2-Chloro-1,4-benzenediamine: Human health tier II assessment

02 March 2018

Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
1,4-Benzenediamine, 2-chloro-	615-66-7
1,4-Benzenediamine, 2-chloro-, sulfate	6219-71-2

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

Grouping Rationale

The chemicals in this group consist of a phenylenediamine derivative (free base; CAS No. 615-66-7) and its sulfate salt (CAS No. 6219-71-2). As the toxicokinetics and toxicity of these chemicals are expected to be similar, they are grouped together for purposes of this human health risk assessment. While there may be differences between the sulfate salt and the free base with respect to local effects, the speciation of the chemicals in biological fluids will be dependent on pH but independent of the original chemical form (SCCS, 2013).

Import, Manufacture and Use

Australian

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

International

The chemicals in this group are listed as hair dyes in the European Commission (EU) Cosmetic Ingredients and Substances (CosIng) database, and as hair colourants in the United States (US) Personal Care Product Council International Cosmetic Ingredients (INCI) Directory. The free base (CAS No. 615-66-7) is used in oxidative hair dye formulations at concentrations up to 4.6 % and for dyeing eyebrows and eyelashes, mixed with 3 % hydrogen peroxide solution in a 1:1 ratio prior to use in both applications (SCCS, 2013). The sulfate salt (CAS No. 6219-71-2) is used in hair dyes at concentrations up to 2 % (before dilution) (CIR, 2011).

Other international uses have been identified for the chemicals through the US Department of Health and Human Services Household Products Database (US HPD) and the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossiers.

The free base has reported domestic use in the following:

- antibacterial hand wash.

The free base has reported non-industrial use in the following:

- weed killer/pesticides; and
- pharmaceuticals.

The free base is not commercially produced in the US (US National Library of Medicine's Hazardous Substances Data Bank (HSDB)). The sulfate salt seems to have limited use in the US with the Compilation of Ingredients Used in Cosmetics in the US (CIUCUS), 2011 listing the sulfate salt in only one product. The manufacture and/or import estimate for the free base is 0–10 tonnes/year in the EU (REACH).

Restrictions

Australian

No known restrictions have been identified for the chemicals in this group.

International

The chemicals in this group have the following international restrictions (Galleria Chemica):

New Zealand Inventory of Chemicals (NZIoC) for possible use as a component in a product covered by a group standard but is not approved for use as a chemical in its own right.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group are not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

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

International

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

Health Hazard Information

The human health hazards of the chemicals in this group have been assessed using data available on the sulfate salt for repeat dose toxicity and carcinogenicity, and data available on the free base for other toxicological end points. The sulfate salt is

represented in the literature by two CAS numbers, differing in the ratio of free base to SO_4—CAS No. 6219-71-2 with an undefined ratio (possibly a mixture) and CAS No. 61702-44-1 (not on AICS) with 1:1 ratio. Data from both these CAS Nos. have been used in this assessment for the sulfate salt. Data available for the free base are considered relevant for the sulfate salt and vice versa for purposes of this health hazard assessment (see **Grouping rationale** section).

Toxicokinetics

The chemical is expected to have poor dermal absorption when used in hair dye formulations. Dermal absorption values, measured as absorbed dose per cm^2 of exposed skin occurring during a single water contact event such as bathing or swimming (contact time 15 minutes) have been estimated for the free base using Dermwin Version 1.43 (the Dermal Permeability Coefficient Program) (US EPA, 1992; Galleria Chemica) to be 0.0043–0.019 mg/cm^2 per event. Since the contact time for hair dye use is usually 30 minutes, dermal absorption can be extrapolated to be around 0.04 mg/cm^2 for hair dye applications.

Acute Toxicity

Oral

The chemicals in this group are considered to have moderate acute toxicity following oral exposure based on data available on the free base, warranting hazard classification (see **Recommendation** section).

