SILICA, CRYSTALLINE (RESPIRABLE DUST)

CAS number: Cristobalite 14464-46-1
Quartz 14808-60-7
Tridymite 15468-32-3
Tripoli 1317-95-9

Synonyms: α quartz, crystallized silicon dioxide, silica, calcined diatomaceous earth

Chemical formula: SiO_2 (monomer) or $(SiO_2)n$

Structural formula:

(monomer)

Workplace exposure standard (amended)

TWA: **0.02 mg/m³**

STEL: –

Peak limitation: –

Notations: **Carc 1A**

IDLH: –

Sampling and analysis: as per AS2985:2009 *Workplace atmospheres – Method for sampling and gravimetric determination of respirable dust*. Analysis can be undertaken using either Fourier Transform Infra-Red (FTIR) spectroscopy or X-ray Diffraction (XRD). Limits of quantitation (LOQ):

Amount on Filter (µg/Filter)	Flowrate (L/min)	Air Volume Full Shift 8 hr (L)	Air Concentration (mg/m³)
10	2.0	960	0.010
20	2.0	960	0.021

Recommendation and basis for workplace exposure standard

A TWA of 0.02 mg/m³ is recommended to protect for fibrosis and silicosis, and consequently minimise the risk of lung cancer, in workers exposed to respirable crystalline silica at the workplace.

Discussion and conclusions

All data sources indicate that chronic exposures above 0.02 mg/m³ are associated with radiographic changes in the lungs. These target organ effects, as described in epidemiological studies, are supported by animal studies in the dog and rat.

There is no clearly defined NOAEC (no observed adverse effect concentration) in humans. However, 0.025 mg/m³ has been noted to be protective of effects in the lungs (ACGIH, 2010). Another data source suggests that this concentration is the LOAEC (lowest observed adverse effect concentration; DFG, 2000), and multiple data sources clearly identify adverse effects in the lungs at 0.05 mg/m³. Uncertainties about exposure information is noted when interpreting the epidemiological studies

available. However, the effects and exposure descriptions are broadly consistent. Consequently, a TWA of 0.02 mg/m^3 is recommended to protect for fibrosis and silicosis, and the risk of lung cancer.

There is limited information available about exposure to respirable crystalline silica and adverse effects on the kidney, the development of connective tissue and autoimmune disease. It does not appear that these are critical effects, rather, these appear to be effects that are seen with higher incidence in those diagnosed with silicosis.

The mechanism for the development of lung cancer due to exposure to respirable crystalline silica is not well defined. However, there is consistent evidence in human studies to indicate an increased risk of lung cancer in those chronically exposed to respirable crystalline silica at the workplace at concentrations above 0.065 mg/m^3.

The evolution of the manufacture and use of crystalline silica is noted. New composites contain comparatively more crystalline silica per unit weight than monolithic stone (e.g. granite, marble). The use of power tools on products consisting of crystalline silica combined with bonding composites results in the generation of fine particulates with more complex considerations than those generated from conventional monolithic stone. There is very limited epidemiology on these composite products, and their toxicology is unknown at this time. Therefore, it is recommended that the data pertaining to silica containing products be examined as priority at the next scheduled review.

Recommendation for notations

Data sources indicate that respirable crystalline silica is carcinogenic, with lung cancer appearing to be a secondary effect of lung fibrosis and silicosis. There are insufficient data to indicate sensitisation of the skin or respiratory tract. A skin notation is not warranted as there is no indication that respirable crystalline silica is absorbed through or reacts with the skin.

