1,4-Benzenediamine, dihydrochloride: Human health tier II assessment

18 September 2014

CAS Number: 624-18-0

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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.

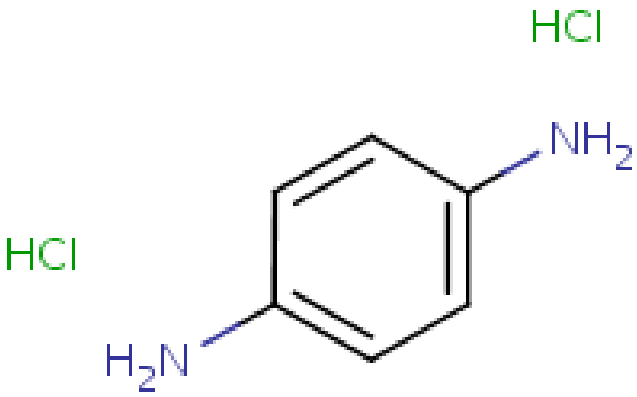
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit:www.nicnas.gov.au

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	p-phenylenediamine hydrochloride (PPD HCl) 4-aminoaniline dihydrochloride p-aminoaniline dihydrochloride p-benzenediamine dihydrochloride 1,4-diaminobenzene dihydrochloride
Structural Formula	
Molecular Formula	C6H8N2.2ClH
Molecular Weight (g/mol)	181.065
Appearance and Odour (where available)	White to slightly reddish crystals
SMILES	c1(N)ccc(N)cc1_Cl_Cl

Import, Manufacture and Use

Australian

The chemical is on the 'List of chemicals used as hair dyes in permanent and semi-permanent hair dyes in Australia' (NICNAS, 2007).

The chemical has reported cosmetic use in hair dye preparations.

International

The following international uses have been identified through the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR), and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use in hair dye preparations.

The chemical has reported commercial uses including in photography developers.

The chemical has reported site-limited uses including as a laboratory reagent.

Restrictions

Australian

This chemical is not individually listed in the *Poisons Standard* (the Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP). However, there is a group entry in Schedule 6 and in Appendix C of the SUSMP (2013) that includes this chemical:

Schedule 6

- 'PHENYLENEDIAMINES and alkylated phenylenediamines not elsewhere specified in these Schedules:

(a) in preparations packed and labelled for photographic purposes;

(b) in preparations packed and labelled for testing water except tablets containing 10 mg or less of diethyl-para-phenylenediamine or dimethyl-para-phenylenediamine in opaque strip packaging provided the directions for use include the statement, "Do not discard testing solutions into the pool";

(c) in hair dye preparations except when the immediate container and primary pack are labelled with the following statements: KEEP OUT OF REACH OF CHILDREN, and WARNING - This product contains ingredients which may cause skin irritation to certain individuals. A preliminary test according to the accompanying directions should be made before use. This product must not be used for dyeing eyelashes or eyebrows; to do so may be injurious to the eye.

written in letters not less than 1.5 mm in height; or

(d) in eyelash and eyebrow tinting products when the immediate container and primary pack are labelled with the following statement: WARNING - This product contains ingredients which may cause skin irritation to certain individuals, and when used for eyelash and eyebrow tinting may cause injury to the eye. A preliminary test according to the accompanying directions should be made before use.

written in letters not less than 1.5 mm in height.'

Schedule 6 chemicals are labelled with 'Poison'. These are substances with a moderate potential for causing harm, the extent of which can be reduced by using distinctive packaging with strong warnings and safety directions on the label.

Appendix C:

- 'PHENYLENEDIAMINES in preparations for skin colouration and dyeing of eyelashes or eyebrows except when included in Schedule 6.'

Appendix C chemicals warrant bans on selling, supplying or using them due to their danger to health.

International

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

- EU Cosmetics Regulation 1223/2009 Annex III—List of substances which cosmetic products must not contain except subject to the restrictions laid down (maximum allowed concnetration in a finished cosmetic product is 6 % calculated as free base);
- Association of Southeast Asian Nations (ASEAN) Cosmetic Directive Annex III Part 1 List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down;
- New Zealand Cosmetic Products Group Standard—Schedule 5—Table 1: Components cosmetic products must not contain except subject to the restrictions and conditions laid down;
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist").

