The MAK-Collection for Occupational Health and Safety

GMS PUBLISSO ZB MED-Publikationsportal Lebenswissenschaften

Polytetrafluoroethene

MAK Value Documentation – Translation of the German version from 2019

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Keywords

mechanism of action, toxicokinetics, metabolism, (sub)acute toxicity, (sub)chronic toxicity, irritation, allergenic effects, genotoxicity, carcinogenicity, peak limitation, prenatal toxicity, germ cell mutagenicity, absorption through the skin, sensitization, occupational exposure, maximum workplace concentration, MAK value, toxicity, hazardous substance

Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has evaluated polytetrafluoroethene [9002-84-0] to derive a maximum concentration at the workplace (MAK value), considering all toxicological endpoints. Available publications are described in detail. As polytetrafluoroethene is an insoluble and chemically inert polymer, showing no systemic toxicity after subchronic oral dosing, polytetrafluoroethene granular dusts are considered to be biopersistent. According to the mechanistic model, chronic inhalative overload of alveolar particle clearance results in particle-induced inflammation and diverse proliferative tissue changes in lungs. The general threshold limit value and all its classifications for the respirable and inhalable fractions are applied to polytetrafluoroethene:

For the respirable fraction, a MAK value of 0.3 mg/m^3 × density (2.2 g/cm^3) is set with Peak Limitation Category II and an excursion factor of 8. It is classified in Carcinogen Category 4 and in Pregnancy Risk Group C. For the inhalable fraction, a MAK value of 4 mg/m^3 is set. The inhalable fraction is also assigned to Pregnancy Risk Group C because polytetrafluoroethene is an insoluble and inert polymer, which is not systemically toxic after oral dosing.

There are no data on genotoxicity, sensitization or dermal absorption. As polytetrafluoroethene is an insoluble polymer, genotoxic and sensitizing effects and a significant contribution of skin absorption to systemic toxicity are not expected.

Citation Note:
Hartwig A, MAK Commission. Polytetrafluoroethene. MAK Value Documentation – Translation of the German version from 2019. MAK Collect Occup Health Saf. 2020 May;5(1):Doc009.
DOI: 10.34865/mb900284e5_1

Manuscript completed:
21 Mar 2018

Publication date:
11 May 2020

MAK value (2018)	**0.3 mg/m³ R (respirable fraction) × material density[a)]** **4 mg/m³ I (inhalable fraction)**
Peak limitation (2018)	**respirable fraction: Category II, excursion factor 8** **inhalable fraction: see List of MAK and BAT Values, Sections V f and V g**
Absorption through the skin	–
Sensitization	–
Carcinogenicity (2018)	**respirable fraction: Category 4** **inhalable fraction: –**
Prenatal toxicity (2018)	**Pregnancy Risk Group C**
Germ cell mutagenicity	–
BAT value	–
Synonyms	1,1,2,2-tetrafluoroethene homopolymer
Chemical name	poly(tetrafluoroethylene)
CAS number	9002-84-0
Molecular formula	$-(C_2F_4)_x-$ x = 4000 to 100 000
Molar mass	400 000 to 10 000 000 g/mol (NLM 2017)
Melting point	327 °C (Zitting 1998)
Boiling point	decomposes on heating (Zitting 1998); decomposition temperature > 400 °C (IFA 2017)
Density	2.2 g/cm³ (NLM 2017)
Vapour pressure	no data
log K_{OW}	no data
Solubility	insoluble in water (IFA 2017), not soluble in any solvent at room temperature (no other details; Zitting 1998)
Stability	extremely stable at room temperature (NLM 2017), chemically inert, higher acidic stability than polyvinyl chloride
Production	polymerization of tetrafluoroethene in the presence or absence of comonomers. Depending upon which production technique is used, the product is a granular polymer, a powder or an aqueous dispersion (NLM 2017)
Purity	no data
Impurities	trace amounts of perfluorooctanoic acid and other related perfluorinated chemicals (NLM 2017)

[a)] The effect of polytetrafluoroethene is based on the effect of biopersistent granular dusts. The MAK value of 0.3 mg/m³ for the respirable fraction applies to a material density of 1 g/cm³.

