

TEFLON

Hazardous Substances DataBank Number
833

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1 Human Health Effects



1.1 Toxicity Summary



IDENTIFICATION AND USE: Teflon (Polytetrafluoroethylene, or PTFE) is a soft, waxy, milk-white solid, or white powder. The major mechanical applications are in seals and piston rings (fluid transmission systems, hydraulic cylinders and nonlubricated compressors) and in machine bearings and bearing pads, and to a lesser extent, in mechanical tapes and impregnated glass fabrics. For medical applications PTFE is used for: (1) vascular grafts when fabricated into textiles; (2) knitted fabrics for treatment of aneurysms; (3) heart valves and aorta implants; (4) shunts in hemodialysis equipment; (5) bone replacements; (6) injections for treatment of dysphonia. One the major uses of PTFE is in anti-stick coatings in consumer applications.

HUMAN EXPOSURE AND TOXICITY: Other than the possible risk of fumes from an overheated pan, there are no known risks to humans from using Teflon-coated cookware. While Perfluorooctanoic Acid (PFOA) is used in making Teflon, it is not present (or is present in extremely small amounts) in Teflon-coated products. Teflon itself is not suspected of causing cancer. In humans, the well-known health effect of PTFE degradation products is the polymer fume fever with flu-like symptoms. Polymer fume fever is a self-limiting symptom complex, which is induced after inhalation of thermal degradation products of PTFE. The smoking of even slightly PTFE contaminated tobacco products is the cause in the great majority of reported cases. Human volunteer studies showed that the lowest amount of PTFE in a burning cigarette necessary to produce polymer fume fever was 0.4 mg. The documented outbreaks of the polymer fume fever involving exposure mechanisms other than contaminated tobacco products are almost always connected to accidental situations like welding near a PTFE block. Surgical use of PTFE can produce Teflon granuloma in patients. Teflon granuloma is an inflammatory giant-cell foreign-body reaction to polytetrafluoroethylene fibers or injection. Tissue augmentation with PTFE has dramatically declined over the past two decades because of its implication in granuloma formation. Nevertheless, PTFE felt is still commonly used in neurosurgical dissection and microvascular decompression.

ANIMAL STUDIES: The toxicity of PTFE decomposition products has been studied in rats, rabbits, guinea pigs and mice. Large doses of PTFE fumes cause pulmonary inflammation, hemorrhage, edema and even death in experimental animals. The ultrafine particles, which are produced in the degradation, have turned out to be the cause of the toxic pulmonary and lethal effects in the experimental animals. These particles probably carry to the lungs small molecular products (e.g. hydrogen fluoride, carbonyl fluoride) and very reactive compounds like free radicals, because their effectiveness strongly depends on the age of the particle. Overheating of nonstick cookware is a known cause of PTFE toxicosis in avian species and has often been reported anecdotally in pet birds in the veterinary clinical literature. PTFE toxicosis due to heat-lamp bulbs has been a less common occurrence, but it is reported in chickens.

ECOTOXICITY STUDIES: Thermolysis of fluorinated polymers, such as the commercial polymer Teflon can produce trifluoroacetate and the similar compound chlorodifluoroacetate. This can occur either directly, or indirectly via products that are known to degrade to these haloacetates in the atmosphere. Thermolysis also leads to longer chain polyfluoro- and/or polychlorofluoro- (C3-C14) carboxylic acids which may be

equally persistent. Some of these products have recently been linked with possible adverse health and environmental impacts and are being phased out of the US market.

1.2 Evidence for Carcinogenicity (Complete)



No data are available in humans. Inadequate evidence of carcinogenicity in animals.

OVERALL EVALUATION: Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. 57 70 (1987)

1.3 Human Toxicity Excerpts (Complete)



/HUMAN EXPOSURE STUDIES/ BACKGROUND: Wound closure by suturing is a critical and significant event in general as well as in oral surgery. Information regarding tissue reactions to different suture materials appears incomplete and inconsistent, particularly in humans. Thus, the purpose of the present study was to evaluate clinically and histologically tissue reactions to silk and expanded polytetrafluoroethylene (ePTFE) suture materials placed in human oral tissues. METHODS: Twelve patients undergoing periodontal treatment, who had bilateral periodontal defects in the maxillary premolar and molar region scheduled for resective surgery, were included. In each patient, one single interrupted ePTFE suture (CV-5) and one single interrupted silk suture (4-0) were inserted in gingival tissues in contralateral jaw quadrants 10 days prior to scheduled surgery and a second set of sutures was inserted at 7 days prior to surgery. After placement, the length of the suture embedded in the tissue as well as the slack of the suture loop were measured and tabulated. The measurements were repeated on the day of surgery. At this time biopsy specimens, including the suture loop and surrounding tissue, were harvested and processed for histologic analysis. The inflammatory response was evaluated by measuring the thickness of the perisutural epithelium and the diameter of the connective tissue infiltrate, by estimating the proportion of inflammatory cells to epithelial cells, and by recording the presence or absence of bacterial plaque along the suture track. RESULTS: At 7 days, silk sutures showed a significantly higher degree of slack of the suture loop than did ePTFE sutures ($P=0.02$), while the difference was not significant at 10 days ($P=0.21$). The mean change of "tissue bite" was greater for silk compared to ePTFE at 7 as well as at 10 days. However, none of the differences were statistically significant ($P=0.43$). The thickness of the perisutural epithelium increased significantly from 7 to 10 days for both suture materials, while the difference in proportion of inflammatory cells to epithelial cells was not significant ($P=0.43$). An overall significantly greater diameter of connective tissue infiltrate was present around the silk sutures. Bacterial plaque was detected in 10 of 11 silk and four of 11 ePTFE suture channels at 7 days, and eight of 10 and four of 11 suture channels at 10 days. CONCLUSIONS: The results revealed that placement of sutures in gingival tissues elicits an inflammatory reaction and that the magnitude of this reaction may vary with the

suture material used. Braided silk sutures apparently cause a more extensive inflammatory tissue reaction in an environment characterized by moisture and infectious potential.

PMID:15830635

Leknes KN et al; J Periodontol. 76 (1): 34-42 (2005)

/HUMAN EXPOSURE STUDIES/ In human experimental data, tracheobronchial deposition reaches its maximum for particles of about 6 microns inhaled at 0.5 L/s. The purpose of the present study was to investigate if tracheobronchial deposition of 6-microns particles could be increased, especially in the smaller bronchi, using an extremely slow inhalation rate. Six healthy nonsmokers inhaled monodisperse 6-microns (aerodynamic diameter) Teflon particles labeled with (111)In at 0.04 L/s. Radioactivity in mouth and throat, lung, and stomach was measured immediately after inhalation by profile scanning and in the lung also after 24, 48, 72, and 96 hr. There was a substantial clearance between 24 and 72 hr; around 20% of the total clearance occurred between 24 and 72 hr. This is in contrast to earlier studies in which only around 1% of 6-microns particles inhaled at 0.5 L/s cleared between 24 and 72 hr. This indicates a markedly higher deposition in the smaller bronchi at 0.04 L/s than at 0.5 L/s. The total tracheobronchial deposition was 50%, compared to about 30% when particles were inhaled at 0.5 L/s. These findings could be therapeutic use. They also implicate the possibility of developing a diagnostic model that can separate between bronchial reactivity in large and small bronchi.

PMID:7729377

Anderson M et al; Exp Lung Res. 21 (1): 187-95 (1995)

/HUMAN EXPOSURE STUDIES/ Human volunteer studies showed that the lowest amount of PFTE in a burning cigarette necessary to produce polymer fume fever was 0.4 mg. The effect was the same irrespective of whether the dose was given in a single cigarette or fractionated among several cigarettes.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and Polytetrafluoroethylene in the Processing of Plastics. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

/SIGNS AND SYMPTOMS/ Thermodegradation products...produce influenza-like symptoms ('polymer-fume fever') in humans. These may incl chills, headaches, rigor-like shaking of limbs, mild resp discomfort & a high fever. These symptoms disappear within a 24- or 48-hr period if the worker is removed from the working environment & rests.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 296

/CASE REPORTS/ A 55-year-old man was admitted to our hospital because of severe dyspnea 30 minutes after inhalation of waterproofing spray. He had used the spray outdoors and had then smoked a cigarette with spray-contaminated fingers. Chest radiography and computed tomography (CT) revealed diffuse ground glass opacities in both lungs. In pulmonary function tests, the lungs showed a moderately decreased diffusing capacity and there was slight hypoxemia. Transbronchial lung biopsy specimens

demonstrated extensive alveolitis and marked eosinophil migration. Without any specific treatment, the patient recovered clinically in 4 days. We speculated that acute lung injury in this patient may have been induced by not only direct inhalation of the waterproofing spray itself, but also by inhalation of spray by-products resulting from decomposition due to heat. When waterproofing spray is used, precautions should be taken to avoid both inhalation and heating of the fumes. /Waterproofing spray/

[PMID:12722332](#)

Tagawa A et al; Nihon Kokyuki Gakkai Zasshi. 41 (2): 123-6 (2003)

/CASE REPORTS/ The cases of three patients with acute pulmonary edema caused by inhalation of fumes from heated polytetrafluoroethylene(PTFE) in a plastic factory are described. One patient died from profound hypoxemia and shock shortly after admission, and the other two patients survived after medical treatment. This is the first report of fatal pulmonary edema in a worker exposed to PTFE heated in a plastic extruding operation. From this observation, it appears that inhalation exposure to pyrolytic products from polytetrafluoroethylene can cause fatal respiratory complications. Special precautions are warranted in this kind of operation to prevent workers from being exposed to these substances.

[PMID:9192951](#)

Lee CH et al; Eur Respir J. 10 (6): 1408-11 (1997)

/CASE REPORTS/ A 25-year-old woman was admitted to our hospital because of dry cough, slight fever, and severe dyspnea 5 hrs after inhalation of waterproofing spray. She had used the spray indoors near an oil heater, and then had smoked with spray-contaminated fingers. Chest roentgenograms revealed diffuse interstitial shadows mixed with patchy alveolar infiltration, and computed tomographic (CT) scans confirmed diffuse infiltration in both lungs. Marked leukocytosis and severe hypoxemia were noted. A transbronchial lung biopsy performed 4 days later demonstrated extensive alveolitis characterized by edema in alveolar septa and marked neutrophil migration into alveoli as well as alveolar septa. Oxygen therapy and the administration of methylprednisolone (1 g/day) achieved a complete recovery in about 1 week. We speculated that acute lung injury in this patient may have been induced by direct inhalation not only of the waterproofing spray itself, but also of spray by-products resulting from heat-decomposition. When using waterproofing spray, precautions should be taken to avoid inhaling the spray fumes or the more toxic by-products of thermal degradation. /Waterproofing spray/

[PMID:10707539](#)

Tanino M et al; Nihon Kokyuki Gakkai Zasshi. 37 (12): 983-6 (1999)

/CASE REPORTS/ A 30-year old man was admitted to our hospital with cough, slight fever, and dyspnea that he had developed several hours after inhaling the fumes produced from a Teflon-coated pan, after evaporation of the water in the pan. Chest radiography revealed diffuse infiltrations, and a computed tomography (CT) scan revealed patchy interstitial shadows in both lungs. In pulmonary function tests, the diffusing capacity of the lungs showed a moderate decrease. Leukocytosis and slight hypoxemia were observed. The

patient recovered clinically in a few days without any specific treatment. We speculated that the pulmonary problems in this patient may have been induced by the products of thermal degradation of Teflon that were present in the fumes. When Teflon is heated, the fumes generated cause an influenza like syndrome (polymer fume fever) or cause severe toxic effects such as pulmonary edema, pneumonitis, and death in the exposed individual.

