TETRAFLUOROETHYLENE

CAS number: 116-14-3

Synonyms: Fluoroplast 4, perfluoroethene, perfluoroethylene, tetrafluoroethene, 1,1,2,2-tetrafluoroethylene, TFE

Chemical formula: C_2F_4

Workplace exposure standard (new)

TWA: **2 ppm (8.2 mg/m^3)**

STEL: **—**

Peak limitation: **—**

Notations: **Carc. 1B**

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 2 ppm (8.2 mg/m^3) is recommended to protect for kidney toxicity in exposed workers.

Discussion and conclusions

Tetrafluoroethylene (TFE) is a highly flammable gas at room temperature. It is primarily used in the synthesis of polytetrafluoroethylene polymers. It is also used in a variety of end products including those for indirect or direct food contact.

The critical effect of exposure is kidney toxicity.

Acute toxicity is considered low, producing kidney toxicity after exposures around 2,000 to 6,000 ppm. It is considered carcinogenic in animals, manifesting predominantly in kidneys and liver. However, there is inadequate evidence for carcinogenicity in humans (ACGIH, 2018; NICNAS, 2015). It is consistently reported across all sources that available data does not provide evidence of genotoxic effect. Data from human studies is not available. Sub-chronic and chronic inhalation studies in rats and mice identified a LOAEC of 156 ppm based on increased incidence of renal tubule degeneration (ACGIH, 2018; ECHA, 2011).

A TWA of 2 ppm (8.2 mg/m^3) is recommended as assigned by ACGIH (2018) and based on the LOAEC from inhalation data in rodents. The recommended TWA is considered sufficiently low to protect for kidney and liver effects.

Recommendation for notations

Classified as a category 1B 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	***NA***	***NA***
No report.		
ACGIH	***2001***	***TLV-TWA: 2 ppm (8.2 mg/m^3)***
TLV-TWA recommended to minimise the potential for kidney toxicity. Summary of data: LOAEC for hepatocellular neoplasms and renal tubule degeneration in female rats is 156 ppm and LOAEC for various types of kidney and liver cancers in male rats and both sexes of mice is 312 ppm; basis for TLV-TWA. No human data available. Animal data: • Low acute toxicity, producing kidney toxicity after exposures around 2,000–6,000 ppm • Inhalation 4 h LC_{50}: 25,000–45,000 ppm (rats); 35,000 ppm (mice); 28,500 ppm (hamster); 28,000 ppm (guinea pig) • Male rats exposed at 0, 1,000, 2,000, 3,000, 4,000 or 6,000 ppm for 6 h produced signs of renal tubule damage at 4,000 and 6,000 ppm: o NOAEC 2,000 ppm for kidney toxicity • 16 d inhalation study in rats and mice exposed at 0, 312, 625, 1,250, 2,500 or 5,000 ppm for 6 h/d, 5 d/wk: o at 625 ppm or greater increased renal tubule degeneration in male and female rats o other effects at greater concentrations included body weight reduction and significantly greater kidney and liver weights o other tissues and organs appeared unaffected o NOAEC 312 ppm • 13 wk inhalation study in rats and mice (same exposure doses as 16 d study): o at 625 ppm or greater increased kidney weight in female rats and slightly increased incidence of renal tubule degeneration in male rats o NOAEC 312 ppm • Carcinogenicity study in rats (103 wk) and mice (95 wk) exposed (whole body) at 0,156 ppm (male rats only), 312, 625 or 1250 ppm (rats of both sexes and female mice only): o evidence of carcinogenic activity in male and female rats and mice • Negative results in genotoxicity studies. Insufficient data available to recommend skin or SEN notations or TLV-STEL.		
DFG	***2005***	***Not assigned***
Summary of additional data: • Increased Fl ion excretion in urine of exposed workers; no other observations in humans • No evidence of a genotoxic effect from available studies		

Source	Year set	Standard
• No dermal absorption data due to gaseous state • No studies available on skin or eye irritation but no such effects observed in inhalation studies • Insufficient data to assess sensitising effect.		
SCOEL	***NA***	***NA***
No report.		
OARS/AIHA	***NA***	***NA***
No report.		
HCOTN	***NA***	***NA***
No report.		

Secondary source reports relied upon

Source		Year	Additional information
NICNAS	✓	2015	• Available information indicates the chemical is not mutagenic or clastogenic potential • Inadequate evidence for carcinogenicity in humans, but there is sufficient evidence in animals.
NTP	✓	1997	• From 2 yr inhalation studies, clear evidence of carcinogenic activity in rats and mice.
ECHA	✓	2011	• LOAEC 156 ppm (rat, 2 yr, inhalation); increased incidences of renal tubule degeneration.

Carcinogenicity — non-threshold based genotoxic carcinogens

Is the chemical mutagenic?	Insufficient data
Is the chemical carcinogenic with a mutagenic mechanism of action?	No

The chemical is not a non-threshold based genotoxic carcinogen.

Notations

Source	Notations
SWA	NA
HCIS	Carcinogenicity – category 1B
NICNAS	Carc. Cat 2
EU Annex	NA
ECHA	NA
ACGIH	Carcinogenicity – A3

Source	Notations
DFG	Carcinogenicity – 2
SCOEL	NA
HCOTN	NA
IARC	Carcinogenicity – Group 2A
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

Insufficient data to assign a skin notation.

IDLH

Is there a suitable IDLH value available? No

Additional information

Molecular weight:	100.02
Conversion factors at 25°C and 101.3 kPa:	1 ppm = 4.09 mg/m^3; 1 mg/m^3 = 0.24 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

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) (2006) Tetrafluorethen – MAK value documentation.

European Chemicals Agency Regulation (ECHA) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

International Agency for Research on Cancer (IARC) Tetrafluoroethylene. IARC Monographs – 110.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2015) Ethene, tetrafluoro-: Human health tier II assessment – IMAP report.

National Toxicology Program (NTP) (1997) NTP TR 450 NIH, Publication No. 97-3366.