Uses	principal use in the chemical processing industry for structures, linings, seals, hose or tubing, applications in the electrical industry for coaxial cables, computer wire, insulating tape, coating materials for architectural applications, for household goods, fabrics and textiles, ingredient of lubricants (NLM 2017), ingredient of medical products such as coating materials, seams, aneurysm clips, vascular grafts and of products in the dental industry (IARC 1999)

This documentation is an evaluation of polytetrafluoroethene and not its thermal degradation or pyrolysis products.

After exposure by inhalation, the thermal degradation products of polytetrafluoroethene cause febrile diseases with pulmonary involvement in animals (Johnston et al. 1996, 2000; Lee and Seidel 1991; Oberdörster et al. 2000; Warheit et al. 1990; Zitting 1998) and in humans (NIOSH 1977; Preiss 1973; Zitting 1998); in humans, this is also known as polymer fume fever. Polymer fume fever is a self-limiting symptom complex characterized by flu-like symptoms (Zitting 1998).

There are no data for the concentration levels found in lubricants.

The substance has been pre-registered at the European Chemicals Agency.

1 Toxic Effects and Mode of Action

Polytetrafluoroethene did not induce toxic effects in rats after single oral and dermal exposures and after oral administration for 90 days or 7 months.

Polytetrafluoroethene did not cause irritation of the skin in animals and humans. Polytetrafluoroethene did not lead to irritation of the upper respiratory tract in workers.

Polytetrafluoroethene is chemically inert and has higher acidic stability than polyvinyl chloride. As polytetrafluoroethene is an insoluble polymer that is systemically non-toxic after long-term oral exposure, but can accumulate in the lungs after inhalation, the particle effects are the critical effect of polytetrafluoroethene dust. For this reason, polytetrafluoroethene dusts are considered biopersistent granular dusts.

As is the case for biopersistent granular dusts, the mechanistic model for the respirable fraction of polytetrafluoroethene dusts assumes that inhalation leads to accumulation and thus to particle-induced overload. Chronic inflammation in the lungs can lead to effects ranging from proliferative tissue changes to the development of tumours.

There is no evidence for the induction of sensitizing effects on the skin or airways in humans by polytetrafluoroethene and no animal studies are available.

There are no studies for reproductive toxicity and genotoxicity.

2 Mechanism of Action

Polytetrafluoroethene is chemically inert and has a higher acidic stability than polyvinyl chloride. Polytetrafluoroethene dusts are biopersistent granular dusts.

After exposure by inhalation, respirable biopersistent granular dusts can accumulate in the lungs and impair clearance. Therefore, long-term exposure leads to overload, which causes particle-induced inflammation and effects ranging from various proliferative tissue changes to the development of tumours in the lungs (see supplement 2012, translated 2014, Hartwig 2014).

3 Toxicokinetics and Metabolism

3.1 Absorption, distribution, elimination

A volunteer study was carried out with 6 healthy non-smokers, 3 men and 3 women, ranging from 22 to 48 years of age (average age: 34 years). The volunteers inhaled ^{111}indium-labelled polytetrafluoroethene particles with a mean aerodynamic diameter of 6 µm at a very low "unphysiological" flow rate of 0.04 l/s. The particles were produced by the spinning disk technique, which involves heating a solution to 240 °C and removing the water with a flow of dry air. Each volunteer took a total of 14 to 23 inhalations lasting 20 to 30 seconds over an average period of 16 minutes (14 to 23 minutes). Radioactivity in the mouth, pharynx, lungs and stomach was determined immediately after inhalation by profile scanning and again in the lungs after 24, 48, 72 and 96 hours. Directly after inhalation, deposition in the tracheobronchial region was calculated to be about 50%, in the mouth/pharynx 21.8% and in the alveolar space 28.4% (Anderson et al. 1995). In contrast to this, an earlier experiment with the same test substance (polytetrafluoroethene particles with a mean aerodynamic diameter of 6 µm, labelled with ^{111}indium) found that tracheobronchial deposition was about 30% at a physiologically normal flow rate of 0.5 l/s (Camner and Philipson 1978). This suggests that deposition in the smaller bronchi would be markedly higher at a lower flow rate of 0.04 l/s (Anderson et al. 1995). Between hours 24 and 72, clearance was 20% at a flow rate of 0.04 l/s (Anderson et al. 1995) and 1% at a flow rate of 0.5 l/s (Camner and Philipson 1978).

