

# Phenol, 2-amino-: Human health tier II assessment

22 November 2013



## CAS Number: 95-55-6

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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.

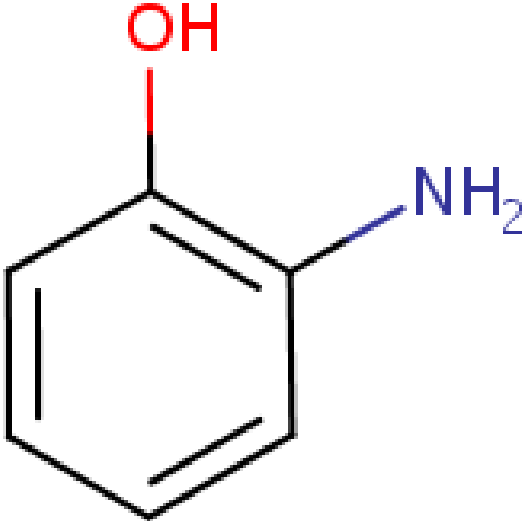
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: [www.nicnas.gov.au](http://www.nicnas.gov.au)

### Disclaimer

NICNAS has made every effort to assure the quality of information available in this report. However, before relying on it for a specific purpose, users should obtain advice relevant to their particular circumstances. This report has been prepared by NICNAS using a range of sources, including information from databases maintained by third parties, which include data supplied by industry. NICNAS has not verified and cannot guarantee the correctness of all information obtained from those databases. Reproduction or further distribution of this information may be subject to copyright protection. Use of this information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. NICNAS does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using this information.

## Chemical Identity

Synonyms	2-amino-1-hydroxybenzene 1-hydroxy-2-aminobenzene o-aminophenol 2-hydroxyaniline o-hydroxyphenylamine
Structural Formula	
Molecular Formula	C6H7NO
Molecular Weight (g/mol)	109.13
Appearance and Odour (where available)	White crystals (or light beige powder)
SMILES	<chem>c1(O)c(N)cccc1</chem>

## Import, Manufacture and Use

### Australian

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

The chemical has reported cosmetic use in permanent hair dye preparations.

### International

The following international uses have been identified through 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; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: 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 chemical has reported domestic use including in:

- paints, lacquers and varnishes;
- cleaning/washing agents; and
- colouring agents.

The chemical has reported commercial use including in:

- anticorrosion lubricating agents;
- additives as a vulcanising agent; and
- textile dyes (leather, fur).

The chemical has reported site-limited use including:

- as an intermediate for the synthesis of various heterocyclic products; and
- as a reducing agent in photographic development.

The following non-industrial uses have been identified internationally:

- as a flavouring agent in food (the chemical is included in the entry 'aromatic alcohols' listed on the Japan Specifications and Standards for Food Additives).

## Restrictions

### Australian

No known restrictions have been identified.

### International

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

- Association of South East Asian Nations (ASEAN) Cosmetic Directive Annex II Part 1 (amended in March 2013): List of substances which must not form part of the composition of cosmetic products;
- EU Cosmetics Regulation 1223/2009 Annex II—List of substances prohibited in cosmetic products; and
- New Zealand Cosmetic Products Group Standard—Schedule 4: Components cosmetic products must not contain.

## 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):

- Xn; R20/22 (acute toxicity)
- Muta. Cat. 3; R68 (mutagenicity)

### Exposure Standards

#### Australian

No specific exposure standards are available.

#### International

The following exposure standards are identified (Galleria Chemica; PAC):

Temporary Emergency Exposure Limits (TEELs) defined by the US Department of Energy (DOE):

TEEL-1 = 4.4 mg/m<sup>3</sup>;

TEEL-2 = 48 mg/m<sup>3</sup>; and

TEEL-3 = 260 mg/m<sup>3</sup>.

## Health Hazard Information

The chemical is one of the three isomers of aminophenol. As data on this chemical are lacking, data available on the other two isomers, p-aminophenol (CAS No. 123-30-8) or m-aminophenol (CAS No. 591-27-5), were used in the assessment. Data on p-aminophenol are preferred for reasons of greater chemical similarity.

### Toxicokinetics

When administered to rabbits as a single oral dose of 1 g, the chemical was almost entirely recovered in urine (~95% administered dose), including 11 % in its unchanged form, 2–4 % as acetamidophenol, 15 % as aminophenolsulfate, 52 % as aminophenylglucuronide and 13 % as acetamidophenylglucuronide (IUCLID, 2000).

### Acute Toxicity

#### Oral

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). The available data support this classification.

