# Silica, Amorphous

| CAS number: | 7631-86-9, (Silica fume [thermally generated])(respirable dust)  7631-86-9, (Fumed silica [respirable dust])  61790-53-2, (Diatomaceous earth [uncalcined])  112926-00-8, (Precipitated silica)  112926-00-8, (Silica gel) |
| --- | --- |
| Synonyms: | Diatomaceous silica (uncalcined): Diatomite, Kieselguhr, silica – amorphous, Fume (thermally generated); synthetic silica (SAS) |
| Chemical formula: | SiO2 |
| Structural formula: | — |

Workplace exposure standard (retained)

| TWA: | **10 mg/m3 - Diatomaceous earth (uncalcined)  10 mg/m3 - Precipitated silica  10 mg/m3 - Silica gel 2 mg/m3 - Silica fume (thermally generated)  2 mg/m3 - Fumed silica (respirable dust)** |
| --- | --- |
| STEL: | — |
| Peak limitation: | — |
| Notations: | — |
| IDLH: | **3,000 mg/m3 (Silica – Amorphous)** |
| **Sampling and analysis:** The recommended value is quantifiable through available sampling and analysis techniques. | |

## Recommendation and basis for workplace exposure standard

The following TWAs are recommended to protect for respiratory effects in exposed workers:

* 10 mg/m3 – Diatomaceous earth (uncalcined)
* 10 mg/m3 – Precipitated silica
* 10 mg/m3 – Silica gel
* 2 mg/m3 – Silica fume (thermally generated)
* 2 mg/m3 – Fumed silica (respirable dust).

## Discussion and conclusions

Diatomaceous earth is a naturally occurring amorphous silica and is used in agriculture, as an anti-caking agent and in food stuffs.

Critical effects of exposure are respiratory irritation. Cases of pneumoconiosis are reported in the literature, especially in connection with mining, production and processing of diatomaceous earth. However, no exposure related information is available (DFG, 1991).

Synthetic amorphous silicas (precipitated silica, silica gel, silica fume (thermally generated) and fumed silica) are used in industrial and consumer applications including food, cosmetics and pharmaceutical products. These products are prepared by vapour-phase hydrolysis, precipitation or other processes which ensure the absence of crystalline free silica. Critical effects of exposure are respiratory irritation.

Fumed silica is commonly used as a thickening and anticaking agent in powders.

Critical effects of exposure include respiratory irritation and possible fibrosis. A review of the evidence regarding silica fume, thermally generated, concluded that in the absence of any other more recent epidemiological studies the TLV should be less than 5 mg/m3 (SWA, 1991).

Three studies involving a total of 353 workers exposed for up to 32 years to fumed silica at concentrations between 1.6 to 53 mg/m3 reported no pulmonary dysfunction (SWA, 1991). No adverse effects were found among 215 workers exposed at up to 100 mg/m3 total dust colloidal amorphous silica, at 12 times a year for 12 years (DFG, 1991). An investigation of 165 employees exposed to precipitated amorphous silica at 1 mg/m3 for an average of 8.6 years found no relationship between lung function parameters and the results of the X-ray examination and the intensity and duration of exposure (DFG, 1991).

Given the data, the TWAs are recommended to be retained as cited by SWA (1991).

## Recommendation for notations

Not classified as a carcinogen according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Not classified as a skin sensitiser or respiratory sensitiser according to the GHS.

There are insufficient data to recommend a skin notation.