[PMID:16922460](#)

Son M et al; Chudoku Kenkyu. 19 (3): 279-82 (2006)

/CASE REPORTS/ The patient was a 59-year-old man who had been treated with continuous positive airway pressure for a diagnosis of obstructive sleep apnea syndrome. While cooking buckwheat noodles, the patient fell asleep with a frying pan on the fire. After four hours, he was awakened by the smell of burning as well as pharyngalgia, and visited this hospital. He was found to have hypoxia, and diagnostic imaging showed diffuse concentration increase with peripheral clear zones in bilateral lung fields, a typical finding of pulmonary edema. In view of the peculiar temporal course of his disease and inhalation of Teflon fumes immediately before its occurrence, he was considered to have polymer fume fever with non-cardiogenic pulmonary edema. After admission, he was treated with oxygen inhalation and diuretics, and experienced a rapid improvement of his general condition and findings on diagnostic imaging. In European countries and the United States, cases with a history of inhalation of Teflon fumes have been given a diagnosis of polymer fume fever.

[PMID:17087340](#)

Toyama K et al; Nihon Kokyuki Gakkai Zasshi. 44 (10): 727-31 (2006)

/CASE REPORTS/ For more than 25 years, Teflon was the most commonly used material for injection laryngoplasty. However, the incidence of Teflon granuloma and the consequent deterioration of glottic function ultimately led to the development of other injectable materials, and as a result, Teflon granulomas are no longer frequently encountered. We present a case of Teflon granuloma that was unusual in that (1) a long period of time had elapsed between the injection and the granuloma formation and (2) there was no change in the patient's glottic function.

[PMID:19172573](#)

Pagedar NA et al; Ear Nose Throat J. 88 (1): 746-7 (2009)

/CASE REPORTS/ CASE 1: A 57-year-old man experienced severe dyspnea 24 hours after inhalation of waterproofing spray. Computed tomography (CT) revealed diffuse ground glass opacities in bilateral lungs. Pulmonary function tests showed mixed ventilatory disturbance with a low expiratory flow rate near the end of forced expiration and a normal diffusing capacity with normal functional residual capacity. The pulmonary function disorder was quickly improved by steroid therapy. CASE 2: A 59-year-old man smoked after inhaling waterproofing spray and soon developed dyspnea. The findings of CT were similar to those of case 1. His pulmonary function test revealed restrictive ventilatory disturbance and normal pulmonary diffusing capacity with low functional residual capacity. These findings improved without steroid treatment. However, it took more time for the

pulmonary function to recover. There was probably specific inflammation around bronchioles, and the inflammation might have spread to the alveolar region in such cases with severe pulmonary function disorder. Steroid treatment seems to be useful to improve both the pulmonary function disorder and the clinical feature due to inhalation of waterproofing spray. /Waterproofing spray/

[PMID:19514496](#)

Hashimoto K et al; Nihon Kokyuki Gakkai Zasshi 47 (5): 367-71 (2009)

/CASE REPORTS/ Sandblasting is one of the occupational causes of silicosis. This report details three cases diagnosed as silicosis caused by sandblasting in Teflon-coated pan manufacturing: Case 1--A 24-year-old man admitted with dyspnea and cough; Case 2--An 18-year-old man admitted with shortness of breath and fever; and Case 3--A 25-year-old man admitted with dyspnea and weight loss. Chest examinations of the first and second cases revealed crackles in both lungs, but the third case was normal, no crackles. Chest x-rays showed bilateral reticulonodular densities and hilar enlargement in all cases. They were clinically and radiologically diagnosed as silicosis due to occupational exposure. All cases had worked in the sandblasting unit at a Teflon-coated pan manufacturing factory for one to three years. Silicosis is a preventable occupational lung disease, but no effective treatment is available for the disease yet. Improving workplace conditions is the most effective way to prevent silicosis.

[PMID:21905388](#)

Koksal N1, Kahraman H; Int J Occup Environ Health. 17(3): 210-3 (2011)

/CASE REPORTS/ A previously healthy 35-year-old Japanese man who developed severe dyspnea presented to our hospital. He had left a polytetrafluoroethylene-coated pan on a gas-burning stove for 10 hours while unconscious. Upon admission, he was in severe respiratory distress. A chest computed tomographic scan showed massive bilateral patchy consolidations with ground-glass opacities and peripheral area sparing. A diagnosis of polytetrafluoroethylene fume-induced pulmonary edema was made. He was treated with non-invasive positive pressure ventilation and a neutrophil elastase inhibitor, which dramatically alleviated his symptoms and improved his oxygenation. He was discharged without sequelae on hospital day 11. A literature review was performed to survey all reported cases of polytetrafluoroethylene fume-induced pulmonary edema. We searched the PubMed, Embase, Web of Science and OvidSP databases for reports posted between the inception of the databases and 30 September 2014, as well as several Japanese databases (Ichushi Web, J-STAGE, Medical Online, and CiNii). Two radiologists independently interpreted all chest computed tomographic images. Eighteen relevant cases (including the presently reported case) were found. Our search revealed that (1) systemic inflammatory response syndrome was frequently accompanied by pulmonary edema, and (2) common computed tomography findings were bilateral ground-glass opacities, patchy consolidation and peripheral area sparing. Pathophysiological and radiological features were consistent with the exudative phase of acute respiratory distress syndrome. However, the contrast between the lesion and the spared peripheral area was striking and was distinguishable from the common radiological features of acute

respiratory distress syndrome. The essential etiology of polytetrafluoroethylene fume-induced pulmonary edema seems to be increased pulmonary vascular permeability caused by an inflammatory response to the toxic fumes. The radiological findings that distinguish polytetrafluoroethylene fume-induced pulmonary edema can be bilateral ground-glass opacity or a patchy consolidation with clear sparing of the peripheral area.

PMID:25971706

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4436768>

Hamaya R ET AL; J Med Case Rep. 9:111 (2015)

/CASE REPORTS/ Teflon granuloma is an inflammatory giant-cell foreign-body reaction to polytetrafluoroethylene fibers or injection. Tissue augmentation with Teflon has dramatically declined over the past two decades because of its implication in granuloma formation. Nevertheless, Teflon felt is still commonly used in neurosurgical dissection and microvascular decompression. We report a patient with a Teflon granuloma of the skull base discovered 1.5 years after endonasal resection of an olfactory groove meningioma. The case highlights the clinical and radiographic diagnosis as well as the management of this unusual finding.

Soose RJ et al; Skull Base 17 (4): 247-252 (2007)

/CASE REPORTS/ A 29-year-old Japanese man presented with fever, dyspnea and non-productive cough after massive inhalation of evaporant from a polytetrafluoroethylene-coated cooking pan. Chest CT scan showed diffuse interstitial infiltration in both lungs. Based on the patient history, images and the pan he brought to the hospital, polymer fume fever was strongly suspected. His symptoms dramatically improved over the following ...days after admission.

PMID:23230259

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4544973>

Shimizu T et al; BMJ Case Rep. 2012 Dec 10;2012. pii: bcr2012007790. doi: 10.1136/bcr-2012-007790.

/CASE REPORTS/ To date, there have been no reports of chronic pulmonary granulomatosis associated with exposure to polytetrafluoroethylene(PTFE). Here, we report three cases of small airway-centered granulomatous lesions in workers employed at facilities that apply coatings to pans and other utensils. The workers were repeatedly exposed to PTFE particles that were probably generated by the drying process when PTFE coatings are dried in a convection oven at high temperatures (380-420 °C). The duration of inhalational PTFE exposure was between 7 and 20 years. We found granulomatous lung lesions around the small airways in lung biopsy specimens obtained from the workers. Scanning electron microscopy/energy-dispersive x-ray spectroscopy analysis was performed focusing on areas where the PTFE particles were suspected to be located in macrophages. The scanning electron microscopy/energy-dispersive x-ray spectroscopy analyses revealed fluorine in the particles. Lung tissue samples from all cases were analyzed using a fully automated Fourier transform infrared spectrometer. Analysis of the spectrum extracted from the position of the foreign particles enabled precise identification of the foreign bodies as PTFE. Fourier transform infrared revealed that all of the lung tissue samples had bands at 1,202 to 1,148

cm(-1) and 1,202 to 1,146 cm(-1), which are characteristic of the asymmetric and symmetric stretching vibrations of the C-F bonds of PTFE. These cases suggest that recurrent inhalational exposure to PTFE particles causes chronic pulmonary granulomatosis.

PMID:24889438

Choi WI et al; Chest. 145 (6): 1397-402 (2014)

/CASE REPORTS/ Microvascular decompression is commonly performed for medically refractory trigeminal neuralgia. A piece of polytetrafluoroethylene (PTFE) is usually placed between the trigeminal nerve and the blood vessel causing the compression. The procedure is effective and relatively safe, and PTFE is presumed to be inert. Reactions to PTFE are rare. We report a patient who developed progressive neurological symptoms 5 years after microvascular decompression surgery. Imaging showed an enhancing cerebellopontine mass resembling a posterior fossa tumor with a large cyst compressing the brainstem. Craniotomy was performed to decompress the cyst. Biopsy of the enhancing mass showed granulomatous inflammation. The patient underwent a second brainstem decompression surgery with placement of a catheter in the cyst connected to an Ommaya reservoir; she has moderate to severe residual neurological deficits.

PMID:17986923

Toth G et al; Neurosurgery. 61 (4): E875-7 (2007)

/CASE REPORTS/ Multiple reports document that a foreign-body giant cell reaction forms around Proplast-Teflon temporomandibular joint (TMJ) implants. This results in destruction of surrounding bone and instability of the implants. This case presents a patient whose Proplast-Teflon TMJ implants became displaced into her middle cranial fossa. The staged reconstruction of this patient is described, including removal of the TMJ implants, reconstruction of the defect, concomitant orthodontic treatment and final reconstruction with TMJ Concepts. This process involved a multidisciplinary approach between several medical and dental specialties. At her 3-year follow up, the patient had a stable postoperative result.

PMID:18375102

Abramowicz S et al; Int J Oral Maxillofac Surg. 37 (8): 763-7 (2008)

/CASE REPORTS/ ...A female worker who had more than 40 attacks of polymer-fume fever without pulmonary edema during a 9-MO period. A few MO after last attack, she had no symptoms; however, 18 MO later...shortness of breath on exertion. Chest x-ray revealed no abnormalities, but pulmonary function studies...alveolar-capillary block.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 296

/CASE REPORTS/ ...4 Cases of pulmonary edema.../reported/ from inhalation of fumes.
/Also/... pulmonary edema in a person who had smoked polytetrafluoroethylene-contaminated cigarettes.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work).

/CASE REPORTS/ ...A case of a fibrosarcoma /reported/ in 31-yr old man, which was diagnosed 10.5 yr after implantation of a 5 cm woven ptfe-dacron arterial prosthesis. The tumor (9x8x4 cm) constricted & encircled more than half of length of femoral artery, incl implant, but did not invade the vessel. ...No evidence of metastasis.