The median lethal dose (LD50) in rats for the free base was reported to be 1190 mg/kg bw and 729 mg/kg bw in two independent non-guideline studies (SCCS, 2013; REACH).

Dermal

No data are available.

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

The free base is not irritating to skin under the test conditions of the available data. No data are available for the sulfate salt. However, since the local irritation effects of the salt are not expected to be greater than those of the free base, the sulfate salt is not likely to be irritating to skin based on data available for the free base.

In a non-guideline study, the free base (2.5 % aqueous solution buffered to pH 7) produced no apparent signs of irritation in 3 albino rabbits, 72 hours after application to intact and abraded skin (CIR, 1992; SCCS, 2013; REACH).

Eye Irritation

Based on the limited data available, the free base may be mildly to moderately irritating to eyes, not warranting hazard classification. No data are available for the sulfate salt. The local irritant effects of the salt are not expected to be greater than those of the free base.

In a non-guideline study, the free base (2.5 % aqueous solution buffered to pH 7) produced mild conjunctival inflammation in 1 out of 3 treated rabbit eyes (CIR, 1992; SCCS, 2013). The remaining animals showed no adverse effects throughout the 7-day observation period.

In a non-guideline standard Draize test, the free base was reported to produce 'moderate reaction' in rabbit eyes when instilled as a neat substance (20 mg) (RTECS). No other study detail is available.

Sensitisation

Skin Sensitisation

The chemicals in this group are considered to be sensitising to skin based on data available on the free base, warranting hazard classification (see **Recommendation** section).

In a non-guideline test, the chemical was found to be a strong sensitiser producing a reaction in 9 out of 15 guinea pigs within 24 hours of challenge (SCCS, 2013). Although the test was described as 'Magnusson-Kligman protocol' (SCCS, 2013), study details showed that it was not a guinea pig maximisation test (GPMT). Female Pirbright white guinea pigs (n=10–15/group) were intracutaneously induced with the chemical at 3 % for 5 consecutive days. After 4 weeks of induction, the animals were challenged with topical application of the chemical at up to 0.3 %. Use of Freunds Complete Adjuvant (FCA) is not mentioned.

Quantitative structure-activity relationship (QSAR) modelling using OECD QSAR Toolbox showed protein binding alerts for the free base and its metabolites for skin sensitisation. One QSAR modelling study based on local lymph node assay (LLNA) data and topological substructural molecular descriptors (TOPS-MODE) predicted a sensitisation potency of 1.6 for the free base (close to p-phenylenediamine with a predicted score of 1.8), identifying the free base as a strong/moderate sensitiser (Søsted et al., 2004).

Observation in humans

The following three individual case reports give evidence of severe allergic reactions/contact dermatitis produced within 24 hours of dyeing eyelashes and eyebrows with a dye containing the free base (Eye, 2010; SCCS, 2013; REACH):

- itchy dermatitis on eyebrows;
- itchy dermatitis on eye lids; and
- swollen eyelids, watering, itchiness and redness in both eyes, followed by severe inflammation of eye lids and conjunctival chemosis (swelling).

Repeated Dose Toxicity

Oral

The chemicals in this group are not expected to cause serious damage to health following repeated oral exposure based on available data.

In 2-year feeding studies in F344 rats and B6C3F1 mice (n=50/sex/group/species) investigating carcinogenicity of the sulfate salt at up to 0.3 % (approximated to 150 mg/kg bw/day) in rats and 0.6 % (approximated to 900 mg/kg bw/day) in mice, the following effects were observed (NTP, 1978; EFSA, 2012; SCCS, 2013):

- rats—slight mean body weight depression was seen; there were no significant treatment-related changes in mortality or clinical parameters; and
- mice—slight mean body weight depression was seen; there was an increase in mortality rate in females; no other significant clinical changes were seen.