APPENDIX

Primary sources with reports

Source	Year set	Standard
SWA		***TWA 0.1 mg/m^3***
Adopted from ACGIH.		
ACGIH	***2010***	***TWA 0.025 mg/m^3 (respirable particulate matter)***

Summary of recommendation:
• ACGIH proposed a TWA of 0.1 mg/m^3 in 1983 and published a reduced TWA of 0.025 mg/m^3 (respirable particulate matter) in 2010.
• Basis of revised TLV-TWA is to protect for pulmonary fibrosis and lung cancer.
• Epidemiological studies show that 0.05 mg/m^3 is associated with pulmonary radiographic changes.
• Increased mortality risk (lung cancer) is observed in workers exposed to levels > 0.065 mg/m^3.
• Increased risk of silicosis is observed in retirees exposed to 0.06 mg/m^3 (average).
• The report notes:
  ○ concerns surrounding fibrosis and inflammatory response and development of lung cancer, and
  ○ uncertainties in epidemiological studies around measurement of past exposure and detection (and diagnosis) of silicosis.
• While animal studies appear to show that cristobalite has an increased fibrogenic response, human studies suggest that exposure-response risks are similar.
• The A2 suspected human carcinogen designation is based on epidemiological evidence of increased risk of lung cancer.
• There is insufficient data to assign a skin or sensitiser notation.		

DFG	***2000***	***Not assigned***
MAK value not assigned due to carcinogenicity effects. Summary of discussion: • Genotoxicity considered to be negative, with limited effects seen *in vitro*. • Evidence suggests that relative lung cancer risk increases with increasing cumulative exposure to respirable quartz dust; however, it is unclear at which exposure level the risk is increased. • Epidemiological studies indicate the prevalence of lung cancer is increased in workers with silicosis. • There is uncertainty in interpreting the epidemiology studies outcomes including the criteria for the diagnosis of silicosis and the exposure measurements or estimates. These factors confound the calculations of silica concentrations at which the cumulative risk of silicosis is reduced. • NOAEL was determined to be below 0.02 mg/m^3 and the LOAEL between 0.02 mg/m^3 and 0.025 mg/m^3. • Concentrations of 0.05 mg/m^3 are associated with a risk of 5-10 % for silicosis. • Studies show a relationship between quartz exposure and disorders of renal function.		
SCOEL	***2003***	***< 0.05 mg/m^3***
Summary of recommendation:		

Source	Year set	Standard
• Exposure limit should protect for silicosis, which will contribute to reducing the risk of lung cancer. • NOAEL lies below 0.020 mg/m^3; a 15-yr exposure at this concentration resulting in a 0.25 % chance of developing silicosis 15-yr post exposure. • No clear threshold for silicosis can be identified. • Epidemiological evidence indicates that a concentration of 0.05 mg/m^3 may result in a 5-10 % silicosis risk and a 1 % risk of death from silicosis in mortality studies. • Exposure-response relationship for silicosis appears sigmoidal, and that for cancer appears linear. • No STEL or skin notation is warranted.		
OARS/AIHA	**—**	**—**
No report.		
HCOTN	***2003***	***TWA 0.075 mg/m^3***
Report not available.		

Secondary source reports relied upon

Source		Year	Additional information
HSE	✓	2002	TWA 0.1 mg/m^3 based on predicted exposure-response relationship and the development of silicosis.
AIOH	✓	2009 2018	TWA 0.1 mg/m^3 with an action level of 0.05 mg/m^3. Position paper (2018) notes that NOAEL appears to be very low. The TWA is recommended with the caveat that all exposure is limited to as low as reasonably practicable below this limit. Additional studies reviewed by the AIOH in 2018 note that: • a tipping point may exist for the risk of lung pathologies and 0.1 mg/m^3 is probably below the threshold for lung diseases • a threshold of 0.25 mg/m^3 for silicosis incidence was identified, and • an estimated excess lifetime risk of 0.51 % at 0.1 mg/m^3 was derived by analysis of the exposure-response relationship between silica exposure and lung cancer in an epidemiology study in a cohort of 34,018 workers in China.
NICNAS	✓	2018	Long-term occupational dermal exposure reported to be associated with connective tissue diseases and a possibility of progressive systemic scleroderma. Epidemiology studies indicated that lung cancer tended to increase with: • cumulative exposure • duration of exposure • peak intensity of exposure, and • presence of silicosis
US EPA	✓	1996	Report is for the purpose of informing health risk and regulatory conclusions about the extent and significance of public exposure to crystalline (and amorphous) silica.