Existing Work Health and Safety Controls

Hazard Classification

The chemical is 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; R36 (irritation)

- Xi; R43 (sensitisation)

Exposure Standards

Australian

No specific exposure standards are available.

International

The following exposure standards are identified (Galleria Chemica):

- an 8-hour exposure limit of 0.1 mg/m^3 in Sweden; and
- maximum allowed concentrations (PDK) of 0.05 mg/m^3 in Russia.

Health Hazard Information

This chemical is a salt resulting from 1,4-benzenediamine (CAS No. 106-50-3; referred to as the parent base in this report) reacting with two molecules of hydrochloric acid. The HSIS contains similar hazard classifications for this chemical and its parent base (NICNAS). Considering the pH-dependent speciation of the parent base and this chemical (dihydrochloride salt) in biological fluid, where there are no hazard data for this chemical, data on the parent base are used in this assessment. However, the local effects might be slightly different for the parent base compared with its dihydrochloride salt.

Toxicokinetics

Following oral administration in rats, the parent base was quickly absorbed and excreted mostly within 24 hours (SCCP, 2006).

Human metabolism studies and rat studies indicate that the topically applied parent base is converted to N-mono- or N,N'-diacetylated metabolites (de-toxified forms) (SCCP, 2006). In vitro studies that used human hepatocytes and microsomes formed 2-acetylated PPD derivatives (SCCP, 2006).

Acute Toxicity

Oral

The chemical is classified as hazardous with the risk phrase ‘Toxic if swallowed’ (T; R25) in HSIS (Safe Work Australia). The available data on rats support this classification.

The median lethal dose (LD50) is reported to be 147 mg/kg bw in rats and 316 mg/kg bw in mice (ChemIDplus).

Dermal

The chemical is classified as hazardous with the risk phrase ‘Toxic in contact with skin’ (T; R24) in HSIS (Safe Work Australia). No data are available for the chemical. While the available data for the parent base do not support this classification, in the absence of more comprehensive information, it is not recommended that this classification be amended.

The Scientific Committee on Consumer Products (SCCP) opinion in 2006 stated that no data were submitted on acute dermal toxicity of the parent base. The National Institute for Occupational Safety and Health (NIOSH) in 2011 reported the dermal LD50 in New Zealand White rabbits as >7940 mg/kg bw for the parent base (study conducted before 1977 and details not available). However, according to a REACH dossier on the parent base, this study was conducted using only one animal per dose and with a 40 % aqueous solution.

Inhalation

The chemical is classified as hazardous with the risk phrase ‘Toxic by inhalation’ (T; R23) in HSIS (Safe Work Australia). Based on the available data for the parent base, this classification is supported.

No data are available for the chemical. The median lethal concentration (LC50) in rats (exposed to the chemical as an aerosol) for the parent base is 0.92 mg/L/4-hours. Reported sublethal signs of toxicity include red nasal discharge, cyanosis, red ocular discharge, brown-stained fur around the eyes,

diarrhoea, no righting reflex (reflex that corrects the orientation of the body) and tremors (REACH).

Corrosion / Irritation

Skin Irritation

No data are available for the chemical. Considering that the parent base can cause slight skin irritation, this chemical is also considered to have the potential to cause skin irritation. The limited information available is not sufficient to warrant a hazard classification.

The parent base is reported to be non-irritating or irritating to the skin, depending on the animal species and the dose tested (NIOSH, 2011; NICNAS; REACH).

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). The available data for the parent base support this classification.

No data are available for the chemical.

In an eye irritation study with two male rabbits, the parent base was found to be moderately irritating with moderate iritis, conjunctivitis and slight corneal cloudiness observed at one, four, 24, 48, 72 hours after application (scores not available) and up to seven days after treatment. Washing the eye reduced the severity of irritation. Effects were reversible within the 14-day observation period (REACH).

Sensitisation

Skin Sensitisation

The chemical is classified as hazardous with the risk phrase ‘May cause sensitisation by skin contact’ (R43) in HSIS (Safe Work Australia). The available data for the parent base support this classification.

No data are available for the chemical.