About 50% of the radioactivity determined in the lungs directly after exposure could still be detected 4 days after exposure (Camner and Philipson 1978). The study of Camner and Philipson (1978) with the physiologically normal respiratory rate is of greater significance for the evaluation of the kinetics during workplace exposure. The study found that clearance was slower than at a lower respiratory rate, probably because of higher alveolar deposition.

A study with 24 non-smoking male volunteers without a history of lung disease investigated Teflon particles labelled with ^{111}indium and larger mean aerodynamic diameters of 8.2, 11.5, 13.7 and 16.4 µm. The average lung deposition of the various particle sizes was 49%, 31%, 21% and 13%, respectively, expressed as a percentage of the total deposition in the body. Alveolar deposition, determined as retention after 24 hours and expressed as a percentage of the total deposition in the body, was 15%, 4%, 4% and 1%, respectively (Svartengren et al. 1987).

A paste containing a 50:50 mixture of polytetrafluoroethene and perfluoroalkyl polyether, which serves as protection against chemical warfare agents, was applied to the entire skin surface area of volunteers on 2 consecutive days (84 g/day). The volunteers then put on full protective gear for 4 hours before showering to remove the substance. Once a day, the volunteers carried out light exercise for 1 hour wearing full protective gear. NMR analysis of urine samples for both organic (limit of detection 0.3 ppm) and inorganic fluorine (limit of detection 2 ppm) revealed no levels of fluorine above the limit of detection (no other details, FDA 2000). Polytetrafluoroethene is therefore not absorbed through the skin.

It is known from veterinary medicine that the polytetrafluoroethene contained in paste materials can be transported by the lymph (no data for the mode of application; NLM 2017).

3.2 Metabolism

There are no data available. Polytetrafluoroethene is not likely to be subjected to any metabolic process because of the strength of the carbon-fluorine bond.

4 Effects in Humans

4.1 Single exposures

In clinical studies, adverse effects were not induced after single dermal applications of 84 g of a paste containing 50% polytetrafluoroethene and 50% perfluoroalkyl polyether for 5 hours (no other details; FDA 2000).

4.2 Repeated exposure

In August and September 1972, the NIOSH (National Institute for Occupational Safety and Health) carried out a study in a factory located in the United States. In this factory, 100 of the 130 employees worked in the production of a wide range of corrosion-resistant products made of polytetrafluoroethene, the remaining 30 carried out administrative duties. In addition to polytetrafluoroethene, some of the workers were exposed to other substances such as fibre glass, coke flour, graphite or polydisulfide and to the pyrolysis products of polytetrafluoroethene resulting from heating in furnaces. Thorax X-ray examinations were carried out once a year. 70 production workers and 7 administrative employees were questioned about dermatoses, chills, fever, altered mental status and upper respiratory symptomatology. Of the 70 production workers, 60 reported that they had experienced the symptoms of polymer fume fever in the past. None of the employees stated that they had experienced symptoms affecting the upper respiratory tract. The soluble fluorine level in the 77 urine samples ranged from 0.098 to 2.19 mg/l. The concentration levels of polytetrafluoroethene dust in the 23 personal air samples and 4 stationary air samples ranged from 0 to 5.5 mg/m^3. The total dust was collected on a filter and the polytetrafluoroethene content was determined by mass spectrometry (Okawa and Polakoff 1974). Polytetrafluoroethene did not cause irritation of the upper respiratory tract. Further conclusions on the toxicity of polytetrafluoroethene could not be drawn because of the mixed exposure.

4.3 Local effects on skin and mucous membranes

Exposure of workers to polytetrafluoroethene at room temperature did not lead to skin damage (no other details; Okawa and Polakoff 1974).

A paste containing 50% polytetrafluoroethene and 50% perfluoroalkyl polyether did not cause irritation of the skin in humans after topical application (no other details; FDA 2000).

4.4 Allergenic effects

There are no data available.

4.5 Reproductive and developmental toxicity

There are no data available.

4.6 Genotoxicity

There are no data available.

4.7 Carcinogenicity

An IARC monograph included 3 studies in which polytetrafluoroethene paste (50% w/w in glycerol) was injected into the tissues of the vocal cords to restore the voices of a total of 11 patients. Granulomatous reactions and

chronic inflammatory foreign-body responses were observed including fibrosis and encapsulation or granuloma formation. There was no evidence of metaplasia or neoplasia (IARC 1999; Wenig et al. 1990).

