Sulfanilic acid and its sodium salt: Human health tier II assessment

27 October 2017

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, 4-amino-	121-57-3
Benzenesulfonic acid, 4-amino-, monosodium salt	515-74-2

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**

Disclaimer

ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemical, sodium 4-aminobenzenesulfonic acid (sodium sulfanilate; CAS No. 515-74-2) is a monosodium salt of 4-aminobenzenesulfonic acid (sulfanilic acid; CAS No. 121-57-3). The sulfanilic acid and its salt have been grouped together for assessment due to their similar toxicological properties and uses.

Import, Manufacture and Use

Australian

No specific Australian use, import, or manufacturing information has been identified for the chemicals.

International

The following international uses have been identified through the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACHa,b) dossiers; Galleria Chemica; the Substances in Preparations in Nordic countries (SPIN) database; the United States (US) Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); the European Commission Cosmetic Ingredients and Substances (CosIng) database; and the US Personal Care Products Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary.

The chemicals may have cosmetic uses in hair dyes and other personal care products.

The chemicals have commercial uses in building and construction materials and in paper products.

The chemicals have site-limited uses as intermediates for dyes and pigments.

The chemicals may have non-industrial uses in pharmaceuticals and pesticides.

Restrictions

Australian

No known restrictions have been identified.

International

The chemicals are listed on the following (Galleria Chemica):

- EU Regulation No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products: Annex II - List of substances prohibited in cosmetic products;
- Association of Southeast Asian Nations (ASEAN) Cosmetic Directive: Annex II - List of prohibited substances;
- Chile list of substances which must not form part of the composition of cosmetic products;
- China list of banned substances for use in cosmetics; and
- New Zealand Cosmetic Products Group Standard: Schedule 4 - Components cosmetic products must not contain.

Existing Worker Health and Safety Controls

Hazard Classification

Sulfanilic acid (CAS No. 121-57-3) is classified as hazardous, with the following hazard categories and hazard statements for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

- Eye irritation – category 2: H319 (Causes serious eye irritation)
- Skin irritation – category 2: H315 (Causes skin irritation)
- Skin sensitisation – category 1: H317 (May cause an allergic skin reaction)

Exposure Standards

Australian

No specific exposure standards are available.

International

No specific exposure standards are available.

Health Hazard Information

Toxicokinetics

No data are available for the chemicals.

Sulfonated aromatic amines, like the assessed chemicals, are generally highly water-soluble. Absorption following oral or dermal exposure is limited for highly water-soluble chemicals (Rozman & Klaassen, 2001). Therefore, the chemicals are expected to be poorly absorbed and mainly rapidly excreted in urine and faeces.

Acute Toxicity

Oral

The chemicals have low acute toxicity based on results from the animal test using oral exposure to sulfanilic acid (CAS No. 121-57-3). The median lethal dose (LD50) in rats is >2000 mg/kg bw.

In the Organisation for Economic Co-operation and Development (OECD) test guideline (TG) 423 (Acute oral toxicity) study, female Sprague-Dawley (SD) rats (6/dose) were orally treated (gavage) with 300 or 2000 mg/kg bw of sulfanilic acid. No mortality or clinical signs of toxicity were reported (REACHa).

Dermal

The chemicals have low acute toxicity based on result from animal test following dermal exposure to sulfanilic acid (CAS No. 121-57-3). The LD50 in rats is >2000 mg/kg bw.

In an OECD TG 402 (Acute dermal toxicity) study, the dermal LD50 of the sulfanilic acid was determined to be > 2000 mg/kg bw. The chemical was applied onto the intact skin of 10 SD rats (5/sex) at the single dose of 2000 mg/kg bw. No mortality or clinical signs of toxicity were reported. Erythema, associated with dryness, was noted on the treatment site of two females on day 2 and of all females between day 3 and day 5 (REACHa).

Inhalation

No data are available.

Corrosion / Irritation

Skin Irritation

Sulfanilic acid (CAS No. 121-57-3) is classified as hazardous with hazard category ‘Skin irritation – category 2' and hazard statement ‘Causes skin irritation’ (H315) in the HCIS (Safe Work Australia). The publicly available information does not support this classification. However, due to limited data, the classification is not changed. The sodium salt of the chemical (sodium sulfanilate; CAS No. 515-74-2) does not have the acidity of sulfanilic acid, and the specific information for the sodium salt indicates lack of irritancy.