IARC. *Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 297

/CASE REPORTS/ In surgical treatment.../reported/ aneurysm developed on a segment of teflon prosthesis after 14 months in body. A real aneurysm due to use of prosthetic structure was involved...

Lefaux, R. *Practical Toxicology of Plastics*. Cleveland: CRC Press Inc., 1968., p. 254

/CASE REPORTS/ A group of 9 men employed in mfr plant developed an illness working with polytetrafluoroethylene. The cause was presumed to be inhalation of fumes from ptfe-contaminated cigarettes. 8 Of 9 reported chest pain, shortness of breath & cough. One had documented pulmonary edema.

BRUBAKER JA; JA OCCUP MED 19(10) 693 (1977)

/CASE REPORTS/ Higher rate of the polymer fume fever among the smokers than non-smokers has been reported after the exposure to fumes from a charred electrical cable in a laboratory.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. *Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and Polytetrafluoroethylene in the Processing of Plastics*. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

/ALTERNATIVE and IN VITRO TESTS/ OBJECTIVES: Customized aortic repair (CAR) is a new concept for endovascular aortic aneurysm repair in which a non-polymerised elastomer is injected to fill the aneurysm sac around a balloon catheter. Amongst other variables, the thrombogenicity of the elastomer should be tested, before further clinical experiments can take place. The aim of this human ex vivo study was to measure the thrombogenicity of the elastomer and to compare it to expanded polytetrafluoroethylene (ePTFE). DESIGN AND MATERIALS: In a validated ex vivo model, non-anticoagulated blood was drawn from the antecubital veins of 10 healthy donors with a 19-gauge needle. It was drawn through elastomer tubes and through ePTFE Gore-Tex vascular grafts, both 60 cm long and with an inner diameter of 3 mm. METHODS: Fibrinopeptide A (FPA) and P-selectin expression was measured in blood samples, collected at the end of the grafts. After the experiments, the deposition of platelets and fibrin onto the grafts was visualised by scanning electron microscopy. RESULTS: For these graft types, a progressive increase in FPA production was observed in time. No significant difference was observed between the elastomer and ePTFE grafts ($p > 0.05$). No increase in P-selectin expression, and thereby no platelet activation, was observed in the perfusate of either grafts ($p > 0.05$). By scanning electron microscopy, numerous platelet aggregates were observed on the ePTFE grafts, whereas just a few adhered platelets and no aggregates were observed in the elastomer grafts.

CONCLUSIONS: The elastomer in its current formulation has a low thrombogenicity, comparable to ePTFE, making it an ideal substance for endovascular aneurysm sac filling. Further research should clarify the feasibility of CAR in vivo.

PMID:22436262

van der Steenhoven TJ et al; Eur J Vasc Endovasc Surg 43 (6): 675-80 (2012)

/OTHER TOXICITY INFORMATION/ The chemical factor that causes fever has not yet been identified. Polymer-fume fever generally occurs when the worker is exposed to polymer @ temp between 300-500 °C...

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 296

/OTHER TOXICITY INFORMATION/ Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are perfluorinated surfactants used to produce polymers and telomers whose carbon chain can be differently long. Polytetrafluoroethylene (PTFE), namely Teflon, is the chief fluoropolymer and it has been widely utilised over the last decades and all over the world. Indeed, its particular physical and chemical properties make it difficult to replace this substance in several industries (textile, paper, chemical, fire-fighting foam industry). Perfluoroalkyl-compounds may be considered ubiquitous and, in particular, it has been shown that PFOS may be concentrated in the food chain. Concerns about possible toxic effects of these chemicals date back to seventies, but only in 2000 the Environmental Protection Agency (EPA) stated PFOA and PFOS withdrawal to avoid environmental pollution. In 2002 the Organisation for Economic Co-operation and Development reported that these substances are bio-persistent, tend to accumulate in different tissues of living organisms and are toxic to mammals. In 2006 EPA established that every PFOA emission will be eliminated not later than 2015. Actually, health effects of perfluoroalkyl-compounds on humans remain controversial, in spite of a number of experimental and epidemiological studies. Research focuses on possible endocrine disruption, thyroid and liver carcinogenicity, and development alteration. Our article reviews the main studies concerning PFOS and PFOA industrial and environmental toxicology.

PMID:18700679

Negri S et al; G Ital Med Lav Ergon. 30 (1): 61-74 (2008)

/OTHER TOXICITY INFORMATION/ Atmospheric concentrations of fluorocarbon polymer dust and decomposition products have been measured in several industrial situations, but no correlations have been found between the measurements and adverse effects in workers. The majority of reports on polymer fume fever are linked to the smoking of contaminated cigarettes, and in these cases the contamination most probably occurs via unwashed hands. The documented outbreaks of the polymer fume fever involving exposure mechanisms other than contaminated tobacco products are almost always connected to accidental situations like welding near a PTFE block. No exposure data in these cases are available.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and

Polytetrafluoroethylene in the Processing of Plastics. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

/OTHER TOXICITY INFORMATION/ Teflon is a brand name for a man-made chemical known as polytetrafluoroethylene (PTFE). It has been in commercial use since the 1940s. It has a wide variety of applications because it is extremely stable (it doesn't react with other chemicals) and can provide an almost frictionless surface. Most people are familiar with it as a non-stick coating surface for pans and other cookware. It is also used in many other products, such as fabric protectors. Perfluorooctanoic acid (PFOA), also known as C8, is another man-made chemical. It is used in the process of making Teflon and similar chemicals (known as fluorotelomers), although it is burned off during the process and is not present in significant amounts in the final products. ...Teflon itself is not suspected of causing cancer.

American Cancer Society; Teflon and Perfluorooctanoic Acid (PFOA); Available from, as of August 12, 2015: <https://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoic-acid--pfoa>

/OTHER TOXICITY INFORMATION/ Other than the possible risk of fumes from an overheated pan, there are no known risks to humans from using Teflon-coated cookware. While PFOA is used in making Teflon, it is not present (or is present in extremely small amounts) in Teflon-coated products.

American Cancer Society; Teflon and Perfluorooctanoic Acid (PFOA); Available from, as of August 12, 2015: <https://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoic-acid--pfoa>

/OTHER TOXICITY INFORMATION/ Major pathways that enable /Perfluorooctanoic acid/ PFOA, in very small quantities, to get into human blood are not yet fully understood. PFOA is used to make fluoropolymers and can also be released by the transformation of some fluorinated telomers. However, consumer products made with fluoropolymers and fluorinated telomers, including Teflon and other trademark products, are not PFOA. Rather, some of them may contain trace amounts of PFOA and other related perfluorinated chemicals as impurities. The information that EPA has available does not indicate that the routine use of consumer products poses a concern. At present, there are no steps that EPA recommends that consumers take to reduce exposures to PFOA. In 2006, EPA and the eight major companies in the industry launched the 2010/15 PFOA Stewardship Program, in which companies committed to reduce global facility emissions and product content of PFOA and related chemicals by 95 percent by 2010, and to work toward eliminating emissions and product content by 2015.

EPA; Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers; Available from, as of August 17, 2015: <https://www.epa.gov/oppt/pfoa/>

/OTHER TOXICITY INFORMATION/ Teflon is a brand name for a nonstick coating found on certain pots and pans. It contains a substance called polytetrafluoroethylene. The nonstick types of these pans should be used only at low or medium heat. They should never be left unattended at high heat. This may cause the release of fumes that can irritate humans and household pets. When left unattended on the stove, empty cookware can heat up to 800

degrees within 5 minutes. There have been concerns about a possible link between Teflon and perfluorooctanoic acid (PFOA), a man-made chemical. The Environmental Protection Agency states that Teflon does not contain PFOA so the cookware poses no danger.

NLM; MedlinePlus; Cooking utensils and nutrition; Available from, as of August 17, 2015:

<https://www.nlm.nih.gov/medlineplus/ency/article/002461.htm>

/OTHER TOXICITY INFORMATION/ Polytetrafluoroethylene (Teflon) is used in coatings for cooking utensils, for making chemical vessels, gaskets and bearings and in sprays as a mould release agent. Polytetrafluoroethylene and polyvinyl fluoride are inert materials but their thermal decomposition products can be very biologically reactive. Cigarettes can be easily contaminated in the workplace and, when smoked, the polymer burns to form fumes which cause "polymer-fume fever": severe gripping chest pain giving rise to difficulty in breathing; trembling and shaking; elevated temperature; and severe diaphoresis. The symptoms pass after a day or two, but recur on again smoking a contaminated cigarette. Before the cause was recognized a case was recorded of a person, who used the polymer in a mold release spray, having some 40 attacks. Another case was a person who referred to the disease as "mould machine pneumonia". Other cases have been reported and better occupational hygiene and a ban on smoking in the workplace resulted in the disappearance of symptoms in those previously affected.

WHO/International Programme on Chemical Safety; Environmental Health Criteria 211, Health effects of interaction between tobacco use and exposure to other agents (1999). Available from, as of August 11, 2015: <https://www.inchem.org/documents/ehc/ehc/ehc211.htm>

/OTHER TOXICITY INFORMATION/ Perfluoroisobutylene (PFIB). PFIB is given off when Teflon burns. Although we know that Teflon is used in many cooking devices, it is less commonly known that it lines the interior of many military vehicles, particularly armored vehicles. Fires in these vehicles release PFIB. Survivors of vehicle fires who are short of breath should be questioned carefully regarding their exposure to the smoke.

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD); FIELD MANAGEMENT OF CHEMICAL CASUALTIES HANDBOOK 2nd ed., p. 19 (July 2000)

1.4 Skin, Eye, and Respiratory Irritations



There have been reports of "polymer fume fever" in humans exposed to pyrolysis products, which are also irritants.

Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 3352

2 Emergency Medical Treatment



2.1 Antidote and Emergency Treatment (Complete)



There has been no proven method thus far to accelerate the clearance of potentially toxic perfluorinated compounds (PFCs) in humans. PFCs are a family of commonly used synthetic

compounds with many applications, including repelling oil and stains on furniture, clothing, carpets and food packaging, as well as in the manufacturing of polytetrafluoroethylene - a non-stick surfacing often used in cookware (e.g. Teflon(r)). Some PFCs remain persistent within the environment due to their inherent chemical stability, and are very slowly eliminated from the human body due, in part, to enterohepatic recirculation. Exposure to PFCs is widespread and some subpopulations, living in proximity to or working in fluorochemical manufacturing plants, are highly contaminated. PFC bioaccumulation has become an increasing public health concern as emerging evidence suggests reproductive toxicity, neurotoxicity and hepatotoxicity, and some PFCs are considered to be likely human carcinogens. A case history is presented where an individual with high concentrations of PFCs in serum provided: (1) sweat samples after use of a sauna; and (2) stool samples before and after oral administration of each of two bile acid sequestrants - cholestyramine (CSM) and saponin compounds (SPCs). Stool samples before and after use of a cation-exchange zeolite compound were also examined. PFCs found in serum were not detected in substantial quantities in sweat or in stool prior to treatment. Minimal amounts of perfluorooctanoic acid, but no other PFCs, were detected in stool after SPC use; minimal amounts of perfluorooctanesulfonate, but no other PFCs, were detected in stool after zeolite use. All PFC congeners found in serum were detected in stool after CSM use. Serum levels of all PFCs subsequently declined after regular use of CSM. Further study is required but this report suggests that CSM therapy may facilitate gastrointestinal elimination of some PFCs from the human body.