Ten years after a patient received a 5 cm long, woven polytetrafluoroethene/dacron prosthesis to repair a lacerated artery in the thigh, a fibrosarcoma was diagnosed at the site of the prosthesis. There was no evidence of metastases (IARC 1979).

The IARC has classified the group of organic polymers in Group 3, that is as non-carcinogenic (IARC 1979, 1999).

5 Animal Experiments and in vitro Studies

5.1 Acute toxicity

5.1.1 Inhalation

There are no data available.

5.1.2 Oral administration

No adverse effects were observed in rats given a single oral dose of up to 3240 mg/kg body weight of a paste containing 50% polytetrafluoroethene and 50% perfluoroalkyl polyether (no other details; FDA 2000).

5.1.3 Dermal application

There are no data available.

5.2 Subacute, subchronic and chronic toxicity

5.2.1 Inhalation

There are no data available.

5.2.2 Oral administration

Toxicity was not induced in male and female rats given feed containing 25% finely ground polytetrafluoroethene resins for 90 days (doses of about 22 500 mg/kg body weight and day, conversion factor 0.09 according to EFSA (2012)) (no other details; Zapp 1962).

In a 7-month study of male and female rats given 21% polytetrafluoroethene (doses of about 18 900 mg/kg body weight and day, conversion factor 0.09 according to EFSA (2012)) with the diet, no signs of adverse effects were detected in any of the animals. No difference was noted in the average body weights of the treated animals and the control animals. Histological examination of the organs revealed no unusual findings (no other details; Harris 1959).

5.2.3 Dermal application

There are no data available.

5.3 Local effects on skin and mucous membranes

5.3.1 Skin

Polytetrafluoroethene did not cause irritation of the skin (no other details; IARC 1979).

5.3.2 Eyes

There are no data available.

5.4 Allergenic effects

There are no data available.

5.5 Reproductive and developmental toxicity

There are no data available.

5.6 Genotoxicity

There are no data available.

5.7 Carcinogenicity

In several studies in rats and mice, local sarcomas were induced by subcutaneously or intraperitoneally implanted polytetrafluoroethene discs, squares, fragments or pellets (IARC 1979, 1999). The term "solid state carcinogenesis" was coined for the induction of tumours by substances with solid surfaces at the site of implantation (IARC 1979). In this case, the sarcomas are not induced by the chemical properties of the implanted foreign bodies, but by their physical composition.

Subcutaneous and intraperitoneal application are not relevant for the workplace and are therefore not included in the evaluation.

5.8 Other effects

A lubricating varnish containing polytetrafluoroethene (no data for the fraction of polytetrafluoroethene) did not lead to a reduction in DNA synthesis in vitro in human embryonal fibroblasts. The labelling index and labelling intensity of ^{3}H-thymidine incorporation in DNA were determined (Mutschler et al. 1978).

To evaluate local and systemic tissue tolerability, small polytetrafluoroethene plates coated with a lubricating varnish containing polytetrafluoroethene were implanted subcutaneously under the dorsal skin (sample size 30 × 20 mm) or subperiosteally in the femur (sample size 12 × 8 mm) of 32 male Sprague Dawley rats. Small uncoated polytetrafluoroethene plates were implanted on the other side of the body as controls. The implant sites, local lymph nodes, spleen, liver, kidneys, lungs and femurs were examined after 2 or 12 weeks. No abnormalities were observed (Mutschler et al. 1978).

6 Manifesto (MAK value/classification)

The particle effects of polytetrafluoroethene dust are the critical effect after exposure by inhalation.

MAK value. Polytetrafluoroethene does not cause irritation of the skin in animals and humans. The substance did not lead to irritation of the upper respiratory tract in workers. Polytetrafluoroethene did not induce toxic effects in rats either after single oral and dermal exposures or after oral administration for 90 days or 7 months. Studies with volunteers demonstrated that occupational exposure by inhalation to respirable polytetrafluoroethene particles over longer periods of time can lead to accumulation in the lungs.