In an OECD TG 439 study (In vitro skin irritation: reconstructed human epidermis), three tissues of the human skin model EpiDerm were treated with 25 mg of the solid sulfanilic acid (neat) for 60 minutes. After the treatment with the chemical, the tissue viability relative to the negative control was 101.5 %. Chemicals reducing the viability below 50 % are classified as irritants. Therefore, the chemical was considered as non-irritant for the skin (REACHa).

In an OECD TG 404 acute skin irritation/corrosion study, three New Zealand White (NZW) rabbits received a single treatment of 0.5 g of sodium sulfanilate (neat) applied to the shaved skin. The exposure lasted 4 hours and the skin was evaluated at 1, 24,

48 and 72 hours and 7 days after the end of the exposure. The mean erythema and oedema scores were 0, indicating that the chemical is not irritating to the skin (REACHb).

Eye Irritation

Sulfanilic acid (CAS No 121-57-3) is classified as hazardous with hazard category ‘Eye irritation – category 2' and hazard statement ‘Causes serious eye irritation’ (H319) in the HCIS (Safe Work Australia). Available data supports this classification. The sodium salt of the chemical (sodium sulfanilate; CAS No. 515-74-2) does not have the acidity of sulfanilic acid and available data indicate that it is only slightly irritating.

In an OECD TG 405 eye irritation study, 3 NZW rabbits received 0.1 mL of sulfanilic acid (neat) placed into the conjunctival sac of one eye of each of three rabbits. The chemical was severely eye irritating with mean scores of 1, 2, and 2.33 for corneal opacity, and conjunctival chemosis and redness, respectively. All effects were fully reversible after 21 days (REACHa).

In an OECD TG 405 eye irritation study, 3 NZW rabbits received 0.1 mL of pulverised sodium sulfanilate (approximately 41 mg) placed into the conjunctival sac of one eye of each of three rabbits and the eyes were rinsed with saline at 24 hours after instillation. The mean scores for eye irritation were in range of 0–1 at 1, 24, 48 and 72 hours and the effects were fully reversible after 7 days (REACHb).

In an in vitro Hen’s Egg Test – Chorioallantoic Membrane (HET-CAM) study under GLP (Test method protocol recommended by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM)), sulfanilic acid (neat) showed potential to be severely irritating to the eye (REACHa).

Sensitisation

Skin Sensitisation

The sulfanilic acid (CAS No. 121-57-3) is classified as hazardous with hazard category ‘Skin sensitisation – category 1' and hazard statement ‘May cause an allergic skin reaction’ (H319) in the HCIS (Safe Work Australia). The publicly available information suggests that due to the very poor skin penetration (and metabolism) of the chemical(s), the sensitisation is expected only when the exposure occurs intradermally (Basketter & Kimber, 2010). While there is conflict between a clearly positive Magnusson and Kligman guinea pig maximisation test (GPMT) result and negative results in humans and from several local lymph node assays (LLNA), the classification is not changed and therefore, should also be applied for the sodium sulfanilate (CAS No. 515-74-2).

In vivo experimental data

A GPMT (comparable to OECD TG 406) result indicated that sulfanilic acid is a strong sensitiser using 0.5 % for intradermal induction, 5 % for topical induction and challenge at 80% (Basketter and Scholes, 1992). It is noted that the GPMT study protocol involves intradermal injection of the chemical.

The results of four LLNA (OECD TG 429) experiments conducted independently in two laboratories were all negative (Basketter et al., 1992; Basketter and Scholes, 1992). The ratio of [3H]thymidine incorporation by test nodes relative to control nodes (T/C ratio) in all experiments (test concentrations up to 25 %) varied between 1.1 to 2.2 with the criteria for sensitisation defined as ≥3.0.

The sulfanilic acid was negative in a guinea pig cumulative contact enhancement test (CCET) (Basketter et al., 1992).