# Appendix

### Primary sources with reports

| Source Year set Standard |
| --- |
| SWA 1991 TWA: 10 mg/m3(Diatomaceous earth (uncalcined), Precipitated silica, Silica gel) TWA: 2 mg/m3 (Silica fume (thermally generated) (respirable dust), Fumed silica (respirable dust)) | |
| Summary of data:  **Diatomaceous earth (uncalcined) (inhalable) 10 mg/m3**   * Naturally occurring amorphous silica diatomaceous earth * TWA originally adopted from ACGIH, 1991. No further information.   **Synthetic amorphous silica**   * Three forms of synthetic amorphous silica according to their method of preparation: * silica gel * precipitated silica * fumed silica.   **Silica gel** **10 mg/m3**   * TWA originally adopted from ACGIH, 1991. No further information.   **Precipitated silica (inhalable)** **10 mg/m3**   * TWA originally adopted from ACGIH, 1991. No further information.   **Silica fume (thermally generated) (respirable dust) 2 mg/m3**   * Silica fume is the by-product of a high-temperature process when elemental silicon is produced by reacting coke and silica sand (crystalline) in an electric arc furnace * TWA based on a review conducted in 1990 which concluded that in the absence of any other more recent epidemiological studies the TLV should be <5 mg/m3: * an Exposure Standards Working Group recommended that an exposure standard of 2 mg/m3 (respirable dust) and that no short-term exposure limit is warranted.   **Fumed silica (respirable dust) 2 mg/m3**   * Fumed silica should not be confused with silica fume * Fumed silica is produced synthetically by a vapour phase hydrolysis of silicon tetrachloride * 3 studies which involved a total of 353 workers exposed for up to 32 years to fumed silica at concentrations 1.6–53 mg/m3; no pulmonary dysfunction was observed except in smokers; no further data * Rats exposed to fumed silica at 50 mg/m3; majority of rats died from pulmonary obstruction and emphysema after 3–5 mo; upon cessation of further exposure, the surviving animals recovered quickly, and the cellular nodules and emphysema almost completely resolved * Rats, guinea pigs and monkeys exposed to fumed silica, silica gel or precipitated silica, for 5.5–6 h/d, 5 d/wk, for up to 18 mo at 15 mg/m3 (total dust) concentration (or 6.9–9.9 mg/m3 respirable dust): * few or no silica-containing macrophages found in the lungs and lymph nodes of the guinea pigs and rats; fumed silica induced early nodular fibrosis in the lungs of the monkeys; fibrogenic action of fumed silica likely due to greater surface area, greater solubility and higher content of aluminium and iron compounds than other amorphous silicas. |
| ACGIH NA NA |
| Silica, amorphous; diatomaceous earth (uncalcined); precipitated silica; silica gel; and silica fume TLV-TWAs withdrawn in 2006 due to insufficient data; no further information. |
| DFG 1991 MAK: 4 mg/m3 (colloidal amorphous silica including pyrogenic and wet process silica (precipitated silica, silica gel) and diatomaceous earth (uncalcined)) (total dust) MAK: 0.3 mg/m3 (silica fume) |
| No specific derivation of TWAs are presented.  Summary of information:  Refers to naturally occurring amorphous silicas, synthetic amorphous silicas and amorphous silicas (silica fume) arising as by-products of industrial processes. The term "amorphous silica" is used in this assessment for the pure forms of SiO2 such as colloidal silica, precipitated silica, silica gel, pyrogenic silica, silica fume, quartz glass, fused silica, and the skeletons of Radiolaria (protozoa) and diatoms (single-celled algae), in the form of diatomaceous earth. Silica occurs naturally in the solid amorphous state as flint, opal or diatomaceous earth. Synthetic amorphous silicas are produced; as wet process silicas (precipitated silica), as thermal, pyrogenic, airborne fumed silica and as arc furnace silica.  Human data:   * Cases of pneumoconiosis are reported, especially in connection with mining, production and processing of diatomaceous earth; no studies with concentrations reported * Regarding synthetic amorphous silica - no adverse effect of exposure found among 215 workers exposed at <100 mg/m3 total dust colloidal amorphous silica 12/yr for 12 yr * Investigation of 165 employees exposed to precipitated amorphous silica at ~1 mg/m3 for an average of 8.6 yr: * no relationship between the lung function parameters and the results of the X-ray examination and the intensity and duration of exposure.   Animal data:   * Rats, guinea pigs and rabbits exposed at 50–150 mg/m3 (various synthetic amorphous silicas) induced signs of desquamative pulmonary catarrh; marked multiplication of macrophages; emphysema-like modifications of the lung parenchyma in rats; all changes reversible after termination of exposure * In an inhalation study in monkeys exposed at 15 mg/m3 pyrogenic silica for 15 mo; collagen fibres observed in the cellular granulomas in some animals; some lung function parameters differed from the control value; at the same concentrations of silica gel and precipitated silica, no adverse effects observed. |
| SCOEL NA NA |
| No report. |
| OARS/AIHA NA NA |
| No report. |
| HCOTN NA NA |
| No report. |

### Secondary source reports relied upon

NIL.

### Carcinogenicity — non-threshold based genotoxic carcinogens

| Is the chemical mutagenic? | No |
| --- | --- |
| **The chemical is not a non-threshold based genotoxic carcinogen.** |  |

## Notations

| Source | Notations |
| --- | --- |
| SWA | — |
| HCIS | NA |
| NICNAS | NA |
| EU Annex | NA |
| ECHA | NA |
| ACGIH | NA |
| DFG | — |
| SCOEL | NA |
| HCOTN | NA |
| IARC | Carcinogenicity – Group 3 (Silica – Amorphous) |
| US NIOSH | NA |

NA = not applicable (a recommendation has not been made by this Agency); — = the Agency has assessed available data for this chemical but has not recommended any notations

### Skin notation assessment

| Calculation |
| --- |
| Insufficient data to warrant a skin notation. |

### IDLH

| Is there a suitable IDLH value available? | Yes |
| --- | --- |

## Additional information

| Molecular weight: | 60.78 |
| --- | --- |
| Conversion factors at 25°C and 101.3 kPa: | 1 ppm = Number mg/m3; 1 mg/m3 = Number ppm |
| This chemical is used as a pesticide: |  |
| This chemical is a biological product: |  |
| This chemical is a by-product of a process: |  |
| A biological exposure index has been recommended by these agencies: | ACGIH  DFG  SCOEL |

## Workplace exposure standard history

| Year | Standard |
| --- | --- |
| Click here to enter year |  |

## References

Deutsche Forschungsgemeinschaft (DFG) (1991) Silica, amorphous – MAK value documentation.

International Agency for Research on Cancer (IARC) (1997) Silica, amorphous. IARC Monographs on the evaluation of the carcinogenic risk to humans.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2018) Crystalline silica: Human health tier II assessment – IMAP report.