

Chemical Name: Silica, Crystalline (respirable PM₄)

CAS: 7631-86-9

Synonyms: silicon dioxide, quartz, cristobalite, tridymite

Non-Cancer Health Based Value (HBV_{acute}) = Not Derived

Non-Cancer Health Based Value (HBV_{subchronic}) = Not Derived

Chronic Health Based Value (HBV_{chronic}) = 3 µg/m³

$$\begin{aligned}
 &= \frac{[\text{Point of Departure (Adjusted BMCL}_{01})] \times [\text{Factor to convert mg to } \mu\text{g}]}{[\text{Uncertainty Factors}]} \\
 &= \frac{0.0098 \text{ mg/m}^3 \times 1,000}{3} \\
 &= 3.27 \text{ rounded to } \mathbf{3 \mu\text{g/m}^3}
 \end{aligned}$$

Source of Toxicity Value:	OEHHA, 2012; Collins et al., 2005
Critical Study:	Hnizdo and Sluis-Cremer, 1993 (Epidemiological study of exposed miners)
Study population:	2235 white South African gold miners
Exposure method:	Workplace inhalation
Exposure continuity:	8 hours/day, 5 days/week, 270 daily shifts per year
Exposure duration:	Average of 24 years of dust exposure (range 10-39 years)
LOAEL:	3 mg/m ³ -years cumulative respirable dust exposure
NOAEL:	2 mg/m ³ -years cumulative respirable dust exposure
BMCL ₀₁ :	2.12 mg/m ³ -years cumulative respirable dust exposure
Silica-Corrected	
BMCL ₀₁ *:	0.636 mg/m ³ -years cumulative respirable silica exposure
Adjusted BMCL ₀₁ **:	0.0098 mg/m ³ (equivalent to 9.8 µg/m ³)
Total Uncertainty/Adjustment:	3***
UF/AF Allocation:	An uncertainty factor of 3
Critical Effect(s):	Silicosis
Additivity Endpoints:	Respiratory

* The study BMCL₀₁ for workplace exposure was calculated using a measure of total dust, which contained 30% crystalline silica. The BMCL₀₁ corrected for silica is (2.12 mg/m³-years) x (0.3) = 0.636 mg/m³-years

**The cumulative workplace BMCL₀₁ must be adjusted for general population exposures. The occupational (Occ) exposure of 8 h/day, 5 days per week is normalized to 7 days/week for an equivalent daily exposure adult to contaminated air of 10 m³ per day for the period of the study (270 daily shifts per year for an average of 24 years). The residential (Res, meaning general population) exposure is assumed to be 20 m³/day.

The residential daily equivalent is calculated as follows:

$$[(\text{BMCL}_{\text{Occ}} \text{ in mg/m}^3\text{-years}) \times (\text{daily air volume}_{\text{Occ}}/\text{volume}_{\text{Res}}) \times (\text{exposure days}_{\text{Occ}}/\text{days}_{\text{Res}})]/\text{years of Occ exposure}$$

$$[(0.636 \text{ mg/m}^3\text{-years}) \times (10 \text{ m}^3/20 \text{ m}^3) \times (270 \text{ days}/365 \text{ days})]/ 24 \text{ years} = 0.0098 \text{ mg/m}^3$$

***Because a BMCL₀₁ could be developed from the study, and because of the large size of the cohort examined, it is likely that the BMCL₀₁ is the result of the response of the most sensitive portion of the adult male population examined. An intraspecies uncertainty factor of 3 has been applied to protect sensitive portions of the general population including children and the elderly. This decision is based on arguments presented in Collins et al., 2005; TCEQ, 2009; and OEHHA, 2012.

Cancer Health Based Value (HBV_{cancer}): Not calculated.

Silica has been classified as a known human carcinogen by both IARC (1987) and the NTP (1998) because of an observed increase in lung cancers in occupationally exposed workers. There is, however, a large body of evidence that indicates that lung cancer attributed to silica occurs only after repeated insult leads to silicosis. While some of controversy remains, MDH has determined that if exposure to silica is maintained at levels below those that result in silicosis the likelihood of increased risk of developing lung cancer is minimal. MDH will continue to monitor this issue and reconsider this decision if sufficient new information becomes available.

Volatile: No

Summary of Guidance Value History: New Value

Summary of toxicity testing for health effects identified in the Health Standards Statute:

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested?	No ¹	Yes	No ¹	No ¹	No ¹
Effects?	No ²	Yes ³	No	No	No

Note: Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. Most chemicals have been subject to multiple studies in which researchers identify a concentration where no effects were observed, and the lowest concentration that caused one or more effects. A toxicity value based on the effect observed at the lowest concentration across all available studies is considered protective of all other effects that occur at higher concentrations.

Comments on extent of testing or effects:

¹ No information was found regarding endocrine, developmental, reproductive or neurotoxic effects of crystalline silica.

² Based on the mechanism of toxicity and data from human and animal studies crystalline silica is not expected to be capable of endocrine disruption

³ A number of autoimmune effects of crystalline silica in humans after inhalation exposure have been reported. The mechanism(s) for these effects is unknown (NIOSH, 2002).

References:

- Collins, J.F., Salmon, A.G., Brown, J.P., Marty, M.A., Alexeeff, G.V. (2005) Development of a chronic inhalation reference value for respirable crystalline silica, *Reg. Tox. Pharm.* 43; 292-300.
- Hnizdo, E. and Sluis-Cremer, G.K. (1993) Risk of silicosis in a cohort of white South African gold miners, *Amer. J. Indus. Med.* 24; 447-457.
- IARC (1987) Silica, some silicates, coal dust and para-aramid fibrils, IARC monographs Vol. 68; 41-242.
- NIOSH (2002) NIOSH Hazard Review: Health effects of occupational exposure to respirable crystalline silica, DHHS (NIOSH) Publication No. 2002-129.
- NTP (1998) Report on Carcinogens background document of silica, crystalline (respirable size).
- OEHHA (2005) Silica (Crystalline, Respirable) Reference Exposure Level, Technical Support Document for Non-Cancer RELs, Appendix D3, pgs 486-533.
- TCEQ (2009) Developmental Support Document: Silica, Crystalline Forms, Texas Commission on Environmental Quality.