The oral LD50 in rats is 951 mg/kg bw. Reported signs of toxicity include changes in motor activity, tremors and cyanosis (blue colouration of the skin and mucous membranes) (REACH a).

In a study (no guideline indicated) which used the chemical at 500, 1000, 1250, 2000 or 2500 mg/kg bw in groups of rats, the oral LD50 was calculated as 1052 mg/kg bw (SCCS, 2010).

#### Dermal

No reliable data are available for this chemical. Based on the data available for an isomer p-aminophenol (CAS No. 123-30-8), the chemical is expected to have low acute dermal toxicity.

The only information available for the chemical is a dermal toxicity study conducted in rabbits showing no toxic effects (details not available) (IUCLID, 2000).

An LD50 of >8000 mg/kg bw in New Zealand White rabbits is reported for p-aminophenol (CAS No. 123-30-8) in an occlusive patch test. There were no mortalities at doses of 2000, 4000 or 8000 mg/kg bw (REACH b).

#### Inhalation

The chemical is classified as hazardous with the risk phrase 'Harmful by inhalation' (Xn; R20) in HSIS (Safe Work Australia). No data are available on the chemical. The data available on the isomers support this classification.

In a study following OECD Test Guideline (TG) 403, rats were exposed to the dust of p-aminophenol (CAS No. 123-30-8) at 3.42 mg/L for four hours. During the 14-day observation period no treatment-related effects were seen. The median lethal concentration (LC50) is >3.42 mg/L (REACH b).

Another study with m-aminophenol (CAS No. 591-27-5) in rats indicated an LC50 of 1162 mg/m<sup>3</sup> (1.162 mg/L). The following effects were recorded: spastic paralysis of peripheral nerves, sensations and change in behaviour (excitement) (REACH c).

### Corrosion / Irritation

#### Skin Irritation

Based on the available data the chemical is not expected to be a skin irritant.

A study was performed with the chemical according to three standard methods (SCCS, 2010; HSDB):

- Official French Cosmetic method (OFC) occlusive patch (air and water-tight dressing) method;
- Association Francaise de Normalisation (AFNOR) occlusive patch method; and
- OECD TG 404 semiocclusive patch method.

In each protocol, a dose of 0.5 g of the chemical (pulverised crystals) was applied to the clipped skin of New Zealand White rabbits for four hours (AFNOR, OECD) or 23 hours (OFC). The primary cutaneous irritation indices (PCI) were 0/8 in all three methods.

In another study (no test guideline indicated), the chemical was applied as a 1 % solution in propylene glycol to the clipped skin of six male New Zealand White rabbits for 23 hours under occlusion. The chemical was not a skin irritant (SCCS, 2010).

The chemical was not irritating to the skin of albino rabbits when applied at a 5 % concentration in ethanol, in a patch test (HSDB).

## Eye Irritation

Based on the available data, the chemical is slightly irritating to the eyes but does not meet the criteria for classification.

In a Draize test (OECD TG 405), 100 mg of the chemical was instilled into the eyes of New Zealand White rabbits for 24 hours. According to the Draize scoring system, the chemical induced an acute ocular irritation index of 9.83/110 after 24 hours and a mean ocular irritation index of 2.33/110 after two days. These results indicate that the chemical was slightly irritating to the eyes (HSDB; IUCLID, 2000).

A cumulative conjunctival score of 3.3/20 was reported in another Draize test in rabbits (details not available), indicating that the chemical is a slight eye irritant (IUCLID, 2000).

The chemical slightly irritated the eyes of six white rabbits when instilled as a 1 % solution in propylene glycol for one hour. The effect was reversible within 24 hours (SCCS, 2010).

In a hen's egg chorioallantoic membrane test, the chemical was administered at 1.5 % concentration and was slightly irritating, but not irritating at a 0.5 % concentration. The study concluded that the chemical was slightly irritating at 1 % concentration (HSDB; IUCLID, 2000).

## Sensitisation

### Skin Sensitisation

The data available indicate that the chemical may have some potential to cause skin sensitisation. However, the data available do not provide sufficient information for the chemical to be classified as a skin sensitizer.

In a Magnusson and Kligman modified study (OECD TG 406), 20 albino guinea pigs were induced using topical applications (10 occlusive applications of 0.5 g of the chemical) and intradermal injections (two, using the immunopotentiator Freund's complete adjuvant on days one and 10). On day 36, 0.5 g of the chemical was applied to a non-treated skin area (challenge phase). The chemical did not induce any sensitisation reaction (SCCS, 2010).