In a mouse local lymph node assay (OECD TG 429) with the parent base, the mean stimulation indices were reported to be 2.6, 10.4 and 16.1 for the concentrations of 0.025, 0.25 and 1.25 % of the chemical, respectively. An estimated concentration to produce a stimulation index of three (EC3) was extrapolated to be 0.06 % (SCCP, 2006; REACH), indicating the parent base is a strong skin sensitiser.

Observation in humans

The parent base is a strong clinical contact allergen in humans; the sensitisation response varies with the vehicle, exposure condition and challenge concentration (SCCP, 2006).

Cases of severe blistering dermatitis were reported in patients who had used skin paints containing the parent base (in temporary tattoos). Patients found to be allergic to the parent base have reacted to concentrations as low as 1 % after only 15 minutes of exposure (SCCP, 2006).

Repeated Dose Toxicity

Oral

No data are available for the chemical. Based on the available data for the parent base, the chemical is not expected to cause serious damage to health from repeated oral exposure.

Several repeated dose toxicity studies are available for the parent base (SCCP, 2006; NICNAS).

In a 13-week study (OECD TG 408) with the parent base, Sprague Dawley (SD) rats showed no significant toxic effects up to 16 mg/kg bw/d, except for increased absolute and relative liver weights in males at 8 and 16 mg/kg bw/d, and minimal degeneration of the skeletal muscle in two animals at 16 mg/kg bw/d. A no observed adverse effect level (NOAEL) of 4 mg/kg bw/d was determined (SCCP, 2006).

A 13-week study in Fischer 344 (F344) rats reported no mortalities or clinical signs associated with the parent base up to the highest dose tested. A NOAEL of 16 mg/kg bw/d was established (SCCP, 2006).

In a 12-week study with the parent base in F344 rats, several animals died at 200 mg/kg bw/d. A NOAEL of 50 mg/kg bw/d was established (SCCP, 2006).

Dermal

No data are available for the chemical.

The repeated dose dermal toxicity studies with the parent base have used only up to 10 % concentrations. No serious health effects are reported in animals in these studies (NIOSH, 2011; NICNAS).

Inhalation

No data are available for the chemical or the parent base.

Genotoxicity

No data are available for the chemical. Based on the available data for the parent base and its metabolites, the chemical is not expected to be genotoxic. Although the parent base and its metabolites showed mixed results for genotoxicity in vitro, all in vivo genotoxicity studies in rats and mice showed negative results with the parent base up to 300 mg/kg bw.

There are several in vitro genotoxicity studies conducted with the parent base and its N-monoacetyl or N,N-diacetyl metabolites. Mixed results were observed in these genotoxicity studies (ACToR):

- negative in Ames assays with *Salmonella typhimurium* strains TA 100, 102, 1535, TA 1537, with or without metabolic activation;
- positive in an Ames assay with *S. typhimurium* strain TA98, with metabolic activation;
- positive in mouse lymphoma cells (L5178Y (TK+/TK-)), with or without metabolic activation;
- negative in human lymphocytes up to 80 ug/mL; and
- positive in human lymphocytes at 50–125 ug/mL without metabolic activation and at 500–1600 ug/mL with metabolic activation.

The SCCP (2006) stated that the in vitro activity of the parent base 'may be related to formation of the Bandrowski’s base which is very unstable'.

In three, short-term in vivo studies (zeste-white, white-ivory and wing spot) conducted to detect mutation and recombination in somatic cells of *Drosophila melanogaster* (using five chemicals, including the parent base, which are reported to be classified by the US National Toxicology Program (NTP) as genotoxic non carcinogens or ambiguous), the parent base showed 'a clear mutagenic response in all three assays'. 'The wing spot test was the most effective of these assays and the white-ivory test was the poorest (Batiste-Alentorn et al., 1995 cited in ACToR).

However, all available mammalian in vivo genotoxicity studies with the parent base gave negative results (SCCP, 2006; NICNAS):

- Wistar rats, orally administered the parent base up to 100 mg/kg bw (OECD TG 474) showed no increase in bone marrow micronuclei after 24 hours;
- a bone marrow micronucleus test in mice treated up to 100 mg/kg bw with the parent base showed no increase of micronuclei; and
- negative results were reported in rats for micronuclei induction, when administered the parent base orally at 300 mg/kg bw.

