Arsenic: Human health tier II assessment

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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	Arsenic black Arsenicum album Grey arsenic Metallic arsenic
Structural Formula	
Molecular Formula	As
Molecular Weight (g/mol)	74.92
Appearance and Odour (where available)	This odourless chemical exists in three allotropic forms, metallic grey, yellow and black. Gives a garlic odour when heated in air.

SMILES	[As]

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported by the National Pollutants Inventory (NPI) and under previous mandatory and/or voluntary calls for information.

The chemical has reported commercial use including:

- as an impregnation and oxidising agent; and
- to harden copper, lead and other alloys.

The chemical has reported site-limited use including:

- as a laboratory reagent.

The chemical has non-industrial uses including:

- in wood preservatives and pesticides.

International

The following international uses have been identified through the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported domestic use including in:

- automotive lubricants and oils.

The chemical has reported commercial use including in:

- automotive products; and
- concrete mixes.

The chemical has reported site-limited use including:

- in alloy and semiconductor production;
- as a catalyst in the manufacture and extraction of metals; and
- in glass manufacturing.

The chemical has non-industrial uses including:

- in wood preservatives and pesticides.

Restrictions

Australian

The chemical, belonging to the group entry 'arsenic', is listed in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons—SUSMP) in Schedule 7 with the following entry:

ARSENIC **except**:

(a) when separately specified in this Schedule;

(b) when included in Schedule 4 or 6;

(c) as selenium arsenide in photocopier drums;

(d) as 10,10'-oxydiphenoxarsine in silicone rubber mastic containing 120 mg/kg or less of arsenic;

(e) as 10,10'-oxydiphenoxarsine contained in polyvinyl chloride and polyurethane extruded and moulded articles containing 160 mg/kg or less of arsenic other than when included in articles:

(i) in contact with food stuffs, animal feeds or potable water;

(ii) of clothing and footwear in contact with the skin;

(iii) used as infant wear; or

(iv) intended for use as packaging materials;

(f) in animal feeds containing 75 g/tonne or less of arsenic; or

(g) in paints containing 0.1 % or less of arsenic calculated on the non-volatile content of the paint.'

Schedule 7 chemicals are labelled with 'Dangerous Poison'. These are substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.

"Arsenic and its compounds " are restricted hazardous chemicals under Schedule 10 (Prohibited carcinogens, restricted carcinogens and restricted hazardous chemicals) of the Work Health and Safety (WHS) regulations (WHS, 2011). Specifically, use is restricted in:

- abrasive blasting at a concentration of greater than 0.1 % as arsenic; and
- for spray painting.

International

International restrictions include:

- European Union (EU) Cosmetic Directive 76/768/EEC Annex II: List of substances which must not form part of the composition of cosmetic products.
- Health Canada List of prohibited and restricted cosmetic ingredients (The Cosmetic Ingredient "Hotlist")
- 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):

T; R23/25 (Acute toxicity).

Exposure Standards

Australian

The chemical has an exposure standard of 0.05 mg/m³ time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica):

An exposure limit (TWA) of 0.01–0.5 mg/m³ in different countries such as the USA (Alaska, Hawaii), Canada (Yukon), Norway and Switzerland.

Health Hazard Information

Arsenic exists in three allotropic forms.

Grey arsenic (alpha-crystalline), is the most common and stable form of elemental arsenic.

Yellow and black arsenic are not reported to occur naturally, but can be prepared by cooling grey arsenic vapours.

Yellow arsenic is not stable and reverts to grey arsenic at room temperature; black arsenic is brittle and does not conduct electricity.

Elemental arsenic is found in nature, as ores (arsenopyrite FeAsS), as orpiment (As2S3) and realgar silver deposits (As4S4) (Jolliffe, 1993). As grey arsenic is the most stable form of elemental arsenic at room temperature, it is used in industry for lead alloy, semiconductor device and optoelectric compound (such as gallium arsenide) manufacturing (HSDB).

Toxicological studies of elemental arsenic have estimated an oral LD50 value of 145 mg/kg in mice and 763 mg/kg in rats. Human exposure to elemental arsenic is considered rare—except through occupational or laboratory exposure (Jolliffe, 1993). Acute toxic effects are likely to occur when grey arsenic is heated (during alloy strengthening) when elemental arsenic oxidises to arsenic trioxide, and the very toxic arsine gas (NICNASa) is released, which has a distinct garlic odour. Further exposure to arsenic is likely to occur through its various oxidation states.

If absorbed, elemental arsenic will transform into the pentavalent (+5 or arsenate) or trivalent (+3 or arsenite) form (Roy & Saha; Jomova et al, 2011). Therefore, human exposure to arsenic is likely to occur through either the pentavalaent or trivalent forms, which have the same long-term systemic effects. The relevant arsenate and arsenite compounds have been assessed separately by NICNAS as arsenic pentoxide and arsenic acid (NICNASb), and trivalent arsenites (NICNASc).

In the absence of toxicological data on arsenic, it is expected that the chemical will have a similar hazard profile to both arsenates and arsenites as these forms can readily interconvert, except for local toxicity such as corrosivity (given the low solubility). Both arsenates and arsenites are acutely toxic through oral and inhalation exposure. Arsenic is currently classified as hazardous with the risk phrase ‘Toxic by inhalation’ (T; R23) and ‘Toxic if swallowed’ (T; R25) in HSIS (Safe Work Australia).

Arsenates and arsenites are also carcinogenic, genotoxic and may cause damage to organs through prolonged or repeated exposure (refer NICNASb and NICNASc for further details). Therefore, the available data on arsenates and arsenites support an amendment to the classification of arsenic (refer to **Recommendation** section).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity and genotoxicity) and systemic acute effects (acute toxicity by the oral and inhalation routes of exposure). The chemical also cause harmful effects following repeated exposure.

Public Risk Characterisation

In Australia, the chemical has commercial and non-industrial uses.

Given the uses identified for the chemical, it is unlikely that the public will be exposed. Hence, the public risk from this chemical is not considered to be unreasonable.

The chemical is currently listed on Schedule 7 of the SUSMP. Schedule 7 chemicals are not available for general public use. The current controls are considered adequate to minimise the risk to public health.

Occupational Risk Characterisation

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

Given the critical systemic long-term and acute health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise ocular 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.

The data available support an amendment to the hazard classification in HSIS (refer to **Recommendation section**).

NICNAS Recommendation

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

Regulatory Control

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical hazards and environmental hazards.

The classification proposed below is based on read across data. It should be used as a default for this chemical. If empirical data become available indicating that a lower (or higher) classification is appropriate for the chemical, this may be used to amend the default classification for the chemical.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Toxic if swallowed (T; R25)* Toxic by inhalation (T; R23)*	Toxic if swallowed - Cat. 3 (H301) Toxic if inhaled - Cat. 3 (H331)
Repeat Dose Toxicity	Danger of serious damage to health by prolonged exposure (Xn; R48)	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 1 - May cause cancer (T; R45)	May cause cancer - Cat. 1A (H350)

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

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

* Existing Hazard Classification. No change recommended to this classification

Advice for industry

Control measures

Control measures to minimise the risk from 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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