The chemical is listed as a skin sensitizer based on murine local lymph node assay (LLNA) results which considered the structure activity relationship for potential skin sensitizers (Ashby et al, 1995). In a modified local lymph node assay (no guideline indicated), groups of female mice were treated with the chemical. In this assay, the chemical was used as a skin sensitizer with other known skin sensitizers to assess the relevance of the test. Significant increase in lymph node weight and proliferation of lymphocytes were observed at the high dose (dose not indicated) (HSDB).

In another study (no guideline indicated), skin sensitisation potential was investigated in albino Hartley guinea-pigs (number not available), using two methodologies (Dossou et al., 1985):

1. Open epidermal induction (0.18 millimolar (mM) concentration) by injection of Freund's complete adjuvant into the foot pad, and challenged using a topical application of 0.09 mM concentration in the lumbar region. No positive reactions were observed;
2. Induction (0.18 mM concentration) by injection of both test substance and adjuvant into the foot pad, and a challenge using a topical application of 0.09 mM concentration in the lumbar region. A positive response was observed in 20 % of the animals (SCCS, 2010).

In a guinea pig maximisation test, p-phenylenediamine (CAS No. 123-30-8) induced cross sensitivity in 4/10 guinea pigs (details not available) (SCCS, 2010; HSDB).

In spite of the available data, the SCCS concluded that only inadequate information on skin sensitisation potential was provided and requested a more acceptable study (SCCS, 2010).

### Observation in humans

Three out of 10 patients that showed sensitisation reactions to p-phenylenediamine in hair dyes also showed weakly positive patch test reactions to the chemical, o-aminophenol (SCCS, 2010).

## Repeated Dose Toxicity

### Oral

Based on the data available, the chemical is not considered to cause serious damage to health from repeated oral exposure.

In a 90-day study, Sprague Dawley (SD) rats (n=10/sex) received the chemical as a 1 % solution in propylene glycol at 0 or 50 mg/kg bw/d. No mortalities were observed. There were no differences between the two groups on body weight gain, haematological parameters, blood biochemistry (except for the alkaline phosphatase level) and urine. The study is of limited value because only a single dose was administered (SCCS, 2010). The SCCS opinion states, 'Histopathological examination showed broncho-pulmonary injuries which did not permit to affirm the toxicity of the substance'.

In a 28-day study (OECD TG 407), the chemical was orally administered (by gavage) to rats at doses of 20, 80 or 320 mg/kg bw/d. Reported signs of toxicity were: orange discolouration of the urine from 80 mg/kg bw/d, signs of regenerative macrocytic anaemia at 320 mg/kg bw/d, increased aspartate aminotransferase (AST) activity at 80 and 320 mg/kg bw/d, increased blood urea nitrogen and urinary proteins at 320 mg/kg bw/d, renal cells in urine at 20 mg/kg bw/d, increased liver and kidney weights at 320 mg/kg bw/d, discolouration of the kidney and renal tubular lesions at 320 mg/kg bw/d, and increased vacuolisation of the urothelium in the bladder at 20 and 80 mg/kg bw/d. A no observed adverse effect level (NOAEL) was not established due to effects being observed in all treatment groups (SCCS, 2010)

In another 28-day study (OECD TG 407), the chemical was orally administered (by gavage) to rats at doses of 2, 5 or 15 mg/kg bw/d. Bodyweight gains were reduced in all treated females (no dose-related response) and high dose group males. Increased plasma glucose level in males and significantly increased relative thyroid weight in females were observed at 15 mg/kg bw/d. No histopathological changes related to the treatment were observed in the thyroid. A NOAEL of 5 mg/kg bw/d was established (SCCS, 2010).

### Dermal

No reliable data are available.

A 90-day study in rabbits (n=12) used a solution containing the chemical at 0.15 % (1 mL/kg bw/d). No toxic effects were reported at this low dose (SCCS, 2010).

### Inhalation

No data are available on the chemical or its isomers.

## Genotoxicity

The chemical is classified as hazardous—Category 3 mutagenic substance—with the risk phrase 'Possible risk of irreversible effects' (Xn; R68) in HSIS (Safe Work Australia). Positive in vitro data with mostly negative in vivo data for genotoxicity support this classification.

