KAOLIN

CAS number: 1332-58-7

Synonyms: Argilla, china clay, hydrated aluminium silicate, porcelain clay, kaopectate, bolus alba

Chemical formula: $H_2Al_2Si_2O_8.H_2O$

Structural formula: —

Workplace exposure standard (interim)

TWA: **10 mg/m^3**

STEL: —

Peak limitation: —

Notations: —

IDLH: —

Sampling and analysis: The recommended value is quantifiable through available sampling and analysis techniques.

Recommendation and basis for workplace exposure standard

A TWA of 10 mg/m^3 (containing no asbestos and less than 1% crystalline silica) is recommended in the interim to protect for potential pneumoconiosis in exposed workers.

A priority in-depth assessment of the toxicological and epidemiological data for the chemical is recommended.

Discussion and conclusions

Kaolin is a clay that consists primarily of kaolinite, a non-fibrous silicate of aluminium. It is commonly used as a filler and coating in paper, paint, plastics and ceramics. Critical effects from exposure include pneumoconiosis (more specifically known as kaolinosis).

Long-term exposure to kaolin dust can lead to kaolin-induced pneumoconiosis. However, a robust dose-response relationship has not been established (DFG, 2011). Based on epidemiologic studies, most kaolinosis cases occurred in workers involved in processing, milling and bagging of kaolin with some cases also reported in those working in pit extraction areas. Exposures in processing scenarios were reported in the range of 2 to 5 mg/m^3 respirable particulates with possible extremely high past exposures. Exposures in pit and mining were reported at 0.2 to 1 mg/m^3 respirable dust (ACGIH, 2018).

Given the limited data available, the current TWA of 10 mg/m^3 is recommended to be retained in the interim. Noting insufficiency of the data, a priority assessment of the toxicological and epidemiological data for the chemical is recommended.

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***
Adopted from ACGIH in 1991.		
ACGIH	***2001***	***TLV-TWA: 2 mg/m³***

TLV-TWA recommended to minimise the potential for development of pneumoconiosis, also known as kaolinosis.

Summary of data:

- Kaolin dust has fibrogenic potential in absence of crystalline silica; pneumoconiosis or kaolinosis exists as a simple or complicated form
- No specific derivation of the TWA is explained; current TWA recommended during 1992 evaluation based on measurements of respirable particulates containing no asbestos and <1% crystalline silica.

Human data:

- A 1960 study of 1,130 kaolin workers identified 44 cases of pneumoconiosis; overall prevalence rate of 3.7%; estimate exposure prior to 1940 of approximately 310 mg/m^3; no crystalline silica; no smoking data
- Study in 553 Cornish China clay workers:
  - 9% exposed >5 yr had pneumoconiosis
  - dustier occupations 6% prevalence 5–15 yr exposure; 23% prevalence >15 yr exposure
  - workers in presumably less dusty roles require 25 yr exposure to reach 17% prevalence
  - evidence of effect of exposure and time on pneumoconiosis; no smoking data
- Study of 459 kaolin workers found a 9.2% prevalence rate of pneumoconiosis; current exposures were <5 mg/m^3; prior to 1960 exposures up to 377 mg/m^3; kaolinosis strongly associated with age and cumulative years of exposure
- Study in kaolin workers found:
  - a 13% prevalence rate of pneumoconiosis in current and 9% in former workers who had greater than 5 years of exposure
  - no pneumoconiosis seen in workers with less than 5 years' experience
  - reduction in forced vital capacity (FVC), forced expiratory volume 1 (FEV_1) and peak flow rate
  - exposure ranged from 1-2 mg/m^3 in the milling and bagging operation and 0.2 mg/m^3 in the mining operation
- 1984 study in kaolin workers found prevalence rate of 7.7%; exposure concentrations (respirable dust) ranged from 0.44 mg/m^3 (mine), 1.74 mg/m^3 (processing area), 5 mg/m^3 in 1997 and <2 mg/m^3 in 1981 (production area):
  - 5 workers with pneumoconiosis had worked in processing area at some point
  - 1 worked entirely in processing area had complicated pneumoconiosis; 4 others had simple pneumoconiosis
  - worker with least exposure of 7 yr had smallest radiological change
  - smoking not considered a factor.

Animal data:

Source	Year set	Standard

• Considered non-toxic *via* the oral route
• Evidence of *in vitro* cytotoxicity in mouse peritoneal macrophages, sheep erythrocytes and rat alveolar macrophages
• Lavage of dust into rat lungs showed lung hysteresis decreased as kaolin dose increased
• Guinea pigs and rats exposed for 6 h/d, 5 d/wk for 1 yr:
  ○ slight pleural mottling in guinea pigs at 23.4 mg/m^3
  ○ scattered dust foci; collagenous fibres observed between the cells and the lymph nodes contained large masses of dust in rats exposed at 27.1 mg/m^3
• Rats exposed to 10 mg/m^3 for 7 h/d, 5 d/wk up to 24 mo; most severe pulmonary change observed was classified as grade 4 fibrosis (minimal); minimal collagen deposit at the level of terminal bronchioles and alveoli; suggestion of glandular pattern in pathology; concluded kaolin exposure would be unlikely to produce severe pulmonary disease.
Classified as A4 (not classified as a human carcinogen); insufficient data to recommend skin notation.		

DFG	***2011***	***Not assigned***
Insufficient exposure data to establish a dose-response relationship and therefore derive a MAK. Summary of additional data: • Induces lung tumours at high doses in rats via intratracheal administration • Induces DNA damage and mutations in lung cells *in vivo*, but only at doses that also cause inflammatory reactions.		
SCOEL	***NA***	***NA***
No report.		
OARS/AIHA	***NA***	***NA***
No report.		
HCOTN	***2007***	***Not assigned***
Insufficient data to derive a health-based OEL. Report that WHO have estimated that kaolin is at least an order of magnitude less potent than quartz in inducing pneumoconiosis.		

Secondary source reports relied upon

Source		Year	Additional information
NICNAS	✓	N.D.	• Human health tier I assessment.

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	Carcinogenicity – A4
DFG	Carcinogenicity – 3B
SCOEL	NA
HCOTN	—
IARC	NA
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 assign a skin notation

IDLH

Is there a suitable IDLH value available?	No

Additional information

Molecular weight:	258.16
Conversion factors at 25°C and 101.3 kPa:	1 ppm = Number mg/m^3; 1 mg/m^3 = Number ppm
This chemical is used as a pesticide:	☐
This chemical is a biological product:	☐
This chemical is a by-product of a process:	☐

Molecular weight:	258.16
Conversion factors at 25°C and 101.3 kPa:	1 ppm = Number mg/m^3; 1 mg/m^3 = Number ppm
This chemical is used as a pesticide:	☐
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

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.

Deutsche Forschungsgemeinschaft (DFG) (2011) Kaolinit – MAK value documentation.

Health Council of the Netherlands (HCOTN) (2007) Kaolin. Health-based calculated occupational cancer risk values. The Hague: Health Council of the Netherlands; publication no. 2007/12OSH.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (N.D.) Kaolin: Human health tier I assessment – IMAP report.