There is no evidence of toxicity specifically induced by polytetrafluoroethene because the insoluble polymer is chemically inert and has a higher acidic stability than polyvinyl chloride. For this reason, the general threshold limit value for dust applies. For all modifications of polytetrafluoroethene dust, the general threshold limit value for dust of 4 mg/m³ is applicable for the inhalable fraction and that of 0.3 mg/m³ × material density is applicable for the respirable fraction (see Hartwig 2014).

Peak limitation. The effects on the lungs are the critical effect. For this reason, like other biopersistent granular dusts, the respirable fraction of polytetrafluoroethene has been classified in Peak Limitation Category II. As biopersistent granular dusts have a clearance half-life of about 400 days, an excursion factor of 8 has been established.

Exposure peaks are limited for the inhalable fraction as described in Sections V f and V g of the List of MAK and BAT Values.

Prenatal toxicity. There are no developmental toxicity studies available for polytetrafluoroethene.

The general threshold limit value for dust has been established for polytetrafluoroethene, which means that neither specific toxic effects nor prenatal toxicity are to be expected.

Respirable fraction:

In analogy to other inhaled, poorly soluble respirable dusts, it is assumed that polytetrafluoroethene leaves the lungs, but is retained by the lymph nodes and the mononuclear phagocyte system and therefore does not reach the placenta. It is known from veterinary medicine that the polytetrafluoroethene contained in paste materials can be transported by the lymph (no other details; NLM 2017). This finding cannot be used to evaluate the distribution of the substance without additional information. However, no other data are available for its distribution in the body. For this reason, like other biopersistent granular dusts, the respirable fraction of polytetrafluoroethene has been classified in Pregnancy Risk Group C.

Inhalable fraction:

The inhalable fraction of polytetrafluoroethene can also be absorbed by swallowing. Polytetrafluoroethene is a chemically inert substance that has an even higher acidic stability than polyvinyl chloride. Polytetrafluoroethene did not lead to systemic toxicity in rats given oral doses for 90 days or 7 months, which is further evidence of the stability of the substance. For this reason, also the inhalable fraction of polytetrafluoroethene has been classified in Pregnancy Risk Group C.

Carcinogenicity. There are no studies suitable for the evaluation of the carcinogenic effects of polytetrafluoroethene at the workplace.

Polytetrafluoroethene dusts are considered biopersistent granular particles. The assumed mechanism of action of the respirable fraction of biopersistent granular particles is accumulation with the potential for particle-induced overload. This primarily leads to inflammation in the alveolar or bronchial regions, which is accompanied by the release of reactive oxygen species. This can induce effects ranging from proliferative tissue changes to the development of tumours in the lungs. The respirable fraction of biopersistent granular dusts has therefore been classified in Carcinogen Category 4 (see Hartwig 2014). It is assumed that respirable polytetrafluoroethene dusts will induce the same effects after exposure by inhalation and the respirable fraction of polytetrafluoroethene has therefore been classified in Carcinogen Category 4. These effects are not to be expected if the above-derived threshold limit value

for the respirable fraction of 0.3 mg/m³ × material density is observed because the underlying mechanisms do not have an effect at this level.

On the basis of the general threshold limit value for dust, the inhalable fraction has not been classified in a category for occupational carcinogens. Accordingly, the inhalable fraction of polytetrafluoroethene has not been classified in a category for occupational carcinogens.

Germ cell mutagenicity. No genotoxicity studies have been carried out for polytetrafluoroethene. The induction of genotoxic effects is unlikely because of its structure. On the basis of the genotoxicity data available for biopersistent granular dusts, the polymer is not expected to induce mutagenic effects in germ cells (Hartwig 2014). Therefore, polytetrafluoroethene has not been classified in a category for germ cell mutagens.

Absorption through the skin. Polytetrafluoroethene is an insoluble polymer. As would be expected for an insoluble polymer, there is no evidence that polytetrafluoroethene is absorbed after epicutaneous application. As polytetrafluoroethene additionally does not induce systemic toxicity, the polymer is not designated with an "H" (for substances which can be absorbed through the skin in toxicologically relevant amounts).

Sensitization. There is no evidence for the induction of sensitizing effects on the skin in humans by polytetrafluoroethene and no animal studies are available. There is also no evidence of sensitizing effects on the airways. Polytetrafluoroethene is therefore not designated with either "Sh" or "Sa" (for substances which cause sensitization of the skin or airways).

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