The following in vitro studies are available on the chemical (SCCS, 2010; IUCLID, 2000):

- Ames tests (OECD TG 471): A bacterial gene mutation test was conducted using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537, with or without metabolic activation at concentrations from 10 to 10,000 µg/plate. Positive results were recorded only for strain TA100 above 333 µg/plate without metabolic activation and 100 µg/plate with metabolic activation. In another Ames test which used *S. typhimurium* strains TA98 and TA100 with the chemical at concentrations from 25 to 500 µg/plate, the only positive results were recorded for strain TA100 at 250-500 µg/plate with metabolic activation. All other bacterial gene mutation tests showed negative results.
- Gene mutation test in yeast (similar to OECD TG 480): Tested at 5, 20, 30 and 50 mM without metabolic activation and at 5, 20 and 30 mM with metabolic activation for 16 hours. The chemical did not induce any mutations.
- DNA synthesis inhibition test (similar to OECD TG 482): V79 Chinese hamster cells showed strong inhibition of replicative DNA synthesis after being exposed to the chemical (concentration not reported) for 30 minutes.
- Sister chromatid exchange (SCE) assays (similar to OECD TG 479): In one study, human fibroblasts were exposed to concentrations of the chemical at 0.01, 0.03, 0.1 or 0.3 mM for two hours. The chemical induced a dose-related increase in the number of SCE and was cytotoxic at the highest concentration. In another SCE study, human lymphocytes were exposed to 1.6, 3.3 or 6.6 µg/mL of the chemical for 72 hours. The chemical was found to be genotoxic.

The following in vivo studies are available on the chemical (SCCS, 2010; IUCLID, 2000):

- Micronucleus test in bone marrow cells (similar to OECD TG 474): The chemical, administered by a single intraperitoneal (i.p.) injection of 125 mg to 40 Swiss mice, did not induce any increase in micronuclei in bone marrow cells.

- Chromosome aberration tests (similar to OECD TG 475): The chemical, administered by single i.p. injection of 16.6, 50 or 150 mg/kg bw to Swiss mice did not induce a significant increase in chromosome aberrations in bone marrow cells.
- SCE tests: Male Chinese hamsters receiving the chemical (by i.p. injections) at 5 mg/kg bw showed no induction of SCE in the bone marrow.
- Unscheduled DNA synthesis test (similar to OECD TG 486): The chemical was administered to male rats as single oral gavage doses of 400 or 2000 mg/kg bw and the hepatocytes were collected four and 12 hours after the treatment. The test showed negative results.
- Chromosome aberration test and SCE test on seedlings: The chemical administered at doses of  $10^{-3}$ ,  $2 \times 10^{-3}$  and  $4 \times 10^{-3}$  Molar (M) to *Vicia faba* seedlings produced mutagenicity. A dose-related increase of SCE was also observed in root cells at doses of  $10^4$ ,  $5 \times 10^4$  and  $10^3$  M.
- Sex-linked recessive lethal tests in *Drosophila melanogaster* (OECD TG 477): In two feeding studies the chemical at doses of 25 and 50 mM or a dose of 200 ppm showed negative results for mutagenicity.

## Carcinogenicity

No carcinogenicity studies are available for this chemical, except for two dermal studies conducted using a hair dye formulation containing the chemical at a very low concentration. The data available do not provide sufficient information to make a conclusion about carcinogenicity of the chemical.

Groups of mice were exposed to a hair dye formulation containing the chemical at 0.3 % (and 6 % hydrogen peroxide) by topical application, once a week for 21 to 23 months. The final concentration of the chemical applied was 0.15 %. The incidence of neoplastic and non-neoplastic lesions (dermal, gastrointestinal, lymphatic and respiratory systems) was not statistically and biologically significant. Under the conditions of the study the chemical was not considered to be carcinogenic (CIR, 1988; SCCS, 2010).

In another study, rats were exposed to the chemical dermally (on clipped skin) at 0.3 % (mixed equally with hydrogen peroxide), twice a week for 105 weeks. The final concentration of the chemical applied was 0.15%. After 18 months, no changes were recorded on haematological parameters. After 24 months, mean haemoglobin and haematocrit levels were slightly lower than the controls and pituitary adenomas had significantly increased compared with one control group (out of three). Other neoplasms and lesions were observed at low frequencies but were not statistically significant (CIR, 1988; IUCLID, 2000).

The chemical is not expected to be carcinogenic when mixed into a hair dye formulation that will contain the final application concentration of 0.15 % (CIR, 1998; SCCS, 2010).

## Reproductive and Developmental Toxicity

Based on the information available (maternal and foetal NOEL of 70 mg/kg bw/d), the chemical is not expected to have reproductive or developmental toxicity.