In vitro and in chemico testing for skin sensitisation

The chemical has been included in test batteries to determine the suitability of alternative testing strategies to predict skin sensitising potential of chemicals (Takenouchi et al., 2015; Natsch et al., 2013; Zang et al., 2017; Hirota et al., 2015; Cottrez et al., 2016; OECD, 2016). The test results from h-CLAT, myeloid U937 skin sensitisation test, SENS-IS, KeratinoSens and DPRA assays are negative for skin sensitisation potential. These assays address the first three key events in the skin sensitisation

adverse outcome pathway (AOP) (OECD, 2012), protein binding (DPRA), keratinocyte activation (KeratinoSens), and dendritic cell activation (h-Clat/MUSST).

Observation in humans

The chemical has been manufactured at a factory site in France for over 20 years, with production levels exceeding 1000 tonnes per annum (as reported in 1992). There have been no skin sensitisation reports in the factory, despite no special containment measures being in place during that time to protect the workforce from skin contact with the chemical (Basketter and Scholes, 1992).

Repeated Dose Toxicity

Oral

Based on the limited data available (28-day study) for the sulfanilic acid, the repeated oral exposure to the chemicals are not considered to cause serious damage to health.

In an OECD TG 407 (Repeated dose 28-day oral toxicity in rodents) study, Wistar rats (5/sex/dose) were treated daily (oral gavage) with 0 (vehicle), 63, 250 or 1000 mg/kg bw/day of sulfanilic acid in water for 28 days. Only mild to moderate changes were reported in liver related clinical chemistry at the highest dose. Histomorphology of the liver was not changed by the chemical. The no observable adverse effect level (NOAEL) was considered to be 1000 mg/kg bw/day (REACHa).

Dermal

No data are available.

Inhalation

No data are available.

Genotoxicity

Sulfanilic acid was negative in all available in vitro genotoxicity tests, including gene mutation (Ames tests) in *Salmonella typhimurium* strains TA1535, TA 1537, TA1538, TA98, and TA100 at concentration levels of 5-5000 µg/plate with and without metabolic activation as well as in DNA damage/repair assays (SOS response and DNA strand breaks) in *Escherichia coli* (Environment & Health Canada, 2015).

No in vivo genotoxicity testing data have been identified for the chemicals. However, the vast majority of the sulfonated aromatic amino acids are negative for genotoxicity in a variety of in vitro and in vivo test systems (Jung et al, 1992).

Carcinogenicity

No data are available for the chemicals.

The food dye Sunset Yellow FCF (CAS No. 2783-94-0) that is broken down by intestinal azo-reductases into aromatic amines including sulfanilic acid, was not carcinogenic in various experimental studies (EFSA, 2009; IARC, 1975).

Reproductive and Developmental Toxicity

Limited data are available for the chemicals. However, based on the available data for the sulfanilic acid, the chemicals are not expected to be toxic for reproduction or development.

In an OECD TG 421 Reproduction / developmental toxicity screening test, Wistar rats (12/sex/dose) received a daily oral (gavage) dose of 0 (vehicle), 62.5, 250 and 1000 mg/kg bw/day of sulfanilic acid in water. Females were dosed 2 weeks prior to mating, during pregnancy and at least 4 days after delivery. Males were continuously treated for at least 3 weeks with dosing starting 2 weeks prior to mating. No clinical signs of toxicity or significant effects on body weight, reproductive organs, foetal development or reproductive parameters were reported (REACHa).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation for the chemicals include local irritating effects on skin and eyes (for the sulfanilic acid only; CAS No. 121-57-3) as well as uncertain likelihood of skin sensitisation.

Public Risk Characterisation

The chemicals could be used as intermediates in the manufacture of dyes and pigments (see **Import, Manufacture and Use** section) which may be used in tattoo inks and textile dyes, and it may then be regenerated by reductive cleavage of the azo dyes. Due to potential for skin sensitisation, sulfanilic acid was indicated as a potential aromatic amine cleavage product of concern from azo dyes (Bruschweiler et al., 2014). As such, further regulatory controls for public health may be determined as part of a Tier III assessment for ‘Azo dyes that cleave to aromatic amines of potential toxicological concern’.