[PMID:20621793](#)

Genuis SJ et al; Public Health. 124 (7): 367-75 (2010)

Inhalational exposure to metal-containing fumes generated by welding and related processes may result in the development of the clinical syndrome known as "metal fume fever." Polymer fume fever is a separate and distinct but related disorder that has been associated with inhalational exposure to specific fluorinated polymer products, such as polytetrafluoroethylene or Teflon. We undertook a review of the peer-reviewed medical literature as it relates to these two disease entities in order to describe their epidemiology, pathophysiology, clinical presentation, diagnosis, treatment, prevention, and prognosis. We performed a search of PubMed (www.pubmed.com) and Ovid MEDLINE (ovidsp.tx.ovid.com) databases for keywords "metal fume fever," "polymer fume fever," and "fume fever," covering the period 1946 to September 2014, which resulted in a total of 141 citations. Limiting the search to articles published in the English language yielded 115 citations. These 115 articles were manually reviewed for relevance. In addition, the reference lists in each article retrieved were reviewed for additional relevant references. This left 48 relevant citations. Metal fume fever occurs most commonly as an occupational disease in individuals who perform welding and other metal-joining activities for a living. It is estimated that 1,500-2,500 cases of metal fume fever occur annually in the United States. Polymer fume fever was initially identified as an occupational disease but increased regulations have resulted in decreased incidence in the occupational setting. Overheating of Teflon-coated cookware is one of the more common mechanisms for exposure. While

the precise pathophysiology associated with the development of metal fume fever is yet to be elucidated, suggested pathophysiologic mechanisms include pro-inflammatory cytokine release, neutrophil activation, and oxygen radical formation. The pathophysiologic mechanism for polymer fume fever has not been definitively elucidated but may involve similar mechanisms to those proposed for metal fume fever. Metal fume fever typically presents with generally non-specific complaints including influenza-like symptoms, fever, shaking chills, arthralgias, myalgias, headache, and malaise. Onset of symptoms typically occurs 4-10 hr following the exposure to metal-containing fumes. While metal fume fever is typically benign and self-limited, severe cases of the disease have been reported. In patients with ongoing metal fume exposure over the course of a workweek, tachyphylaxis occurs resulting in improvement in symptoms over the course of the workweek and maximal symptoms occurring after an exposure-free period such as a weekend. The clinical presentation of polymer fume fever is indistinguishable from metal fume fever, with an exposure history being necessary to distinguish the two entities. Chest radiographs are typically normal in cases of metal fume fever and polymer fume fever; however, mild vascular congestion may be demonstrated and severe cases may feature diffuse patchy infiltrates. Laboratory studies are typically not necessary but may demonstrate leukocytosis with leftward shift or an elevated erythrocyte sedimentation rate. The primary treatment for both metal fume fever and polymer fume fever is supportive and directed at symptom relief. Oral hydration, rest, and the use of antipyretics and anti-inflammatory medications (e.g., non-steroidal anti-inflammatory drugs and aspirin) are recommended. A careful workplace exposure assessment analysis conducted by an occupational medicine specialist or clinical toxicologist in concert with a qualified industrial hygienist should be performed. A careful workplace exposure assessment including measurement of ambient zinc and other metal (e.g., chrome, nickel, copper and manganese) fume concentrations or concentrations of fluorocarbon polymer decomposition products at different locations within the workplace should be performed. Metal fume fever is typically a benign and self-limited disease entity that resolves over 12-48 hr following cessation of exposure. Metal and polymer fume fevers generally follow a benign course with spontaneous resolution of symptoms, though both have the potential to be serious, especially in those with significant preexisting cardiorespiratory disease.

[PMID:25706449](#)

Greenberg MI, Vearrier D.; Clin Toxicol (Phila). 53 (4):195-203 (2015)

/SRP:/ Immediate first aid: Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand valve resuscitator, bag-valve-mask device, or pocket mask, as trained. Perform CPR if necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on the left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature. Obtain medical attention. /Poisons A and B/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds.); Emergency Care For Hazardous Materials Exposure. 3rd revised edition, Elsevier Mosby, St. Louis, MO 2007, p. 160

/SRP:/ Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if needed. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary Monitor for shock and treat if necessary Anticipate seizures and treat if necessary For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool Cover skin burns with dry sterile dressings after decontamination /Poisons A and B/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds.); Emergency Care For Hazardous Materials Exposure. 3rd revised edition, Elsevier Mosby, St. Louis, MO 2007, p. 160

/SRP:/ Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary edema, or is in severe respiratory distress. Positive-pressure ventilation techniques with a bag valve mask device may be beneficial. Consider drug therapy for pulmonary edema Consider administering a beta agonist such as albuterol for severe bronchospasm Monitor cardiac rhythm and treat arrhythmias as necessary Start IV administration of D5W TKO /SRP: "To keep open", minimal flow rate/. Use 0.9% saline (NS) or lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Watch for signs of fluid overload Treat seizures with diazepam or lorazepam Use proparacaine hydrochloride to assist eye irrigation /Poisons A and B/

Currance, P.L. Clements, B., Bronstein, A.C. (Eds.); Emergency Care For Hazardous Materials Exposure. 3rd revised edition, Elsevier Mosby, St. Louis, MO 2007, p. 160-1

3 Animal Toxicity Studies



3.1 Non-Human Toxicity Excerpts (Complete)



/LABORATORY ANIMALS: Acute Exposure/ Ambient fine particles consist of ultrafine particles (< 100 nm) and accumulation-mode particles (approximately 100 to 1,000 nm). Our hypothesis that ultrafine particles can have adverse effects in humans is based on results of our earlier studies with particles of both sizes and on the finding that urban ultrafine particles can reach mass concentrations of 40 to 50 ug/cu m, equivalent to number concentrations of 3 to 4 x 10⁵ particles/cu cm. The objectives of the exploratory studies reported here were to (1) evaluate pulmonary effects induced in rats and mice by ultrafine particles of known high toxicity (although not occurring in the ambient atmosphere) in order to obtain information on principles of ultrafine particle toxicology; (2) characterize the generation and coagulation behavior of ultrafine particles that are relevant for urban air; (3) study the influence of animals' age and disease status; and (4) evaluate copollutants as modifying factors. We used ultrafine Teflon (polytetrafluoroethylene [PTFE]) fumes (count median diameter [CMD] approximately 18 nm) generated by heating Teflon in

a tube furnace to 486 degrees C to evaluate principles of ultrafine particle toxicity that might be helpful in understanding potential effects of ambient ultrafine particles. Teflon fumes at ultrafine particle concentrations of approximately 50 ug/cu m are extremely toxic to rats when inhaled for only 15 minutes. We found that neither the ultrafine Teflon particles alone when generated in argon nor the Teflon fume gas-phase constituents when generated in air were toxic after 25 minutes of exposure. Only the combination of both phases when generated in air caused high toxicity, suggesting the existence of either radicals on the particle surface or a carrier mechanism of the ultrafine particles for adsorbed gas-phase compounds. We also found rapid translocation of the ultrafine Teflon particles across the epithelium after their deposition, which appears to be an important difference from the behavior of larger particles. Furthermore, the pulmonary toxicity of the ultrafine Teflon fumes could be prevented by adapting the animals with short 5-minute exposures on 3 days prior to a 15-minute exposure. This shows the importance of preexposure history in susceptibility to acute effects of ultrafine particles. Aging of the fresh Teflon fumes for 3.5 minutes led to a predicted coagulation resulting in particles greater than 100 nm that no longer caused toxicity in exposed animals. This result is consistent with greater toxicity of ultrafine particles compared with accumulation-mode particles. When establishing dose-response relationships for intratracheally instilled titanium dioxide (TiO₂) particles of the size of the urban ultrafine particles (20 nm) and of the urban accumulation-mode particles (250 nm), we observed significantly greater pulmonary inflammatory response to ultrafine TiO₂ in rats and mice. The greater toxicity of the ultrafine TiO₂ particles correlated well with their greater surface area per mass. Ultrafine particles of carbon, platinum, iron, iron oxide, vanadium, and vanadium oxide were generated by electric spark discharge and characterized to obtain particles of environmental relevance for study. The CMD of the ultrafine carbon particles was approximately 26 nm, and that of the metal particles was 15 to 20 nm, with geometric standard deviations (GSDs) of 1.4 to 1.7. For ultrafine carbon particles, approximately 100 ug/cu m is equivalent to 12×10^6 particles/cu cm. Homogeneous coagulation of these ultrafine particles in an animal exposure chamber occurred rapidly at 1×10^7 particles/cu cm, so that particles quickly grew to sizes greater than 100 nm.

[PMID:11205815](#)

Oberdorster G et al; Res Rep Health Eff Inst (96): 75-86 (2000)

/LABORATORY ANIMALS: Acute Exposure/ PTFE (polytetrafluoroethylene) fumes consisting of large numbers of ultrafine (uf) particles and low concentrations of gas-phase compounds can cause severe acute lung injury. Our studies were designed to test three hypotheses: (i) uf PTFE fume particles are causally involved in the induction of acute lung injury, (ii) uf PTFE elicit greater pulmonary effects than larger sized PTFE accumulation mode particles, and (iii) preexposure to the uf PTFE fume particles will induce tolerance. We used uf Teflon (PTFE) fumes (count median particle size approximately 16 nm) generated by heating PTFE in a tube furnace to 486 degrees C to evaluate principles of ultrafine particle toxicity. Teflon fumes at ultrafine particle concentrations of 50 ug/cu m were extremely toxic to rats when inhaled for only 15 min. We found that when generated in argon, the

ultrafine Teflon particles alone are not toxic at these exposure conditions; neither were Teflon fume gas-phase constituents when generated in air. Only the combination of both phases when generated in air caused high toxicity, suggesting either the existence of radicals on the surface or a carrier mechanism of the ultrafine particles for adsorbed gas compounds. Aging of the fresh Teflon fumes for 3.5 min led to a predicted coagulation to >100 nm particles which no longer caused toxicity in exposed animals. This result is consistent with a greater toxicity of ultrafine particles compared to accumulation mode particles, although changes in particle surface chemistry during the aging process may have contributed to the diminished toxicity. Furthermore, the pulmonary toxicity of the ultrafine Teflon fumes could be prevented by adapting the animals with short 5-min exposures on 3 days prior to a 15-min exposure. Messages encoding antioxidants and chemokines were increased substantially in nonadapted animals, yet were unaltered in adapted animals. This study shows the importance of preexposure history for the susceptibility to acute ultrafine particle effects.

PMID:11042093

Johnston CJ et al; Toxicol Appl Pharmacol. 168 (3): 208-15 (2000)

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Polypropylene (PP), Polyethylene (PE) and polytetrafluoroethylene (FE) are high molecular materials in medical use. They are also used as the negative control materials for ISO 10993-6 international standard biological evaluation of medical devices. We examined tissue reactions to these materials embedded subcutaneously in the dorsal area of male ddY mice. One week and 12 weeks after embedding, the tissue surrounding the embedding site was removed and then histopathological examination was performed. Our results demonstrate that the basic histopathological reaction is the formation of fibrous capsule consisting of granulation tissue around the embedded materials. Based on our results, we believe that the high molecular materials such as, PP, PE and FE, can be considered for medical use as a biomaterials within the body.