In a non-guideline 90-day study in Fischer rats and B6C3F1 mice (n=5/sex/dose/species), incorporation of the sulfate salt (0.03, 0.1, 0.3, 1 or 3 %) in the feed produced the following adverse effects (SCCS, 2013). The dose values can be approximated to 15, 50, 150, 500 and 1500 mg/kg bw/day in rats; and 45, 150, 450, 1500, 4500 mg/kg bw/day in mice (EFSA, 2012) :

- depression in mean body weights in rats (both sexes at 0.3 % and 1 %) and mice (females at 0.3 %; both sexes at 1 %); and
- mortality at 1 % in rats (5 males and 1 female) and mice (1 male).

No results were given for 3 %.

In a non-guideline 14-day study, a no observed adverse effect level (NOAEL) of 200 mg/kg bw/day was established for the free base in Sprague Dawley (SD) rats (REACH). The free base (0, 100, 200 or 400 mg/kg bw/day) was administered to female SD rats (n=11/dose) by oral gavage for 10 days. There were no mortalities. The only adverse effect observed was a reduction in mean body weight gain in the 200 and 400 mg/kg bw/day dose groups.

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

The chemicals in this group are not expected to be genotoxic based on available data. Although the free base tested positive for gene mutations in vitro, it was negative for genotoxicity in vivo. Furthermore, read-across data on 1,4-benzenediamine (CAS No. 106-50-3) and its analogues indicate that the chemicals in this group are not likely to be genotoxic.

The following in vitro data are available (SCCS, 2013):

In several non-guideline studies, the free base was positive for gene mutations/DNA damage in *Salmonella typhimurium* in the following:

- TA98, TA100 and TA1538 at 1–1000 µg/plate (with metabolic activation);
- TA98, TA100 and TA1538 at 1–1000 µg/plate (free base mixed 1:1 with hydrogen peroxide), at highest concentration only (with metabolic activation); and
- TA1535/pSK1002 up to 5 mg/mL (with metabolic activation).

In the same non-guideline studies, the free base was negative for gene mutations in *S. typhimurium* TA1535 and TA1537 (with and without metabolic activation), and in TA98, TA100 and TA1538 (without metabolic activation). In an independent non-guideline study, the free base tested negative in *Escherichia coli* 343/113 at 1–100 µg/mL.

The following in vivo data are available (SCCS, 2013):

In a non-guideline study, the free base did not induce an increase in the number of micronucleated polychromatic erythrocytes in the bone marrow of CFY SPF rats (n=5/sex/group) treated orally at a dose of 900 mg/kg bw/day.

Read-across data on 1,4-benzenediamine (CAS No. 106-50-3), and its analogues 1,4-benzenediamine, 2-nitro- (CAS No. 5307-14-2) and 1,4-benzenediamine, 2-methyl- (CAS No. 95-70-5) indicate that the chemicals in this group are not likely to be genotoxic (NICNAS; NICNASa; NICNASb).

Carcinogenicity

The chemical is not expected to be carcinogenic based on available data.

In 2-year feeding studies in F344 rats and B6C3F1 mice (n=50/sex/group/species) investigating carcinogenicity of the sulfate salt at up to 0.3 % (approximated to 150 mg/kg bw/day) in rats and 0.6 % (approximated to 900 mg/kg bw/day) in mice, the following effects were observed (NTP, 1978; EFSA, 2012; SCCS, 2013):

- rats—slight mean body weight depression was seen; no significant treatment-related mortality or incidences of tumours were seen; there was an increased incidence of transitional-cell hyperplasia of the renal pelvic epithelium in both sexes and the presence of transitional-cell tumours of urinary bladder in 3 dosed rats.
- mice—slight mean body weight depression was seen; there was an increase in mortality rate in females; a variety of proliferative hepatocellular lesions were seen in both sexes; the combined incidence of hepatocellular carcinomas/adenomas in males was positively related to the chemical diet but was not found to be statistically significant based on Fisher exact tests.

