STEARATES

CAS number: —

Synonyms: —

Chemical formula: —

Workplace exposure standard (amended)

TWA:	**10 mg/m^3 (as inhalable dust)** **3 mg/m^3 (as respirable dust)**
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 for inhalable dust and 3 mg/m^3 for respirable dust are recommended to protect for adverse effects in the lungs of exposed workers.

Discussion and conclusions

Stearates are used in cosmetics, as a stabiliser in plastics (sodium stearate), lubricant and dusting agent for rubber. It is also used to soften polyvinyl chloride (zinc stearate), waxes, pharmaceuticals and waterproofing agents.

The critical effects of exposure are lower respiratory tract irritation.

No data are available for human exposures to stearates at the workplace. One case of pneumoconiosis is reported in a worker who was occupationally exposed to zinc stearate dust for 29 years; although airborne concentrations are not reported. A separate case study concluded that zinc stearate was not the cause of lung fibrosis in a worker occupationally exposed for seven years. Severe pulmonary infection is reported in a rat feeding study for 209 days at a dose of 3,000 ppm, which was the only dose used in this study (ACGIH, 2018). Additionally, the outcome of pulmonary infection is considered a secondary effect involving other unknown factors and not as a direct exposure to stearates. The evidence from this study is the basis of recommendation by the ACGIH (2018), albeit with a rat-to-human dose conversion calculation error that overestimated the toxicity.

Given the limited available data, the TWA of 10 mg/m^3 is recommended to be retained for inhalable dust. A TWA of 3 mg/m^3 for respirable dust is also recommended as derived by ACGIH (2018). These values are adopted directly from ACGIH (2018) and apply only to stearic acid and magnesium, sodium and zinc stearates. It excludes stearates of other metals. The recommended TWA are considered appropriate for non-toxic, nuisance dusts such as stearates.

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/m^3***
ACGIH	***2017***	***TLV-TWA: 10 mg/m^3 (inhalable particulate matter)*** ***TLV-TWA: 3 mg/m^3 (respirable particulate matter)***

TLV-TWAs are recommended to protect for adverse effects in the lungs such as lower respiratory tract irritation. Applies only to stearic acid and Mg, Na and Zn stearates. It excludes stearates of other metals.

Summary of data:

- TLV–TWA is based on extrapolation from rat feeding studies that showed severe pulmonary infection at 3,000 ppm (the only dose used in the study) for 209 d
- Extrapolation to human inhalation exposures:
  - in the diet of rats, 3000 ppm is ~150 to 300 mg/kg/d; no further information
  - if inhaled by workers, ≡1,050 mg/d; no further information; (this appears to be calculating or administrative error because: assuming 150 mg/kg/d x 70 kg worker= 10,500 mg/d)
  - estimating 10 m^3 breathed per 8 h workday, ≡105 mg/m^3
  - based on this calculation, 10 mg/m^3 (inhalable) and 3 mg/m^3 (respirable) are estimated to be protective of adverse effects in most workers.

Human data:

- No data available from human exposures to stearates in the workplace
- 12 cases of infants who were sickened after aspirating Zn-stearate baby powder, including one fatal case; no further information
- A case of pneumoconiosis is reported in a rubber worker occupationally exposed to Zn stearate dust for 29 yr; no air concentrations reported:
  - histological examination of the lungs showed an increase in connective tissue and chronic inflammation
  - numerous “granules and needles” in the fibrotic tissue containing Zn found at autopsy
- A case of pulmonary fibrosis in a chemical worker exposed to Zn stearate dust for 7 yr; the amount of Zn retained in the lung was not significantly different from that found in lungs of persons not occupationally exposed:
  - the authors concluded Zn stearate not the cause of lung fibrosis in this worker
- Stearates are used in many cosmetic products; contact dermatitis confirmed by patch testing occurred in a woman of 61 yr with a 20 yr history of dermatitis who used an ostrich oil cream containing sodium stearoyl lactylate.

Animal studies

- Zn stearate injected into the peritoneal cavity of guinea pigs produced initial granulomata:
  - animals sacrificed at 100 and 105 d had no abnormalities
  - concluded that Zn stearate is acutely irritating but has no long-term effects
- Studies summarised in a review concluded that these compounds are of low toxicity, no further information

Source	Year set	Standard
• Sterile Zn stearate was insufflated into the lungs of soon to be anesthetised dogs (a bulb on a 1 cm diameter tube squeezed 4–5 times); weight of Zn stearate insufflated was not reported: o the clinical response was from no adverse effect to acute pneumonitis o pathology described as pneumonitis, bronchitis and haemorrhage reported in dogs sacrificed 3–10 d after exposure o the authors attributed the increased pathological effects of Zn stearate compared with talcum powder (talc) to the more adhesive nature of the stearate powder • Rats fed stearic acid in their diet at 3,000 ppm for 209 days had severe pulmonary infection consisting of tracheobronchitis, lobular pneumonia, lipoid histiocytic response and abscess formation. Insufficient data to recommend a Skin or sensitiser notation or TLV-STEL.		
DFG	***NA***	***NA***
No report.		
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	Carcinogenicity – A4

Source	Notations
DFG	NA
SCOEL	NA
HCOTN	NA
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:	284.48
Conversion factors at 25°C and 101.3 kPa:	1 ppm = 24.18 mg/m^3; 1 mg/m^3 = 0.041 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

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