PMID:21810558

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3353399>

Tomida M et al; Eur J Med Res. 16 (6): 249-52 (2011)

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ Electron paramagnetic resonance (EPR) oximetry is a powerful technology that allows the monitoring of oxygenation in tissues. The measurement of tissue oxygenation can be achieved using lithium phthalocyanine (LiPc) crystals as oxygen reporters. In order to have biocompatibility for the sensing system and to assure long-term stability in the responsiveness of the system, we developed films of Teflon AF 2400 with embedded LiPc crystals. These systems can be used as retrievable inserts or parts of an implantable resonator or catheter. Atomic force microscopy studies revealed that the surface of the films was regular and planar. The response to oxygen of the sensor (EPR linewidth as a function of pO₂) remained unchanged after implantation in mice, and was not affected by sterilization or irradiation. The use of resonators, holding LiPc embedded in Teflon AF 2400, implanted in the gastrocnemius muscle of rabbits allowed the monitoring of oxygen during several weeks.

Several assays also demonstrated the biocompatibility of the system: (1) no hemolytic effect was noted; (2) no toxicity was found using the systemic injection test of extracts; (3) histological analysis in rabbit muscle in which the films were implanted for 1 week or 3 months was similar to standard polyethylene biocompatible devices. These advanced oxygen sensors are promising tools for future pre-clinical and clinical developments of EPR oximetry. These developments can be applied for other applications of biosensors where there is a need for oxygen permeable membranes.

[PMID:16368480](#)

Dinguizli M et al; Biosens Bioelectron. 21 (7):1015-22 (2006)

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ BACKGROUND: Expanded polytetrafluoroethylene (ePTFE) and silicone are safe and relatively biocompatible materials. OBJECTIVE: To compare, using multiple histologic parameters, the tissue response to a standard silicone soft tissue implant with the response to a modified ePTFE implant. The modified form of ePTFE is reinforced with fluorinated ethylene propylene (FEPRePTFE), which provides increased pliability and material integrity. METHODS: The implants were placed into a subperiosteal pocket over the skull of adult New Zealand white rabbits. At 7, 30, and 90 days after implantation, en bloc tissue specimens, including skin, implants, surrounding soft tissue, and underlying bone were harvested for gross and histologic evaluation. OUTCOME MEASURES: The tissue response to the implants was assessed with respect to the number of foreign body giant cells present, the thickness of the fibrous capsule, and the general inflammatory response (n = 6 for each implant at each evaluation period). RESULTS: There were no cases of rejection, extrusion, or infection. The silicone implants elicited a significantly thicker capsule and less neovascularization ($P < .05$). CONCLUSION: The FEPRePTFE demonstrated a favorable tissue response when compared with silicone, particularly in regard to capsule thickness and vascular ingrowth.

[PMID:12020206](#)

Batniji RK et al; Arch Facial Plast Surg. 4 (2):111-3 (2002)

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ The purpose of this study was to examine the effect of the in vivo maturing ePTFE graft surface on platelet activation. Ten canines were randomized to receive either a carotid to infrarenal aorta ePTFE graft or sham operation. Animals were sampled at specific time points up to 3 months postoperatively. Whole blood platelet aggregometry (arachidonic acid, ADP, and collagen agonists) and ATP secretion (in response to arachidonic acid, ADP, collagen, and thrombin) were measured. Additionally, complete hematologic analysis and histology were performed. With time, graft animals showed significantly more decrease in platelet aggregation in response to ADP compared to sham animals ($P = .023$). The total amount of ATP per platelet was not different, as demonstrated by equivalent ATP release per platelet in response to thrombin. Over the first week, grafted dogs developed a decrease in systemic platelet count of 50% ($P < .001$) that persisted over the 3-month follow-up period. With time, overall regression model slopes of graft and sham platelet count data were not statistically different ($P = .29$). Histologically, the grafts demonstrated limited cellular ingrowth at both anastomoses, with fibrin matrix along the remainder of the blood-

biomaterial interface. These data suggest that, similar to Dacron, exposure to an ePTFE surface results in significant changes in platelet biology, and these platelet-ePTFE interactions persist even after the graft has formed a mature pseudointima. The pseudointima appears to be the primary determinant of the blood-biomaterial interaction.

PMID:7622550

Ozaki CK et al; J Biomed Mater Res. 29 (5): 647-53 (1995)

/LABORATORY ANIMALS: Subchronic or Prechronic Exposure/ No toxicity was observed in male & female rats fed polytetrafluoroethylene for 90 days, even with a level of 25% in the diet. The polymer has not been found to produce skin irritation or to act as an allergenic agent.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 295

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ A group of 89 random-bred female swiss mice, 7-9 wk old, received SC implant in left flank of a square sheet of polytetrafluoroethylene (ptfe) measuring 12x12x1.2 mM. The first local tumor developed 25 wk after implantation; a total of 11 (12.5%) fibrosarcomas were found after an avg latent period of 54.5 weeks.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 293

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Groups of 7-9 wk old...swiss mice...given SC implant of /12x12x1.2 mM sq, 15 mM diam disc, teflon fragment, 20 mM diam disc/. Tumors developed around implant of 8/89 (10%) & 1/61 (2%), 23/103 (22.7%), 10/53 (21.2%) & 7/54 (15.2%) & 4/50 (8%)...respectively. /All fibrosarcomas, some angiosarcomatous areas/.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 293

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ A group of 19 male & 27 female 7-9 wk old inbred c57bl mice received SC implants of 15x1.2 mM...discs. Four local sarcomas (20%) developed in 20 females that retained the inplant and were considered to be at risk at weeks 39, 47, 52 and 58, and 4 local sarcomas were found in the 15 males considered to be at risk (26%) at weeks 49, 51, 60, & 91. Mice were observed for 90 weeks, at which time only 3 males & 3 females were still alive.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 293

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ A group of 40 male & 40 female 8-wk old random-bred ctm albino mice received SC implants into right flank of 15x1.2 mM...discs & were observed for lifespan; 18 females & 9 males developed sarcomas

around the disc, a total incidence of 38% of the 69 mice still alive at time of appearance of first tumor.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 294

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ 3 Groups of 38, 38 & 39 6-7 wk old female Balb/c, C3Hf/dp & c57Bl/he mice received sc implants of...discs (15x1.2 mm) in dorsal area. Fibrosarcomas developed around discs in 17/38 (44%) Balb/c, 36/38 (94%) C3Hf/dp & 12/39 (30%) C57Bl/he animals... of 56 tumors examined...2 were rhabdomyosarcomas and rest fibrosarcomas.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 294

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ A group of 65 weanling wistar rats of both sexes received single SC...implants (4x5x0.16 mm) in abdominal wall; 55 rats were still alive after 300 days & 45 @ the time of appearance of the first tumor (659 days)... two SC sarcomas were induced; no tumors were observed in 20 control animals receiving glass implants...

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 294

/LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Weanling Wistar rats...implanted ip with 10x2x2 mM...rods (16 rats) or equiv amt of...powder (17 rats). ...27 MO after implantation...no tumors found in rod-implanted rats...2 sarcomas...in powder-treated /rats/...

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 295

/ALTERNATIVE and IN VITRO TESTS/ PURPOSE: This study examined the nature of protein interactions with particulate polytetrafluoroethylene (PTFE, Teflon) to elucidate possible mechanisms involved in the foreign body response directed against failed Proplast/Teflon implants. MATERIALS AND METHODS: Fifty milligrams PTFE prepared to particle sizes ranging from < 32 microns to > 300 microns was incubated with newborn bovine serum. The total amount of protein adsorbed to the PTFE particles was determined using a standard colorimetric assay. The structural and functional integrity of the proteins adsorbed to PTFE was also examined. For these studies, xanthine oxidase was substituted for serum, and the enzymatic activity of xanthine oxidase adsorbed to PTFE was determined. Finally, primary interactions between protein and PTFE particles were assessed in experiments using water, 2 or 8 mol/L urea, 1 mol/L NaCl, or 1% sodium dodecyl sulfate in an attempt to dissociate bound protein from the surfaces of PTFE particles. RESULTS: Serum proteins bind almost instantly to the surface of PTFE particles. The effective surface area of PTFE increases dramatically with reduction of the material to small particles, as does the total amount of

protein adsorbed by the particulate PTFE. Proteins bind to PTFE principally by hydrophobic interactions, and their three-dimensional structure is significantly perturbed by this interaction. In the case of xanthine oxidase, adsorption to PTFE distorts protein structure to the extent that biologic activity is eliminated. CONCLUSIONS: The amount of serum protein adsorbed to PTFE particles varies inversely with particle size for a constant mass of material. It is believed that the foreign body response directed against this material is related to the amount and relative distortion of proteins adsorbed to its surface. If so, it appears that reduction of an implant to small particles (typically 50 micron or less) will dramatically increase the biologic signal to local cell populations. Thus, the severity of the biologic response to PTFE debris may be dependent largely on the size of the debris particles.

PMID:8676233

Zardeneta G et al; J Oral Maxillofac Surg. 54 (7): 873-8 (1996)

/VETERINARY CASE REPORTS/ Two groups of chickens (*Gallus domesticus*; White Leghorn; age, 4 d and 2 wk) housed in a university research vivarium were found dead or moribund without prior signs of illness. The overall mortality rates were 92.3% (60 of 65 birds) for the 4-d-old birds and 80% (8 of 10) for the 2-wk-old birds. All chicks were housed in brooders with heat lamps in a temperature- and humidity-controlled room. Primary gross findings were mild to moderate dehydration and hepatic lipidosis. The most consistent histologic findings were pulmonary hemorrhage and edema in all 7 of the 4-d-old birds evaluated and in all 4 of the 2-wk-old birds assessed. In addition, 1 of the 4-d-old birds had multifocal centrilobular hepatic necrosis. These findings suggested an inhaled toxicant and hypoxia, respectively. Inspection of the animal room revealed that approximately 50% of the heat lamp bulbs in the brooder cage were coated with polytetrafluoroethylene (PTFE). Two published case reports detail similar experiences in birds exposed to PTFE-coated heat-lamp bulbs. Birds are highly sensitive to inhaled toxicants owing to the high efficiency of their respiratory systems, and PTFE toxicosis is known to cause pulmonary edema and hemorrhage in pet birds after exposure to overheated nonstick cookware. In the present case, the bulbs were replaced, and no similar problems subsequently have been noted. This case illustrates the sensitivity of avian species to respiratory toxicants and serves as a reminder that toxicosis can be encountered even in the controlled environment of a laboratory vivarium.

PMID:22330651

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3276392>

Shuster KA et al; Comp Med. 62 (1): 49-52 (2012)

/VETERINARY CASE REPORTS/ A poultry research facility that housed 2400 Peterson x Hubbard cross broilers (48 pens of 50 chicks each) experienced 4% mortality within 24 hr of chick placement. Mortality started within 4 hr of placement, and within 72 hr, cumulative mortality had reached 52%. Mild dyspnea was the only clinical sign noted in some chicks prior to death. The primary gross lesion noted in the chicks submitted was moderate to severe pulmonary congestion. The lungs of four of these chicks sank in formalin, and blood-tinged fluid was noted in the mouth and nares of two chicks. The microscopic lesions noted in the affected chicks were moderate to severe pulmonary edema and

congestion. The diagnosis indicated to the submitter was that pulmonary edema caused by exposure to an unidentified noxious gas caused the death of the chicks. The poultry house environment was tested for sulfur dioxide, oxides of nitrogen, carbon monoxide, carbon dioxide, and volatile organic compounds (as produced by combustion engines); all tests were negative for significant levels of these compounds. A second broiler flock was placed in the same facility and the mortality at 6 wk was 11%, which was greater than the 2.5%-4.7% mortality seen in the previous four flocks on the farm. Further investigation revealed that the only change in management practice in this facility prior to the onset of the severe mortality problem was the replacement of 48 heat lamp bulbs (one for each pen). The new heat lamp bulbs were polytetrafluoroethylene (PTFE) coated. PTFE gas intoxication has been reported in several exotic avian species, but this intoxication has not been previously reported in a poultry flock.

