Kyanite (Al2O(SiO4)): 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.

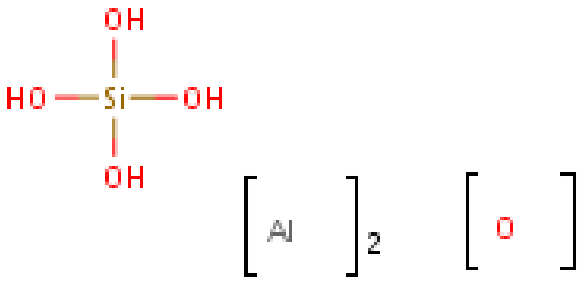
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	refractory ceramic fibres (RCF) aluminium silicate Disthene Kaopolite Valfor
Structural Formula	
Molecular Formula	Al.O4Si.O
Molecular Weight (g/mol)	166.0
Appearance and Odour (where available)	blue, white, rarely reen, grey, yellow, pink, orange and black, can be zoned
SMILES	O.[Al].[Al].O[Si](O)(O)O

Import, Manufacture and Use

Australian

Kyanite is one of the mineral phases found in refractory ceramic fibres (RCFs).

The following Australian industrial uses for RCFs were reported under Safe Work Australia (SWA, 2013) as being commercial uses including in:

- thermal insulation applications such as in the form of bulk fibres, blankets, papers, boards, plug cones, ropes and tapes;
- adsorbent for the removal of heavy metals from electroplating wastewater; and
- lining furnaces, kilns and other industrial heaters.

The SWA has reported site-limited uses in:

- ceramics;
- backup insulation in melting and holding furnaces in ingot moulding; and
- sealing and packing joints in molten metal transfer troughs and pit covers in furnaces.

The SWA's Guide to Handling RCFs (2013) has reported site-limited uses as an insulation medium and thermal barrier in the automotive, marine, petrochemical, steel, aluminium, ceramic, glass and construction industries.

International

The following international uses have been identified through Galleria Chemica; the Substances and Preparations in Nordic countries (SPIN) database; the OECD High Production Volume chemical program (OECD HPV); the US Environmental Protection Agency's Aggregated Computer Toxicology Resource (ACToR); the US National Library of Medicine's Hazardous Substances Data Bank (HSDB); and Government of Canada, Priority Substances List Assessment Report on Mineral Fibres (CAESAR, 1993).

RCFs have reported commercial uses, including as an:

- thermal insulating material in the form of bulk fibres, blankets, papers, boards, plug cones, ropes and tapes; and
- adsorbent for the removal of heavy metals from electroplating wastewater.

RCFs have reported site-limited uses in:

- ceramics;
- backup insulation in melting and holding furnaces in ingot moulding; and
- sealing and packing joints in molten metal transfer troughs and pit covers in furnaces.

Bulk kyanite is also a semi-precious gemstone.

Restrictions

Australian

No known restrictions have been identified.

International

The chemical is listed on the candidate list of Substances of Very High Concern (SVHC) for eventual inclusion in Annex XIV (ECHA, 2016). In the European Union (EU), companies could have legal obligations if the chemical that they produce, supply, or use is included on the candidate list whether on its own, in mixtures, or present in articles. 'In 2009, an Annex XV Dossier was submitted and accepted, to identify aluminosilicate refractory ceramic fibres (RCFs) as SVHC' (ECHA, 2011).

Existing Work Health and Safety Controls

Hazard Classification

The chemical and other refractory ceramic fibres are classified as hazardous, with the following hazard category and hazard statement for human health in the Hazardous Chemical Information System (HCIS) (Safe Work Australia):

Carcinogenicity—category 1B; H350 (May cause cancer)

Exposure Standards

Australian

The chemical and other RCFs have exposure standard of 2 mg/m^3 (inhalable dust) (0.5 fibre per mL (f/mL) respirable) time weighted average (TWA).

International

The following exposure standards are identified (Galleria Chemica).

An exposure limit of 0.5 fibre per cubic centimetre (f/cm^3) time weighted average (TWA) and 3-6 mg/m^3 short-term exposure limit (STEL) in different countries such as the United States of America (USA) (Washington, Vermont), Canada and Columbia.

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a threshold limit value (TLV) of 0.2 f/cm^3 time weighted average (TWA).

Health Hazard Information

The chemical, kyanite is a member of the aluminosilicate family, is a natural occurring mineral that has the formula (Al_2O (SiO_4)) and is mainly found in the metamorphic rocks. The chemical's most identifiable feature is its anisotropism (ability to cleave perfectly in two directions with two distinctly different hardnesses on the perpendicular axes). The chemical can form aluminosilicate fibres and these are mainly used in the manufacture of high-alumina refractory materials, known as refractory ceramic fibres (RCFs) (Espenshade and Potter, 1960). Therefore, for the purpose of this assessment, the chemical will be considered as an example of an RCF.