Due to the lack of statistical significance, the tumours seen in the treated animals are suggestive of, but not considered as sufficient evidence of carcinogenicity (NTP, 1978; SCCS, 2013). The US National Toxicology Program (NTP) did not provide individual conclusions of carcinogenicity for this study. The SCCS considered that at the most, the study on the chemical represented equivocal evidence of carcinogenicity (SCCS, 2013).

Reproductive and Developmental Toxicity

The chemicals in this group are not expected to have specific developmental toxicity based on the limited data available on the free base. No data is available for reproductive toxicity.

In a non-guideline teratogenicity study, a maternal NOAEL of 100 mg/kg bw/day and a developmental NOAEL of 200 mg/kg bw/day were established for the free base (SCCS, 2013). The free base was administered to SD rats (n=11/dose) at 100, 200 or 400 mg/kg bw/day on days 6–15 of gestation. Significant reduction of maternal body weight gain was observed at dose levels 200 and 400 mg/kg bw/day. Significant increase in number of resorptions was reported at the higher doses (REACH). At 400 mg/kg bw/day dose level, there was a significant reduction in foetal body weights. No other adverse effects were observed.

Risk Characterisation

Critical Health Effects

The critical health effects for the chemicals in this group for risk characterisation include the following:

- skin sensitisation; and
- systemic acute effects (acute toxicity from oral exposure).

Public Risk Characterisation

No use has been identified for the chemicals in this group in Australia. The chemicals may be used overseas in dyeing hair, eyebrows and eyelashes.

The EU Scientific Committee on Consumer Safety (SCCS) is of the opinion that the use of the free base (CAS No. 615-66-7) for dyeing hair, eyelashes and eyebrows is not safe for the consumer due to the following reasons (SCCS, 2013):

- the inability to calculate margin of safety for use in oxidative hair dye formulations for eyebrows and eyelashes for a maximum concentration of 4.6 %; and
- insufficient evidence to conclude genotoxic potential.

The chemicals in this group are strong sensitisers. Although the chemicals in this group currently have not been reported to have cosmetic use in Australia, there is a potential for public exposure through products imported from overseas. In the absence of any regulatory controls for the chemicals in Australia, the characterised critical health effect (skin sensitisation) has the potential to pose an unreasonable risk for the identified uses.

Occupational Risk Characterisation

Given the critical acute and systemic health effects, the chemicals in this group could pose an unreasonable risk to workers unless adequate control measures to minimise oral and dermal exposure are implemented. Oral and dermal exposure can be prevented by good hygiene practices. 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 the appropriate controls.

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

NICNAS Recommendation

Further risk management is required. Sufficient information is available to recommend that risks to public health and safety from the potential use of the chemicals in this group in hair/eyebrow/eyelash dyeing products be managed through changes to the Poisons Standard, and risks for workplace health and safety be managed through changes to the HCIS classification and labelling.

Assessment of the 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

Given the risk characterisation, it is recommended that the chemicals be included in the *Poisons Standard — The Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) for use in hair/eyebrow/eyelash dyeing products to ensure appropriate restrictions and labelling.

Consideration should be given to the following:

- the chemicals are strong skin sensitisers; and
- there is evidence of severe allergic reactions in humans when used to dye eyebrows and eyelashes.

Work Health and Safety

The chemicals in this group are 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)
Sensitisation	Not Applicable	May cause an allergic skin reaction - Cat. 1B (H317)

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

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemicals in this group should be used according to the instructions on the label.

Advice for industry

Control measures:

Control measures to minimise the risk from oral and dermal exposures 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 chemicals are used.

Examples of control measures which could minimise the risk include, but are not limited to:

- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemicals.

Guidance on managing risks from hazardous chemicals is 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 chemicals 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 these chemicals has not been undertaken as part of this assessment.