Occupational Risk Characterisation

During product formulation, dermal and ocular exposure might occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical local health effects, the chemicals could pose an unreasonable risk to workers unless adequate control measures to minimise dermal and ocular 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 the appropriate controls.

NICNAS Recommendation

Assessment of these chemicals are 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.

The chemicals are recommended for a Tier III assessment as part of the assessment of 'Azo dyes that cleave to aromatic amines of potential toxicological concern' (NICNAS).

Regulatory Control

Public Health

The need for regulatory control for public health will be determined as part of the Tier III assessment.

Work Health and Safety

The chemicals are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. The irritation classifications do not apply for sodium sulfanilate (CAS No. 515-74-2); however, the skin sensitisation classification should be applied.

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]
Irritation / Corrosivity	Not Applicable	Causes serious eye irritation - Cat. 2A (H319)* Causes skin irritation - Cat. 2 (H315)*
Sensitisation	Not Applicable	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 chemicals should be used according to the instructions on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal and ocular exposure 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 that could minimise the risk include, but are not limited to:

- health monitoring for any worker who is at risk of exposure to the chemicals, 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 chemicals.

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 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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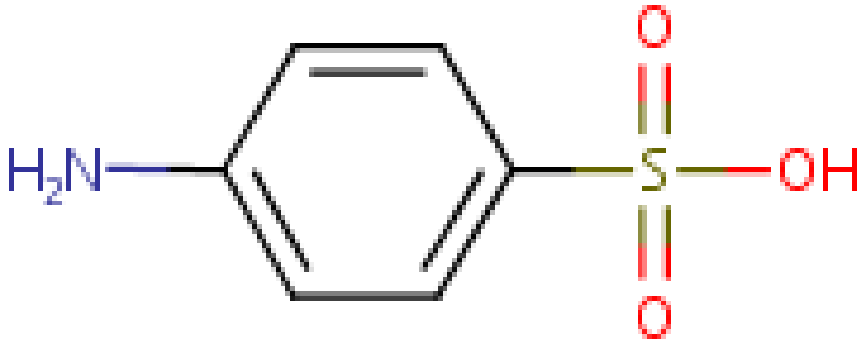
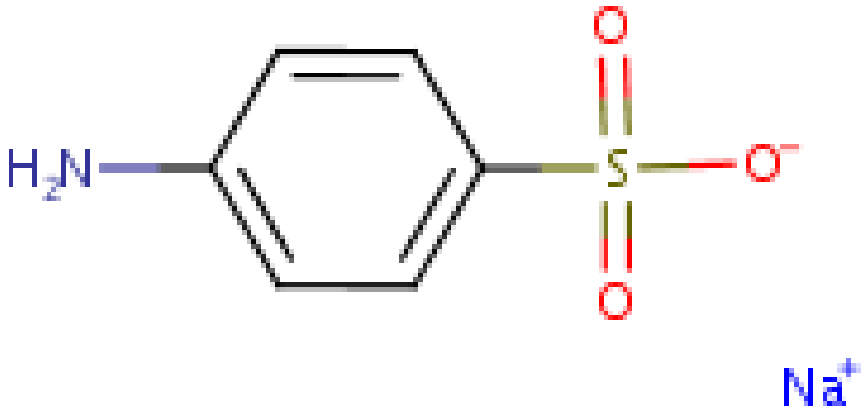
Last Update 27 October 2017

Chemical Identities

Chemical Name in the Inventory and Synonyms	**Benzenesulfonic acid, 4-amino-** sulfanilic acid aniline-4-sulfonic acid 4-aminobenzenesulfonic acid
CAS Number	121-57-3
Structural Formula	

	
Molecular Formula	C6H7NO3S
Molecular Weight	173.19

Chemical Name in the Inventory and Synonyms	**Benzenesulfonic acid, 4-amino-, monosodium salt** sodium 4-aminobenzenesulfonate sodium sulfanilate sulfanilic acid monosodium salt sodium aniline sulfonate
CAS Number	515-74-2
Structural Formula	

	
Molecular Formula	C6H7NO3S.Na
Molecular Weight	195.17

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