In a teratogenicity study, pregnant SD rats were orally administered the chemical at doses of 20, 70 or 250 mg/kg bw/d during gestation days 6–15. Maternal treatment-related effects included brown colouration of the urine at all doses and decreased mean body weight gain. A few foetal anomalies such as bilateral anophthalmia (absence of one or both eyes) associated with micrognathia (hypoplasia of the jaw) and dilatation of the lateral cerebral ventricles were observed at 250 mg/kg bw/d, probably caused by maternal toxicity. Slight ossification retardation was observed in foetuses at 250 mg/kg bw/d. A NOEL of 70 mg/kg bw/d was established for maternal and foetal toxicity (SCCS, 2010).

Reproductive toxicity was investigated in a two-generation dermal study on Charles River rats (OECD TG 416), using a hair dye formulation containing the chemical. The formulation (0.5 mL containing 0.3 % of the chemical equally mixed with 6 % hydrogen peroxide) was applied on the clipped skin of rats, twice a week during growth, mating, gestation and lactation through to weaning, in all generations (F0 to F2). After 24 months, mean values of haemoglobin and haematocrit were slightly lower than the controls. No other signs of toxicity were recorded and reproductive functions (fertility, gestation and viability of pups) were not altered (CIR, 1988; SCCS, 2010).

Teratogenicity was evaluated in a dermal study which used 20 female Charles River CD rats during gestation (no details). A dose of 2 mL/kg bw of a mixture containing the chemical at 0.15 % (in 6 % hydrogen peroxide) was applied to the skin every third day. A total of seven applications were made. No teratogenic effects were recorded (CIR, 1988; IUCLID, 2000).

A study was performed on female Syrian golden hamsters (n=7) using an i.p. administration of the chemical on day eight of gestation at doses of 100, 150 or 250 mg/kg bw. The foetuses were examined on day 13 for external gross malformations. Three foetuses from each litter that showed at least one malformation were also examined for soft tissue anomalies. No maternal toxicity was observed. The signs of embryo-lethal and teratogenic effects observed include encephalocele (protrusion of brain tissue), spina bifida (defect of the spine and spinal cord), exencephaly (abnormal brain tissue located out of the skull) and defects of the limbs, ribs, tail and eyes occurring at the lowest dose of 100 mg/kg bw/d (SCCS, 2010; IUCLID). The route of exposure used in this study is not relevant for human exposure.

## Risk Characterisation

### Critical Health Effects

The critical health effects for risk characterisation include:

- systemic long-term effects (mutagenicity); and
- systemic acute effects (from oral and inhalational exposure).

The chemical may have some potential to cause skin sensitisation. Only limited data are available on carcinogenic effects with no effects noted at very low concentrations and a lack of information on higher concentrations.

## Public Risk Characterisation

ASEAN countries, New Zealand and the European Union have restricted the use of this chemical in cosmetics whereas currently there are no restrictions in Australia on using this chemical in cosmetics or domestic products.

Considering the use of this chemical in permanent hair dyes in Australia, and other potential domestic uses (based on overseas information), the main routes of public exposure are expected to be through the skin, and inhalation from products applied as aerosols or sprays.

In the absence of any regulatory controls, the characterised critical health effects (mutagenicity, acute toxicity and skin sensitisation) have the potential to pose an unreasonable risk under the uses identified.

## Occupational Risk Characterisation

Given the critical health effects (mutagenicity, acute toxicity and potential for skin sensitisation), the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise dermal and inhalation exposure to the chemical 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 appropriate controls.

Based on the available data, the hazard classification in HSIS is considered appropriate. Although there are concerns for skin sensitisation (not classified), the control measures that will be implemented based on other hazards are expected to protect workers from any skin sensitisation effects. The classification for skin sensitisation will be reconsidered if new validated data become available.

## 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 chemical in hair dyes and domestic products be managed through changes to poisons scheduling, and risks for workplace health and safety be managed through classification and labelling.

Assessment of the chemical 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 chemical is recommended for scheduling to prohibit its sale, supply and use in cosmetic products and hair dyes. Appropriate scheduling and labelling should be undertaken to mitigate risk from its use in domestic products such as paints, lacquers, varnishes, cleaning/washing agents.

Matters to be taken into consideration include the potential for skin sensitisation, mutagenicity and prohibition of its use in cosmetics in other countries. Conclusive data are lacking on carcinogenicity of the chemical.

### 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 hazards and environmental hazards.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302) Harmful if inhaled - Cat. 4 (H332)



Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)*	Suspected of causing genetic defects - Cat. 2 (H341)

<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 consumers

Products containing the chemical should be used according to the instructions on the label.

## Advice for industry

### Control measures

Control measures to minimise the risk from oral, 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 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

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