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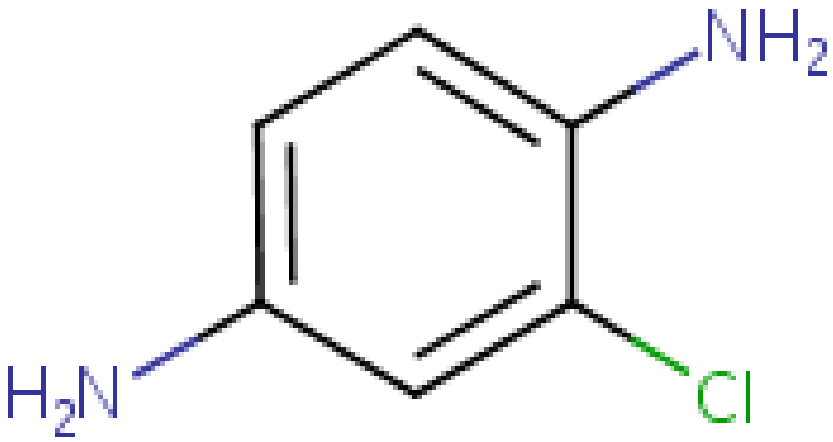
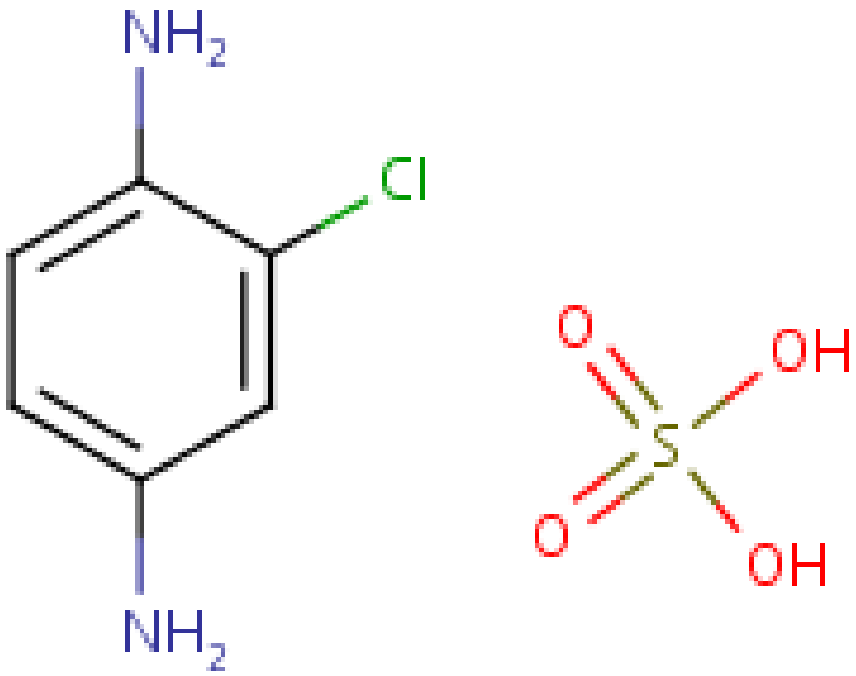
Last Update 02 March 2018

Chemical Identities

Chemical Name in the Inventory and Synonyms	**1,4-Benzenediamine, 2-chloro-** 2-chloro-1,4-benzenediamine 3-chloro-4-aminoaniline Ursol Brown O C.I. 76065 2-chloro-p-phenylenediamine
CAS Number	615-66-7
Structural Formula	

	
Molecular Formula	C6H7ClN2
Molecular Weight	140.6

Chemical Name in the Inventory and Synonyms	**1,4-Benzenediamine, 2-chloro-, sulfate** 2-chloro-p-phenylenediamine sulfate C.I. 76066 C.I. Oxidation Base 13A Rodol Brown SO 2-chlorobenzene-1,4-diammonium sulphate
CAS Number	6219-71-2
Structural Formula	

	
Molecular Formula	C6H7ClN2.xH2O4S
Molecular Weight	240.7

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