[PMID:10879927](#)

Boucher M et al; Avian Dis. 44 (2): 449-53 (2000)

/VETERINARY CASE REPORTS/ Psittacine birds can develop severe and often fatal pneumonitis when exposed to various noxious inhalants. Toxicosis in these birds caused by inhalation of pyrolysis products produced from overheated polytetrafluoroethylene-coated cooking pans on stove tops is well known, but compounds emitted from burned foods and other materials can also be toxic. We present a case of fatal pneumonitis in 10 psittacine birds associated with the operation of an oven in the self-cleaning mode.

[PMID:1455609](#)

Stoltz JH et al; Vet Hum Toxicol. 34 (5): 420-1 (1992)

/VETERINARY CASE REPORTS/ Overheating of nonstick cookware is a known cause of PTFE toxicosis in avian species and has often been reported anecdotally in pet birds in the veterinary clinical literature. PTFE toxicosis due to heat-lamp bulbs has been a less common occurrence but may begin to increase in frequency, given that the US Food and Drug Administration now requires the use of PTFE-coated heat-lamp bulbs in the food service industry, to prevent shattering. A few companies do still manufacture noncoated bulbs.

Shuster KA et al; Comp Med 62 (1): 49-52 (2012)

/VETERINARY CASE REPORTS/ Five cockatiels (*Nymphicus hollandicus*) died within 30 minutes following exposure to fumes from a frying pan coated with the "non-stick" plastic polytetrafluoroethylene (PTFE) that had accidentally overheated. Within an hour the owner developed symptoms of "polymer fume fever" but recovered in the next 24 hours. Clinical signs and post mortem lesions of the cockatiels are described and reference is made to the unusual susceptibility of parakeets to the pyrolysis products of frying pans coated with PTFE.

[PMID:1119084](#)

Blandford TB et al; Vet Rec. 96 (8): 175-8 (1975)

/VETERINARY CASE REPORTS/ ...Because birds are very sensitive to fumes released by non-stick cookware, some organizations of pet bird owners recommend minimizing a bird's

exposure to these fumes by keeping pet birds out of the kitchen or by increasing ventilation if non-stick cookware is used.

American Cancer Society; Teflon and Perfluorooctanoic Acid (PFOA); Available from, as of August 12, 2015: <https://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoic-acid--pfoa>

/OTHER TOXICITY INFORMATION/ /Pan temperatures at which the pyrolysis products from PTFE-coated frypans were lethal to Japanese quail, parakeets or rats exposed for 4 hrs were/ 330 °C /for Quail/, 280 °C /for Parakeets/, 425-450 °C /for Rats/. /From table/

PMID:1175553

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1475183>

Waritz RS; Environ Health Perspect 11: 197-202 (1975)

/OTHER TOXICITY INFORMATION/ Polytetrafluoroethylene heated to 300 °C in air was lethal to rats... gases identified during pyrolysis...incl tetrafluoroethylene, hexafluoroethylene, hexafluoropropylene, octafluorocyclobutane & octafluoroisobutylene.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 295

/OTHER TOXICITY INFORMATION/ Rodents exposed to...pyrolysis products showed signs of pulmonary irritation & edema & diffuse degeneration of the brain, liver, & kidneys.

/Pyrolysis products/

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 296

/OTHER TOXICITY INFORMATION/ /Teflon/...implanted in peritoneal cavities of 3 dogs, caused only slight surface tissue reaction, while a few giant cells were found at site of foreign body.

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 233

/OTHER TOXICITY INFORMATION/ Mice exposed to pyrolysis products developed necrosis of epithelium of distal & proximal convoluted tubules. Abnormalities in renal weight, & urine output were noted immediately following exposure. /Pyrolysis products/

LUCIA HL ET AL; J COMBUST TOXICOL 5(3) 270 (1978)

/OTHER TOXICITY INFORMATION/ Thermal decomp products of polytetrafluoroethylene caused pathological changes of upper resp tract in mice. PTFE was most toxic in relation to acute lethality, sensory irritation, & histopathological changes of other compd.

BARROW CS ET AL; AM IND HYG ASSOC J 40(5) 408 (1979)

/OTHER TOXICITY INFORMATION/ Rabbits inhaling thermal decomp products formed at 400 deg showed lung damage. /Thermal decomposition products/

LIANG Y ET AL; CHUNG-HUA YU FANG I HSUEH TSA CHIH, 14(2) 128 (1980)

/OTHER TOXICITY INFORMATION/ The max allowable concn of tetrafluoroethylene in rabbits was 6-8 mg/cu M for 3 MO. These products caused damage to the lung.

/OTHER TOXICITY INFORMATION/ Acid products of polytetrafluoroethylene degraded @ 550 deg adsorbed on aerosol particles, exerted pyrogenic effects on rabbits. The fever was accompanied by short-lasting leukopenia followed by leukocytosis.

KALININ BY; KHIM PROM-ST, SER: TOKSIKOL SANIT KHIM PLASTMASS, (2): 17 (1979)

/OTHER TOXICITY INFORMATION/ Suburothelial injections of particulate poly(tetrafluoroethylene) (PTFE) is becoming a widely accepted treatment for a number of urological disorders. Because little is known about the long-term histologic morphology of the injection site, this animal study was performed. Three populations, each consisting of two mongrel dogs, five New Zealand White rabbits, and 10 BALB/c mice, were injected with poly(tetrafluoroethylene) particulate in a glycerine carrier (Polytef Paste) and were followed for a period of 1 week, 3 months, 6 months, and 1 year. Mice received one subcutaneous dorsal injection each, rabbits received two subareolar injections each, and dogs received three subareolar injections each in addition to two periurethral injections. Histologic examination of the biopsy sites revealed a persistent chronic inflammatory reaction with progressive growth of the involved tissue volume. In addition to giant cells and macrophages, lymphocytes became apparent at 3 months and constituted up to 40% of the cellular infiltrate by 1 year. Plasma cells were also noted at the 1-year period in the rabbit model. The progressive growth of the inflammatory pseudo-tumors evoked by injected PTFE may compromise the long-term safety of certain urological procedures involving particulate PTFE.

[PMID:1812120](#)

Kossovsky N et al; J Biomed Mater Res. 25 (10): 1287-301 (1991)

/OTHER TOXICITY INFORMATION/ Polytetrafluoroethylene (PTFE), a synthetic polymer widely used as a nonstick surface in cookware, releases toxic pyrolysis products when exposed to excessive heat. Thirty-two budgerigars (*Melopsittacus undulatus*) were exposed to pyrolysis products of either heated PTFE cookware or plain aluminum cookware in a specially designed exposure chamber for given periods. Clinical signs were recorded and necropsies were done on all birds at the termination of each exposure period. The PTFE products caused acute respiratory distress and rapid death in many of the exposed birds. At necropsy, lesions were seen only in the respiratory tract--extensive pulmonary hemorrhage and congestion.

[PMID:7103205](#)

Wells RE et al; Am J Vet Res. 43 (7): 1238-42 (1982)

/OTHER TOXICITY INFORMATION/ In addition to the usual toxicology studies necessary for the safe manufacture and use of polymers at room temperature, special studies are needed for polymers which will be used at elevated temperatures. This paper discusses various areas to be investigated and principles for deciding on test materials, tests, and test conditions, polytetrafluoroethylene (PTFE) and fluorinated polyethylene-propylene (PFEP) pyrolysis studies being used as an illustrative case history. Some limitations of animal

testing also are mentioned. A toxicological spectrum relating toxicological determinants to PTFE temperature is developed.

[PMID:1175553](#)

Full text: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1475183>

Waritz RS; *Environ Health Perspect* 11: 197-202 (1975)

3.2 Ecotoxicity Excerpts (Complete)



/AQUATIC SPECIES/ Trifluoroacetate (CH_3COO^- , TFA) is a breakdown product of hydrochlorofluorocarbons and hydrofluorocarbons and is released by the heating of Teflon products. Because of its chemical properties, concentrations in evaporative wetlands are predicted to increase with time. This study focused on assessing the impact of this haloacetic acid on vernal pool soil microbial communities as well as vernal pool and wetland plant species. Microbial respiration for three vernal pool soils and an agricultural soil was not affected by TFA exposures (0, 10, 100, 1,000, and 10,000 $\mu\text{g/L}$), and degradation of TFA by microbial communities was not observed in soils incubated for three months. Trifluoroacetate accumulated in foliar tissue of wetland plant species as a function of root exposure concentration (100 and 1,000 $\mu\text{g/L}$ TFA), and accumulation was found to stabilize or decrease after the second or third month of exposure. Seeds accumulated TFA as a function of root exposure concentration; however, germination success was not affected. No adverse physiological responses, including general plant health and photosynthetic and conductance rates, were observed for root exposures at the TFA concentrations used in this study. Based on the soils and plant species used in this study, predicted TFA concentrations will not adversely affect the development of soil microbial communities and vernal pool plant species. /Trifluoroacetate; degradation product/

Benesch JA et al; Environ Toxicol Chem 21 (3): 640-47 (2002)

3.3 FIFRA Requirements (Complete)



Residues resulting from the use of the following substances, that meet the definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR 723.250, as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices. Polytetrafluoroethylene is included on this list.

40 CFR 180.960 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

4 Metabolism / Pharmacokinetics



4.1 Absorption, Distribution and Excretion (Complete)



Exposure to pyrolysis products equiv to 50 ppm carbonyl fluoride for 1 hr daily incr the fluoride ion content of urine of rats from 3 to 42 ug/ml in 5 days...

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 295

Fluoride levels in urine are greater than normal in workers exposed to fumes of polytetrafluoroethylene.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 296

/Teflon/ paste material can be transported by lymphatics.