Source		Year	Additional information
			No NOAEL were identified in animal studies. However, the animal data available qualitatively supports silicosis as the critical effect in humans. Dose response data for healthy workers in a mining environment indicates a cumulative silicosis risk of zero for cumulative exposures less than 1 mg/m^3 × yr (equivalent to 0.015 mg/m^3 for 40 yr). However, these estimates assume continuous exposure and a linear dose-response relationship. Using workplace data for continuous, ambient, lifetime exposure, a limit of 0.05 mg/m^3 (PM_{10} fraction) should be protective against silicotic effects. Diagnostic differences, exposure measurement estimations and lack of follow-up studies were noted as uncertainties when interpreting the data available.
US NIOSH	✓	1994	Notes that the approach to setting a REL for crystalline silica is consistent with policy for potential occupational carcinogens and takes into account feasibility of implementing engineering controls and limitations of measurement techniques. The REL 0.05 mg/m^3 is based on current measurement capabilities and reported to be associated with a prevalence of 1-7 % silicosis cases in workers estimated to be exposed to concentrations of 0.025 mg/m^3 in epidemiology studies.

Carcinogenicity — non-threshold based genotoxic carcinogens

Crystalline silica is not a non-threshold based genotoxic carcinogen.

Notations

Source	Notations
SWA	—
HCIS	Carcinogenicity – category 1A
NICNAS	Carcinogenicity – category 1A
EU Annex	—
ECHA	—
ACGIH	Carcinogenicity – A2
DFG	Carcinogenicity – 1
SCOEL	—
HCOTN	—
IARC	Carcinogenicity – Group 1
US NIOSH	SK:SYS

Immediately dangerous to life and health (IDLH)

Is there a suitable IDLH value available? Yes

IDLHs of 25 mg/m^3 for cristobalite and tridymite and 50 mg/m^3 for quartz and tripoli are assigned based on a multiple of 500 times the OSHA permissible exposure limits.

As these are not considered to be health based limits that are foreseen to impede escape or cause irreversible health effects within 30 minutes, an IDLH notation is not recommended.

Additional information

Molecular weight:	60.1 (monomer)
This chemical is a by-product of a process:	✓

Workplace exposure standard history

Year	Standard
Click here to enter year	

References

American Conference of Industrial Hygienists (ACGIH®) (2018) TLVs® and BEIs® with 7th Edition Documentation, CD-ROM, Single User Version. Copyright 2018. Reprinted with permission. See the *TLVs® and BEIs® Guidelines section* on the ACGIH website.

Australian Institute of Occupational Hygienists (AIOH) (2009) Respirable crystalline silica and occupational health issues.

Australian Institute of Occupational Hygienists (AIOH) (2018) Position paper respirable crystalline silica.

Deutsche Forschungsgemeinschaft (DFG) (2000) Silica, crystalline: quartz dust, cristobalite dust and tridymite dust (respirable fraction) [MAK value documentation, 2000].

EU Scientific Committee on Occupational Exposure Limits (SCOEL) (2003) Recommendation from the scientific committee on occupational exposure limits for silica, crystalline (respirable dust). SCOEL/SUM/94.

Health Council of the Netherlands (HCOTN) (2003) Committee on updating occupational exposure limits. Slate dust; health-based reassessment of administrative occupational exposure limits. The Hague: Health Council of the Netherlands, 2003, 200/15OSH/089.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2016). Crystalline silica: Human health tier II assessment – IMAP report.

Safe Work Australia (SWA) (2018a). Hazardous Chemical Information System.

Safe Work Australia (SWA) (2018b). Workplace exposure standards for airborne contaminants.

UK Health and Safety Executive (HSE) (2002) Silica, respirable crystalline – EH64: Summary criteria for occupational exposure limits.

US Environmental Protection Agency (US EPA) (1996) Health effects of inhaled crystalline and amorphous silica.

US National Institute for Occupational Safety and Health (NIOSH) (1974) Criteria for a recommended standard: Occupational exposure to crystalline silica.

US National Institute for Occupational Safety and Health (NIOSH) (1994) Immediately dangerous to life or health concentrations – Silica, crystalline (as respirable dust).