

Microcrystalline Silica: Human health tier II assessment

08 March 2019

CAS Number: 1317-95-9



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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

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Acronyms & Abbreviations

Chemical Identity

Synonyms	tripoli crystalline silica randanite
Structural Formula	No Structural Diagram Available
Molecular Formula	Unspecified
Molecular Weight (g/mol)	Unspecified

Import, Manufacture and Use

Australian

The chemical has reported non-industrial use as a rubbing compound in marine applications.

International

The following international uses have been identified through Galleria Chemica.

The chemical has reported domestic use as a filler for paint, rubber and plastic.

The chemical has reported commercial uses as:

- an abrasive agent in abrasive blasting; and
- a buffing compound (usually a component of a waxy matrix) for silver, copper, aluminium and zinc.

Restrictions

Australian

Free silica (crystalline silicon dioxide) is listed in Schedule 10 (Prohibited carcinogens, restricted carcinogens and restricted hazardous chemicals) of the Work Health and Safety Regulations (WHS, 2011) for restricted use in abrasive blasting at a concentration greater than 1%.

International

No known restrictions have been identified.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is not listed on the Hazardous Chemical Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available. The chemical is listed with 'no interim value' assigned on the HCIS (Safe Work Australia).

International

The following exposure standards are identified (Galleria Chemica).

An occupational exposure limit (OEL) of 0.1 mg/m³ time weighted average (TWA) in different countries such as the USA (Hawaii and Tennessee), Canada (Ontario, Quebec and Saskatchewan), Mexico, South Africa and Spain.

Health Hazard Information

No specific toxicity data are available for the chemical.

The chemical is a form of silica with an undefined degree of crystallinity in its lattice. The presence of crystalline domains in the lattice of this chemical makes it analogous to chemicals in the group 'Crystalline silica' (NICNAS) and so the health hazard information for these chemicals (i.e. silica, CAS No. 7631-86-9; cristobalite, CAS No. 14464-46-1; quartz, CAS No. 14808-60-7; and fumes, silica, CAS No. 69012-64-2) is relevant.

The chemicals in the 'Crystalline silica' group are recommended for classification as hazardous through repeated dose inhalation toxicity and carcinogenicity arising from inhalation of the respirable fraction of silica. The available data supported these recommendations, including evidence of toxicity through epidemiological studies in human workers who have suffered from silicosis. Since silica is generally recognised as safe (GRAS) for food use (FDA), acute toxicity, repeated dose toxicity, irritation and sensitisation from oral and dermal exposure were not considered relevant for risk assessment. These data and recommendations are considered relevant to microcrystalline silica (see **Recommendation** section).

The Tier II assessment report for the group 'Crystalline silica' is available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1120. The report should be read in conjunction with this Tier II assessment.

Risk Characterisation

Critical Health Effects

Based on information for the analogous group of chemicals—Crystalline silica (NICNAS), the critical health effects for risk characterisation of microcrystalline silica are local long-term effects (carcinogenicity) and toxic effects following repeated exposure through inhalation (silicosis).

Public Risk Characterisation

The public may be exposed to the chemical through potential domestic uses (as a filler). Inhalation is the major route of concern under circumstances of long-term high level exposure to crystalline forms of silica, including this chemical. Reported international domestic uses are not likely to be as dusty formulations and, so not expected to be a risk to the public. Therefore this chemical is not considered to pose an unreasonable risk to public health and further risk management is not considered necessary for public safety.

Occupational Risk Characterisation

Given the critical local long-term health effects, the chemical may pose an unreasonable risk to workers unless adequate control measures to minimise 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 *Guidance on the Interpretation of workplace exposure standards for airborne contaminants* advises that 'exposure to carcinogens should be eliminated or minimised so far as is reasonably practicable' (Safe Work Australia, 2013).

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

Internationally, the Scientific Committee on Occupational Exposure Limits' (SCOEL) assessment of crystalline silica concludes that there is sufficient evidence from epidemiological studies to indicate that silicosis, the main effect in humans after occupational inhalation of respirable silica dust, is associated with the development of lung cancer. Therefore, preventing the onset of silicosis is likely to reduce the risk of lung cancer (SCOEL, 2003). According to the SCOEL assessment of crystalline silica, a dose-response curve for silicosis indicates that maintaining the respirable exposure below 0.05 mg/m^3 would reduce the prevalence of silicosis in exposed individuals. Therefore, the SCOEL committee has recommended that the OEL is below 0.05 mg/m^3 of respirable silica dust (SCOEL, 2003). Recently, the United States Department of Labour Occupational Safety and Health Administration (OSHA) issued a final rule to reduce toxicity related to exposure to respirable crystalline silica by reducing the permissible exposure limit to $50 \text{ }\mu\text{g/m}^3$ (i.e. 0.05 mg/m^3) of air, averaged over an eight hour shift (OSHA, 2016).

Based on the available epidemiological data for the analogous group, Crystalline silica (NICNAS), there is a concern that the current occupational exposure standard for these chemicals (0.1 mg/m^3) in the HCIS may not be sufficiently protective to

workers' health.

NICNAS Recommendation

It is recommended that Safe Work Australia consider whether current controls adequately minimise the exposure risks to workers. The chemical should be included in any Tier III assessment of crystalline silica considered necessary to provide further information about whether the current exposure controls offer adequate protection to workers.

All other risks are considered to have been assessed sufficiently at the Tier II level, 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 aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below. This does not consider classification of physical hazards and environmental hazards.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Repeat Dose Toxicity	Not Applicable	Causes damage to lungs through prolonged or repeated exposure through inhalation - Cat. 1 (H372)
Carcinogenicity	Not Applicable	May cause cancer - Cat. 1A (H350i)

^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 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 that could 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 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 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 08 March 2019

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