Rossoff, I.S. Handbook of Veterinary Drugs. New York: Springer Publishing Company, 1974., p. 467

4.2 Mechanism of Action (Complete)



The major gaseous degradation products of PTFE are hydrogen fluoride, carbonyl fluoride, and various fluorinated hydrocarbons. The health effects of the gaseous fraction at the concentrations, which occur in the PTFE processing industry, are not clearly known. The ultrafine particles, which are produced in the degradation, have turned out to be the cause of the toxic pulmonary and lethal effects in the experimental animals. These particles probably carry to the lungs small molecular products (e.g. hydrogen fluoride, carbonyl fluoride) and very reactive compounds like free radicals, because their effectiveness strongly depends on the age of the particle. The agents in the degradation products, which cause polymer fume fever, are not known.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and Polytetrafluoroethylene in the Processing of Plastics. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

It seems that ultrafine particles with a median diameter of approximately 26 nm cause the high pulmonary toxicity and mortality /in animals/. The effects are eliminated if the particles are filtered away from the exposure atmosphere. It has been suggested that particles contain very reactive compounds, e.g. free radicals. If an additional vessel is placed into the degradation product stream between the degradation system and the animals, thus ageing of the particles, the toxicity decreases.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and Polytetrafluoroethylene in the Processing of Plastics. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

Pet birds are susceptible to developing PTFE toxicosis. Most of these cases have been due to overheated frying pans within the household. At temperatures above 280 °C, PTFE-coated surfaces begin to emit degradation products in the form of particulates and gas. Subsequent inhalation of these by-products by birds can result in various clinical signs,

including open-beak breathing, chirping, incoordination, lateral recumbency, convulsions, and death. The most common pathologic lesion is severe, extensive, necrotizing and hemorrhagic pneumonitis and edema. The primary mechanism of injury is direct injury of type I pneumocytes and capillary endothelial cells by PTFE degradation products, allowing fluid and blood to leak into the airways. Although PTFE toxicosis has been reported infrequently in humans as 'polymer fume fever,' birds are much more sensitive to inhaled toxicants. This unique sensitivity of birds is due to the anatomy of their respiratory system. Most birds have 9 air sacs (with some species-dependent variations) surrounding the lungs. The lungs are very rigid and do not expand; instead, the air sacs act as a bellows to ventilate the lungs, which are the site of gas exchange. Due to this structural arrangement, airflow within the avian respiratory system is unidirectional. Gas exchange occurs in the lungs as a cross-current system. Specifically, this situation means that air passing through the parabronchi and blood moving through the capillaries travel at right angles to each other. This arrangement allows for very efficient gas exchange as carbon dioxide and oxygen pressure gradients are preserved along the length of the connection between the parabronchus and capillary system. However, other gases (for example, PTFE degradation products, carbon monoxide) that are contained in the inhaled air will also be present at increased levels with oxygen. If the gas is toxic, this increased concentration will lead to significant respiratory compromise, resulting in hypoxia and associated hepatic damage.

Shuster KA et al; Comp Med 62 (1): 49-52 (2012)

5 Pharmacology



5.1 Therapeutic Uses (Complete)



EXPL THER Here, we described the in vitro biocompatibility of a novel nanostructured surface composed of PTFE as a potential polymer for the prevention of adverse host reactions to implanted devices. The foreign body response is characterized at the tissue-material interface by several layers of macrophages and large multinucleated cells known as foreign body giant cells (FBGC), and a fibrous capsule. The nanofibers of nanofibrous PTFE (nPTFE) range in size from 20 to 30 nm in width and 3-4 mm in length. Glass surfaces coated with nPTFE (produced by jet-blowing of PTFE 601A) were tested under in vitro conditions to characterize the amount of protein adsorption, cell adhesion, and cell viability. We have shown that nPTFE adsorbs 495 +/- 100 ng of bovine serum albumin (BSA) per sq cm. This level was considerably higher than planar PTFE, most likely due to the increase in hydrophobicity and available surface area, both a result of the nanoarchitecture. Endothelial cells and macrophages were used to determine the degree of cell adsorption on the surface of the nanostructured polymer. Both cell types were significantly more round and occupied less area on nPTFE as compared to tissue culture polystyrene (TCPS). Furthermore, a larger majority of the cells on the nPTFE were dead compared to TCPS, at dead-to-live ratios of 778 +/- 271 to 1 and 23 +/- 5.6 to 1, respectively. Since there was a high amount of cell death (due to either apoptosis or necrosis), and the foreign body

response is a form of chronic inflammation, an 18 cytokine Luminex panel was performed on the supernatant from macrophages adherent on nPTFE and TCPS. As a positive control for inflammation, lipopolysaccharide (LPS) was added to macrophages on TCPS to estimate the maximum inflammation response of the macrophages. From the data presented with respect to IL-1, TNF-alpha, IFN-gamma, and IL-5, we concluded that nPTFE is nonimmunogenic and should not yield a huge inflammatory response in vivo, and cell death observed on the surface of nPTFE was likely due to apoptosis resulting from the inability of cells to spread on these surface. On the basis of the production of IL-1, IL-6, IL-4, and GM-CSF, we concluded that FBGC formation on nPTFE may be decreased as compared to materials known to elicit FBGC formation in vivo.

[PMID:17209629](#)

Ainslie KM et al; Langmuir. 23 (2): 747-54 (2007)

We previously showed that ringed polytetrafluoroethylene (PTFE) grafts combined with small allograft patches showed high patency rates similar to those of iliac vein grafts and therefore that they can be used for middle hepatic vein (MHV) reconstruction. Although such use of PTFE graft showed high patency rates, its long-term safety regarding infection and other types of complications were not presented. In this study, we investigated the actual risk of complications directly associated with PTFE graft interposition for MHV reconstruction. METHODS: During the study period of 30 months, we performed 215 cases of adult living-donor liver transplantation with modified right lobe graft and PTFE grafts. We classified the potential complications directly associated with PTFE graft interposition as infectious and surgical complications. The medical records of study patients were retrospectively reviewed. RESULTS: MHV graft patency rate was 76.3% at 6 months and 36.7% at 12 months. Their 1-year graft and patient survival rates were 92.6% and 93.5%, respectively. The 1-year actual incidences of infectious complication and surgical complication were near zero and 1 case (0.5%), respectively. In 1 recipient, the PTFE graft penetrated into the stomach wall 6 months after transplantation, but the patient did not complain of any specific symptoms. The PTFE graft was removed with the use of laparotomy, and the patient recovered uneventfully. CONCLUSIONS: Although the incidence of PTFE graft-associated complication rate is very low, we suggest that it is necessary to closely monitor the PTFE graft, because unexpected complications can happen during long-term follow-up.

[PMID:24767363](#)

Ha TY ET AL; Transplant Proc. 46 (3): 845-9 (2014)

A 73-year-old female with sick sinus syndrome and atrial fibrillation was implanted with a ventricular demand inhibit pacemaker. She subsequently developed multiple episodes of skin irritation and necrosis. Skin patch testing revealed sensitivity to almost every component of the pacemaker system. The pacemaker was removed and replaced with a new pacemaker in which the generator was covered with a polytetrafluoroethylene (PTFE) sheet and the lead was covered with PTFE conduit. The patient suffered no further episodes of pacemaker-associated contact dermatitis.

[PMID:24899091](#)

The teflon hip arthroplasty design was used by Sir John Charnley in the early 60's but was taken off the market due to high complication rates. A case is reported of an intrapelvic granuloma after total hip arthroplasty following the use of a teflon socket. This appears to be the last surviving patient treated by Sir John Charnley using a Teflon hip socket design.
/Former use/

[PMID:20306978](#)

Gheorghiu D et al; *Acta Orthop Belg*. 76 (1):129-31 (2010)

Management of unilateral vocal fold paralysis continues to generate controversy. Various techniques, but essentially teflon injection and thyroplasty I have been widely used for medialization. Assessment procedures largely differ from author to author: a few authors report objective superiority of thyroplasty (small series). In our own material (19 teflon injections and 9 thyroplasties), when considering objective functional outcomes and patient satisfaction, we cannot demonstrate a statistically significant superiority of one of the techniques, both of them giving very satisfactory results. When considering the literature, the main problem with teflon is delayed (up to 25 years) occurrence of granulomas, which is reported as not unfrequent and to some extent unpredictable. Management of teflon granulomas is difficult. Most major complications of thyroplasty (airway obstruction/prosthesis extrusion) occur quite early after surgery and can better be controlled.

[PMID:9865105](#)

Dejonckere PH; *Rev Laryngol Otol Rhinol (Bord)*. 119 (4): 265-9 (1998)

5.2 Drug Warnings (Complete)



Soft tissue reactions to materials in joint prostheses include discoloration, fibrosis, florid histiocytic reaction, and granulomatous inflammation with foreign body giant cell reaction. Clinical manifestations include pain and swelling. We report a case of temporomandibular joint Proplast-Teflon prosthesis, followed by the development of large cell lymphoma in the left parotid gland 10 years after joint replacement. While it is unclear whether the implant directly contributed to the development of lymphoma, this association has not been previously documented, prompting this report.

[PMID:22533111](#)

Ong MG et al; *J La State Med Soc*. 164 (1): 31-2 (2012)

Expanded polytetrafluoroethylene implant is usually considered as a wonderful implant for chin cosmetic augmentation with no or less bone resorption compared with solid silicone implant. However, one severe bony erosion in expanded polytetrafluoroethylene chin augmentation was found in our clinical work. We consider that the possible reason about severe bone resorption in such situation is most relative to the mentalis muscle hyperactivity, rather than the kinds of materials. We also strongly advise that genioplasty is suitable for the cases with mentalis muscle hyperactivity caused by a dentofacial deformity.

[PMID:24036760](#)

Shi L et al; J Craniofac Surg. 24 (5): 1711-2 (2013)

Positron emission tomography with (18)F-fluorodeoxyglucose (18FDG) has been increasingly used in the diagnostic investigation of patients with neoplasms of the head and neck. Positron emission tomography and computed tomography have also proven useful for surveillance of thyroid cancers that no longer concentrate radioiodine. However, certain benign or inflammatory lesions can also accumulate (18)F-fluorodeoxyglucose and lead to misdiagnosis. We review and discuss the pitfalls of using positron emission tomography and computed tomography for surveillance of thyroid cancer. We present the case of a 48-year-old woman who was diagnosed with a laryngeal neoplasm on integrated positron emission tomography and computed tomography scanning, after a routine ultrasound demonstrated an enlarged thyroid nodule. On physical examination, she had a laryngeal mass overlying an immobile vocal fold. The mass was biopsied and found to harbour a Teflon granuloma. Positron emission tomography positive Teflon granulomas have previously been reported in the nasopharynx and vocal folds, and should be considered in the differential diagnosis of patients who have undergone prior surgery involving Teflon injection. It is important for otolaryngologists and radiologists to recognise potential causes of false positive positron emission tomography and computed tomography findings, including Teflon granulomas.

[PMID:18976510](#)

Ondik MP et al; J Laryngol Otol. 123 (5): 575-8 (2009)

6 Environmental Fate & Exposure



6.1 Environmental Fate / Exposure Summary



Teflon's production and use in packaging, bearings, filters, electrical insulation, high temperature industrial plastics, anti-stick coatings for cooking vessels, plumbing sealants, coatings and other applications may result in its release to the environment through various waste streams. If released to air, Teflon will exist solely in the particulate phase in the atmosphere since Teflon is a high molecular weight polymer. Teflon is highly resistant to oxidation, UV rays, ozone and weathering. Particulate-phase Teflon may be removed from the air by wet and dry deposition. If released to soil, Teflon is expected to have no mobility since it is a polymer that is not wetted by water. Teflon is reported to be non-biodegradable and inert to microbiological attack. If released into water, volatilization from water surfaces is not expected to be an important fate process. Occupational exposure to Teflon may occur through inhalation and dermal contact with this compound at workplaces where Teflon is produced or used. Use data indicate that the general population may be exposed to Teflon via dermal contact with consumer products containing Teflon. (SRC)

6.2 Probable Routes of Human Exposure (Complete)



According to the 2012 TSCA Inventory Update Reporting data, 2 reporting facilities estimate the number of persons reasonably likely to be exposed during the manufacturing, processing, or use of Teflon (9002-84-0) are 50-99 and Unknown, respectively, workers per plant; the data may be greatly underestimated due to confidential business information (CBI) or unknown values(1).