The RCFs are a group of different types of amorphous or crystalline mineral fibres with 1.2–3.5 μm as the nominal fibre diameter. Their toxicity is driven by their fibrous nature—their fibre size, shape and biopersistance (Harrison et al, 2015; WHO, 2000). Due to the fibre characteristics and insolubility of these RCFs, the most relevant toxic effects occur via the inhalation route. Available data mainly consists of inhalation, intraperitoneal or intrapleural studies. The EU Scientific Committee on Occupational Exposure limits (SCOEL, 2011) and ATSDR 2004, provided various human epidemiological studies and noted that

for humans, fibres >3μm in diameter are non-respirable and those with 1μm diameter and 8μm length have greatest pulmonary deposition. Fibres with the smaller length than the diameter of macrophages are readily phagocytised and removed/or transported to local lymph nodes. Longer fibres in the alveolar region are cleared more slowly depending on their biopersistance. The thin fibres (<0.1μm) are durable to penetrate the epithelial surface of the alveoli and are translocated to the lung parenchyma and pleural space. Fibres greater than 5μm may get trapped and cause inflammation. The mucociliary system removes any inhaled fibres that are deposited high up in the respiratory tract (ATSDR, 2004; Harrison et al, 2015). Various epidemiological studies have shown that occupational exposure to RCFs in workers led to increased risk for non-malignant respiratory disease, including decreased pulmonary function, high incidence of pleural plaques and increased pleuritic chest pain (IARC, 2000; WHO, 2000).

The International Agency for Research on Cancer (IARC), the World Health Organisation and the Agency for Toxic Substances and Disease Registry (ATSDR) and SWA, provided scientific reports on RCFs and cancer risk (SWA, 2013; WHO, 2000; IARC, 2002; ATSDR, 2004) based on animal studies and occupational exposure studies. It was reported that there is a critical relationship between fibre dimension and disease. Pulmonary diseases were caused mainly by inhaled fibres with 0.1μm thickness and 20μm or more length and pleural diseases were caused by thinner fibres (~0.1μm) and length of ~5μm (Harrison et al, 2015; Glass et al, 1995).

The RCFs are classified by the IARC as a Group 2B carcinogen (Possibly carcinogenic to humans) (IARC, 2002). The European Commission (EC) has identified RCFs as carcinogens (Carc. 1B) in Annex VI, Part 3 (ECHA, 2011). This classification is based on carcinogenicity and possible genotoxicity in mechanistic studies. Animal studies have shown that significant pulmonary fibrosis, lung tumours and mesothelioma were reported by exposing the experimental animals to RCFs by injection, implantation and inhalation.

Results from various inhalation studies in rodents and hamsters indicated that RCFs' exposure in rats significantly increased the incidence of lung cancer and similar exposures resulted in mesothelioma in hamsters. The IARC has stated that there is sufficient evidence of carcinogenicity in experimental animals. The IARC (2002) also concluded that 'inflammation is the predominant manifestation of fibre toxicity and triggers other effects such as release of reactive oxygen species from inflammatory cells leading to DNA damage'. Since it is well established that chronic inflammation contributes to cancer development, it can be concluded that inflammation is the relevant mechanism for carcinogenicity.

Intrapleural and intraperitoneal studies have been used to investigate the potency of the RCFs and other man-made fibres to induce tumours in rats and hamsters. These studies should be considered as mechanistic studies to demonstrate the capacity if the fibres in vivo to cause mesothelioma and other tumours. The RCFs that are long (>3μm) and biopersistent are shown to interact with target cells in the lungs or to be translocated to the interstitium or the pleura, causing disease. A consistent relationship between persistent inflammation, fibrosis and tumour development or mesothelioma in animals models has been established. The relevance of these studies to humans is limited because of lack of clearance mechanisms mediated by pulmonary macrophages. Although pleural thickening and plaques have been associated with impaired respiratory functions in workers in the manufacture of RCFs, localised pleural plaques were not mechanistically linked to increased risks of lung fibrosis, lung cancer or mesothelioma (ATSDR, 2004). No adequate genotoxicity data were available for RCFs; however, there is some evidence that they may have a direct effect on generation of reactive oxygen species (ROS) resulting in oxidised DNA bases and strand breaks, leading to gene mutations and other *in vitro* cytogenetic activities (ATSDR, 2004; IARC, 2002).

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity).

Public Risk Characterisation

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

Occupational Risk Characterisation

During product formulation, inhalation exposure may occur, particularly where manual or open processes are used. These could include activities such as installing or removing insulation, in manufacturing facilities, in demolition work, quality control analysis, and cleaning and maintaining equipment. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic long-term health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise inhalation 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.

An exposure standard has been established by SWA for when the chemical is used as RCFs–2 mg/m^3 (inhalable dust) (0.5 fibre per mL (f/mL) respirable) TWA and a guide to handling RCFs is available to industry. This guide provides information for PCBUs on how to manage health and safety risks associated with using and removing materials containing refractory ceramic fibres (RCFs) and other high biopersistance fibres (HBF) (Safe Work Australia, 2013).

Based on the available data, the hazard classification in the HCIS (Safe Work Australia) 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. No further assessment is required.

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]
Carcinogenicity	Not Applicable*	May cause cancer - Cat. 1B (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 inhalation 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:

- using closed systems or isolating operations;
- using local exhaust ventilation to prevent the chemicals from entering the breathing zone of any worker;
- 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;
- 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 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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