# Ammonium perfluorooctanoate

| CAS number: | 3825-26-1 |
| --- | --- |
| Synonyms: | AFPO, Ammonium pentadecafluorooctanoate, octanoic acid, pentadecafluoroammonium salt |
| Chemical formula: | C8H4F15NO2 |

Workplace exposure standard (amended)

| TWA: | **0.01 mg/m3** |
| --- | --- |
| STEL: | **—** |
| Peak limitation: | **—** |
| Notations: | **Carc. 2, Sk.** |
| IDLH: | **—** |
| Sampling and analysis: | There is uncertainty regarding quantification of the recommended value with currently available sampling and/or analysis techniques. |

## Recommendation and basis for workplace exposure standard

A TWA of 0.01 mg/m3 is recommended to protect for liver damage in exposed workers.

## Discussion and conclusions

Ammonium perfluorooctanoate (APFO) is an industrial surfactant in chemical processes and used in some feedstocks. It is well absorbed after ingestionand inhalation and to a lesser extent after dermal exposure.

APFO has been associatedwith liver damage in animal studies. No evidence of liver damage is reported in human epidemiological studies. Animal studies report an increased incidence of testicular tumours; with no evidence of human cancer effects identified. No health effects were reported in workers exposed to concentrations as low as 0.032 mg/m3 (ACGIH, 2018; DFG, 2011).

A reported NOAEL of 1 mg/m3 for liver effects in rats(ACGIH, 2018; DFG, 2011) is considered an appropriate point of departure. This NOAEL was identified from a repeat inhalation study that is representative of the type of exposure likely encountered at the workplace. An interspecies safety factor of 10 and an intraspecies uncertainty factor of 10 are applied resulting in the recommended TWA of 0.01 mg/m3, which is considered sufficient to protect for liver damage in exposed workers.

## Recommendation for notations

Classified as a category 2 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.

A skin notation is recommended based on the low NOAEL following repeated dermal dosing to animals.

# Appendix

### Primary sources with reports

| Source Year set Standard |
| --- |
| SWA 1986 TWA: 0.1 mg/m3 | |
|  |
| ACGIH 2001 TLV-TWA: 0.01 mg/m3 |
| TLV-TWA recommended to minimise the potential for chronic asymptomatic accumulation in the blood, potential liver damage and testicular cancer; the latter two reported only in animals.  Summary of data:  Human data:   * Organic fluoride concentrations higher in the blood of exposed workers than workers with no exposure * half-life in blood >1–2 yr * No health effects reported in exposed workers (0.032–7.6 mg/m3; no further information available).   Animal data:   * NOAEL: 1 mg/m3 (repeat inhalation study in male rats) * liver damage at concentrations of 7.6 and 84 mg/m3 * liver effects were reversible * Increase incidence of testicular tumours in rats fed APFO * LD50: 4,300 mg/kg (rabbits, dermal); 7,000 mg/kg (male rats, dermal); >7,500 mg/kg (female rats, dermal) * Liver damage observed with repeated dermal doses between 20–2,000 mg/kg to rats * No teratogenic effects in rats after inhalation <25 mg/m3 (chronic study; no duration) * Negative mutagenic results in *Salmonella typhimurium.* |
| DFG 2005 MAK: 0.005 mg/m2 |
| MAK for perfluorooctanoic acid and its inorganic salts, including ammonium perfluorooctanoate, is recommended to protect for liver damage.  Summary of additional data:   * APFO absorbed following ingestion and inhalation but to a lesser extent *via* dermal pathway * Distributed as perfluorooctanoic acid (PFOA) in rodents via plasma * No evidence of liver damage in epidemiological studies * LD50: 4,300 mg/kg (rabbits; dermal); duration not provided * Liver hypertrophy observed in monkeys (no further information) * Reduced foetal weights in rats and maternal toxicity after 25 mg/m3 (no further information) * LC50: 980 mg/m3 (rats; 4 h) * NOAEL of 7 mg/L serum liver weight increase in rats corresponds to 0.06 mg/kg APFO * Reports that a NOAEL of 7 mg/L in rats also applies to humans and the concentration in blood corresponds to concentration in air of 0.005 mg/m3; based on the following: . * Cair = (Cblood x Vd x BW)/(R/100 x AV x t1/2) x 1000 * assuming: half-life (t1/2) = 3.8 yr = 1,387 d; respiratory volume (AV) = 10,000 L; body weight (BW) = 70 kg; distribution volume (Vd) = 0.21 L/kg; retention (R) = 100%   Summary of additional data (2011; prenatal toxicity)   * NOAEC in rats of 10 mg/m3 (6 h/d exposure to dust, highest dose tested, whole body exposure) for toxic effects on prenatal development * range finding study at 25 mg/m3 for 6 h/d reported 3/12 maternal deaths and reduced foetal weight. |
| 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 | * NOAEL of 10 mg/m3 developmental toxicity in rat pups (statistically significant reduced bw at birth) * Endocrine system effects noted for PFOA in human epidemiological findings. |

### 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 | Carc. 2 |
| HCIS | Carcinogenicity – category 2 |
| NICNAS | — |
| EU Annex | Carcinogenicity – category 2 |
| ECHA | — |
| ACGIH | Carcinogenicity – A3; Skin |
| DFG | Carcinogenicity – 4; H (skin) |
| SCOEL | NA |
| HCOTN | NA |
| IARC | — |
| US NIOSH | — |

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 |
| --- |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Adverse effects in human case study: |  |  |  |  | | Dermal LD50 ≤1000 mg/kg: | no |  |  |  | | Dermal repeat-dose NOAEL ≤200 mg/kg: | yes | 3.00 |  |  | | Dermal LD50/Inhalation LD50 <10: |  |  |  |  | | *In vivo* dermal absorption rate >10%: |  |  |  |  | | Estimated dermal exposure at WES >10%: |  |  |  |  | |  |  | 3 | **consider assigning a skin notation** | | |

### IDLH

| Is there a suitable IDLH value available? | No |
| --- | --- |

## Additional information

| Molecular weight: | 431.10 |
| --- | --- |
| 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

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*](http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations) on the ACGIH website.

Deutsche Forschungsgemeinschaft (DFG) (2011) Perfluorooctanoic Acid and its Inorganic Salts– MAK value documentation.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2015) Perfluorooctanoic Acid (PFOA) and its Direct Precursors: Human health tier II assessment – IMAP report.

Tenth Adaptation to Technical Progress Commission Regulation (EU) No 2017/776 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the CLP Regulation).