Carcinogenicity

Based on the available data, the chemical is not considered to be carcinogenic.

In a two-year carcinogenicity study, F344 rats (n = 50/sex/dose) and B6C3F1 mice (n = 50/sex/dose) were administered the chemical at 625–1250 ppm in the diet for 103 weeks. No significant increase in tumour incidences were reported compared with controls in either species (NCI, 1979; HSDB), indicating that the chemical is not carcinogenic up to dietary doses of 1250 ppm.

The parent base, p-phenylenediamine (CAS No. 106-50-3) alone has not been demonstrated to be carcinogenic in rats or mice, but 'p-phenylenediamine, together with hydrogen peroxide, may be carcinogenic in experimental studies with rats' (SCCP, 2006). The International Agency for Research on Cancer (IARC) classified the parent base as a category 3 carcinogen 'based on no data in human studies and inadequate data in animal studies' (IARC, 1978).

Reproductive and Developmental Toxicity

No data are available for the chemical. Based on the available data for the parent base, the chemical is not expected to cause reproductive or developmental toxicity.

In a developmental toxicity study (OECD TG 414) in pregnant SD rats exposed (from gestation day (GD) 6–9) to the parent base, a NOAEL of 5 mg/kg bw/d was determined for maternal toxicity, due to transiently lower mean body weight gain at 10 and 20 mg/kg bw/d. A NOAEL of 10 mg/kg bw/d was determined for developmental toxicity based on slightly retarded ossification (supraoccipital, sternebrae, thoracic vertebrae and metacarpals) and reduced mean foetal weight (not statistically significant) at 20 mg/kg bw/d (SCCP, 2006; REACH). These results were supported by another study (OECD TG 414) that administered the parent base at 5, 10, 15, 20 or 30 mg/kg bw/d in pregnant SD rats (GD 6–15). A NOAEL of 10 mg/kg bw/d was established for maternal toxicity, based on decreased body weight gain and food consumption at 20 and 30 mg/kg bw/d (SCCP, 2006; REACH). There were no teratogenic or embryotoxic effects (Re et al., 1981).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include:

- local effects (skin sensitisation and eye irritation); and
- systemic acute effects through oral, dermal and inhalation exposure.

Public Risk Characterisation

The chemical is reported to be used in hair dye preparations in Australia. Many countries, including Canada, New Zealand and the European Union have imposed restrictions for the use of this chemical in cosmetics.

Based on the data available for the parent base, this chemical is considered to be a strong skin sensitiser. The chemical is not carcinogenic. However, mixing the parent base with hydrogen peroxide has shown a potential for carcinogenicity (inconclusive).

If this chemical is included in cosmetic products containing N-nitrosating agents, carcinogenic N-nitrosamine compounds could be formed (SCCS, 2012).

In Australia, a chemical group (phenylenediamines), including this chemical, is listed on Schedule 6 and Appendix C of the SUSMP, with restriction and prohibition on certain uses. The Schedule 6 entry in the SUSMP allows phenylenediamines to be included in hair dye preparations and in eyelash and eyebrow tinting products with specific labelling requirements, which include conducting a preliminary sensitisation test before being used as a hair dye.

The existing control measures imposed through the SUSMP are considered adequate to protect the public from the identified uses of this chemical.

Occupational Risk Characterisation

Given the critical health effects (skin sensitisation, eye irritation and acute toxicity), the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise exposure to the chemical are implemented. Based on the available data, the hazard classification in HSIS is considered appropriate.

NICNAS Recommendation

Current risk management measures are considered adequate to protect public and workers' health and safety, provided that 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 chemical falls within the scope of the listing of 'Phenylenediamines' in Schedule 6 of the SUSMP for use in hair dye preparations under specified conditions.

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 the classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
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)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)*	Causes serious eye irritation - Cat. 2A (H319)
Sensitisation	May cause sensitisation by skin contact (Xi; R43)*	May cause an allergic skin reaction - Cat. 1 (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 chemical should be used according to the instructions on the label.

Advice for industry

Control measures to minimise the risk from oral, dermal, ocular 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 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.

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Last update 18 September 2014

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