredients (CosIng) database or in the US Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) directory, and there is currently no documented use of the chemicals in the United States Household Products Database (US HPD).

However uses identified for the related monosulfate chemical (CAS No. 39156-41-7) are considered relevant to the chemical. These were:

- historical use in permanent and oxidative hair dyes;
- corrosion inhibitor for steel; and
- intermediate in hair and fur dye production and the dye C.I. Basic Brown 2 (CAS No. 6358-83-4) (NICNAS).

There was no recent documented use of the chemical in cosmetic products in the US and no reports of the parent chemical (CAS 615-05-4) being detected in tattoo inks or textiles, clothing or leather goods (NICNAS).

Restrictions

Australian

No known restrictions have been identified.

International

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

- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient ‘Hotlist’).

The related chemical monosulfate chemical (CAS No. 39156-41-7) is prohibited in cosmetics and substances and preparations placed on the market for sale to the general public in several countries (NICNAS).

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

No specific toxicity data are available for the chemical.

The chemical is the salt of 2,4-diaminoanisole (CAS No. 615-05-4) with an unknown ratio of sulphuric acid to diamine.

The health hazard information for parent chemical, 2,4-diaminoanisole and the monosulfate (CAS No. 39156-41-7) is relevant to CAS No. 6219-67-6.

These chemicals are classified as hazardous, on the Hazardous Chemical Information System (HCIS) (Safe Work Australia), for acute toxicity (harmful), genotoxicity and carcinogenicity. The available data supported these classifications including evidence of carcinogenicity in long term studies in rats and mice and positive results from both in vitro and in vivo genotoxicity studies. Based on the limited data available, the chemicals were not skin and eye irritants or skin sensitisers. Further regulatory controls were not required due to the limited intentional inclusion of the chemicals in consumer products.

The Tier II assessment report for these chemicals is available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1162. The report should be read in conjunction with this Tier II assessment.

Risk Characterisation

Critical Health Effects

Based on information for the parent chemical, 2,4-diaminoanisole and the monosulfate (CAS No. 39156-41-7) (NICNAS), the chemical is considered to be carcinogenic following long-term repeated exposure. A genotoxic mode of action cannot be excluded.

The critical health effects for risk characterisation also include systemic acute toxicity from oral exposure.

Public Risk Characterisation

Based on the current information available, the intentional inclusion of the chemical in consumer products is not expected. Hence, the public risk from the chemical is not considered to be unreasonable.

Occupational Risk Characterisation

Occupational exposure to the chemical can occur (dermal contact and inhalation) particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure 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).

The data available support an amendment to the hazard classification in the Hazardous Chemical Information System (HCIS) (Safe Work Australia) (refer to **Recommendation** section).

NICNAS Recommendation

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

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Not Applicable	Harmful if swallowed - Cat. 4 (H302)
Genotoxicity	Not Applicable	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Not Applicable	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 dermal and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using 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[s], 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

Galleria Chemica. Accessed December 2016 at http://jr.chemwatch.net/galleria/

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