(1) US EPA; Chemical Data Reporting (CDR). Non-confidential 2012 Chemical Data Reporting information on chemical production and use in the United States. Available from, as of Sept 22, 2015: https://java.epa.gov/oppt_chemical_search/

NIOSH (NOES Survey 1981-1983) has statistically estimated that 867,257 workers (277,117 of these were female) were potentially exposed to Teflon in the US(1). Occupational exposure to Teflon may occur through inhalation and dermal contact with this compound at workplaces where Teflon is produced or used. Use data indicate that the general population may be exposed to Teflon via dermal contact with consumer products containing Teflon(SRC).

(1) NIOSH; NOES. National Occupational Exposure Survey conducted from 1981-1983. Estimated numbers of employees potentially exposed to specific agents by 2-digit standard industrial classification (SIC). Available from, as of Sept 22, 2015: <https://www.cdc.gov/noes/>

Polytetrafluoroethylene dust (Teflon) has been detected in workplace environments during the thermal processing of fluoroplastics(1). A group of nine men employed in manufacturing of Teflon developed an illness while working with Teflon; the cause was presumed to be inhalation of fumes from cigarettes contaminated with Teflon dust(2). Over-heating of Teflon-coated cookware can potentially release dangerous fumes, from the degradation product perfluorooctanoic acid, that can cause flu-like symptoms in people and is fatal to birds(3).

(1) IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Some Monomers, Plastics and Synthetic Elastomers, and Acrolein. 19: 285-301 (1979). Available from, as of Sept 23, 2015: <https://monographs.iarc.fr/ENG/Monographs/vol1-42/index.php> (2) Walker B, Stokes LD; Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012. (3) American Cancer Society; Teflon and Perfluorooctanoic Acid (PFOA). Available from, as of August 12, 2015: <https://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoic-acid--pfoa>

6.3 Natural Pollution Sources (Complete)



Teflon is not known to occur as a natural product(1).

(1) IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Some Monomers, Plastics and Synthetic Elastomers, and Acrolein. 19: 285-301 (1979). Available from, as of Sept 23, 2015: <https://monographs.iarc.fr/ENG/Monographs/vol1-42/index.php>

6.4 Artificial Pollution Sources (Complete)



Teflon's production and use in packaging, bearings, filters, electrical insulation, high temperature industrial plastics, anti-stick coatings for cooking vessels, plumbing sealants, coatings and other applications(1) may result in its release to the environment through various waste streams(SRC).

(1) Lewis RJ Sr; *Hawley's Condensed Chemical Dictionary*. 15th ed., New York, NY: John Wiley & Sons, Inc., p. 1019, 1209 (2007)

6.5 Environmental Fate (Complete)



TERRESTRIAL FATE: Teflon is a high molecular weight polymer(1) that is not wetted by water(2). This suggests that Teflon is expected to be immobile in soil(SRC). Teflon is reported to be non-biodegradable(3) and inert to microbiological attack(4).

(1) Walker B, Stokes LD; *Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides*. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012. (2) O'Neil MJ, ed; *The Merck Index*. 15th ed., Cambridge, UK: Royal Society of Chemistry, p. 1412 (2013) (3) Simonovsky F; *Biomaterials Tutorial, Polytetrafluoroethylene (PTFE)*. University of Washington Engineered Biomaterials. Available from, as Sept 23, 2015:

<https://www.uweb.engr.washington.edu/research/tutorials/ptfe.html> (4) Norva Plastics; Teflon. Available from, as of Sept 23, 2015: <https://www.norvaplastics.com/teflon.asp>

AQUATIC FATE: Teflon is a high molecular weight polymer(1) that is not wetted by water(2). This suggests that Teflon is expected to be nonvolatile from water(SRC). Teflon is reported to be non-biodegradable(3) and inert to microbiological attack(4). Teflon is completely resistant to hydrolysis(4).

(1) Walker B, Stokes LD; *Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides*. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012. (2) O'Neil MJ; *The Merck Index*. Cambridge, UK: Royal Society of Chemistry, p. 1412 (2013) (3) Simonovsky F; *Biomaterials Tutorial, Polytetrafluoroethylene (PTFE)*. University of Washington Engineered Biomaterials. Available from, as Sept 23, 2015:

<https://www.uweb.engr.washington.edu/research/tutorials/ptfe.html> (4) Norva Plastics; Teflon. Available from, as of Sept 23, 2015: <https://www.norvaplastics.com/teflon.asp>

ATMOSPHERIC FATE: Teflon is a high molecular weight polymer (molecular weight in the range of 4×10^5 to 1×10^7)(1). Therefore, Teflon is expected to exist solely in the particulate phase in the ambient atmosphere(SRC). Teflon is highly resistant to oxidation, UV rays, ozone and weathering(2). Particulate-phase Teflon may be removed from the air by wet and dry deposition(SRC).

(1) Walker B, Stokes LD; *Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides*. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012. (2) Lewis RJ Sr; *Hawley's Condensed Chemical Dictionary* 15th ed., New York, NY: John Wiley & Sons, Inc., p. 1019 (2007)

6.6 Environmental Biodegradation (Complete)



Teflon is reported to be non-biodegradable(1) and inert to microbiological attack(2).

(1) Simonovsky F; *Biomaterials Tutorial, Polytetrafluoroethylene (PTFE). University of Washington Engineered Biomaterials. Available from, as Sept 23, 2015: <https://www.uweb.engr.washington.edu/research/tutorials/ptfe.html>* (2) Norva Plastics; Teflon. Available from, as of Sept 23, 2015: <https://www.norvaplastics.com/teflon.asp>

6.7 Environmental Abiotic Degradation (Complete)



Teflon is highly resistant to oxidation, UV rays, ozone and weathering(1). Teflon exhibits excellent retention of properties after a long period of time, even at elevated temperatures and in the presence of oils, solvents, UV light, oxidizing agents and other environmental agents(2). However, Teflon is subject to thermolysis (degradation to trifluoroacetate) in industrial and consumer high-temperature applications (ovens, non-stick cooking utensils and combustion engines)(3). Teflon is completely resistant to hydrolysis(2).

(1) Lewis RJ Sr; *Hawley's Condensed Chemical Dictionary. 15th ed., New York, NY: John Wiley & Sons, Inc., p. 1019 (2007) <https://www.norvaplastics.com/teflon.asp>* (2) Norva Plastics; Teflon. Available from, as of Sept 23, 2015: (3) Ellis DA et al; *Nature 412: 321-324 (2001)*

Following the introduction of hydrochlorofluorocarbon (HCFCs) and hydrofluorocarbon (HFCs) gases as replacements for the ozone-destroying chlorofluorocarbons (CFCs), it has been discovered that HCFCs/HFCs can degrade in the atmosphere to produce trifluoroacetic acid, a compound with no known loss mechanisms in the environment, and higher concentrations in natural waters have been shown to be mildly phytotoxic. Present environmental levels of trifluoroacetic acid are not accounted by HCFC/HFC degradation alone. Here we report that thermolysis of fluorinated polymers, such as the commercial polymers Teflon and Kel-F, can also produce trifluoroacetate and the similar compound chlorodifluoroacetate. This can occur either directly, or indirectly via products that are known to degrade to these haloacetates in the atmosphere. The environmental significance of these findings is confirmed by modelling, which indicates that the thermolysis of fluoropolymers in industrial and consumer high-temperature applications (ovens, non-stick cooking utensils and combustion engines) is likely to be a significant source of trifluoroacetate in urban rain water (approximately 25 ng L⁻¹, as estimated for Toronto). Thermolysis also leads to longer chain polyfluoro- and/or polychlorofluoro- (C3-C14) carboxylic acids which may be equally persistent. Some of these products have recently been linked with possible adverse health and environmental impacts and are being phased out of the US market. Furthermore, we detected CFCs and fluorocarbons-groups that can destroy ozone and act as greenhouse gases, respectively-among the other thermal degradation products, suggesting that continued use of fluoropolymers may also exacerbate stratospheric ozone-depletion and global warming.

PMID:11460160

Ellis DA et al; Nature. 412 (6844): 321-4 (2001)

6.8 Soil Adsorption / Mobility (Complete)



Teflon is a high molecular weight polymer(1) that is not wetted by water(2). This suggests that Teflon is expected to be immobile in soil(SRC).

(1) Walker B, Stokes LD; *Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012.* (2) O'Neil MJ, ed; *The Merck Index. 15th ed., Cambridge, UK: Royal Society of Chemistry, p. 1412 (2013)*

6.9 Volatilization from Water / Soil (Complete)



Teflon is a high molecular weight polymer(1) that is not wetted by water(2). This suggests that Teflon is expected to be nonvolatile from water and soil(SRC).

(1) Walker B, Stokes LD; *Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012.* (2) O'Neil MJ, ed; *The Merck Index. 15th ed., Cambridge, UK: Royal Society of Chemistry, p. 1412 (2013)*

7 Environmental Standards & Regulations



7.1 Allowable Tolerances (Complete)



Residues resulting from the use of the following substances, that meet the definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR 723.250, as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices. Polytetrafluoroethylene is included on this list.

40 CFR 180.960 (USEPA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

7.2 State Drinking Water Guidelines (Complete)



(CT) CONNECTICUT 55 ug/l

USEPA/Office of Water; Federal-State Toxicology and Risk Analysis Committee (FSTRAC). Summary of State and Federal Drinking Water Standards and Guidelines (11/93) To Present

7.3 FDA Requirements (Complete)



Polytetrafluoroethylene is an indirect food additive for use only as a component of adhesives.

21 CFR 175.105 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

An intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene is a fabric device placed in the heart that is used to repair septal defects, for patch grafting, to repair tissue, and to buttress sutures.

21 CFR 870.3470 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

Polytetrafluoroethylene injectable is an injectable paste prosthetic device composed of polytetrafluoroethylene intended to be used to augment or reconstruct a vocal cord.

21 CFR 878.4520 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

Polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon intended for use in maxillofacial alveolar ridge augmentation (building up the upper or lower jaw area that contains the sockets in which teeth are rooted) or intended to coat metal surgical implants to be placed in the alveoli (sockets in which the teeth are rooted) or the temporomandibular joints (the joint between the upper and lower jaws).

21 CFR 872.3680 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

21 CFR 874.3450 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrane to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.

21 CFR 874.3495 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.

21 CFR 874.3695 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue

near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient's need.

21 CFR 878.3500 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

Nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE and is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

21 CFR 878.5035 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.

21 CFR 874.3430 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptoms of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. This device is made of polytetrafluoroethylene or silicone elastomer.

21 CFR 874.3820 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

21 CFR 874.3880 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A vascular graft prosthesis is an implanted device intended to repair, replace, or bypass sections of native or artificial vessels, excluding coronary or cerebral vasculature, and to provide vascular access. It is commonly constructed of materials such as polyethylene terephthalate and polytetrafluoroethylene, and it may be coated with a biological coating, such as albumin or collagen, or a synthetic coating, such as silicone. The graft structure itself is not made of materials of animal origin, including human umbilical cords.

21 CFR 870.3450 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

21 CFR 874.3930 (USFDA); U.S. National Archives and Records Administration's Electronic Code of Federal Regulations. Available from, as of August 26, 2015: <https://www.ecfr.gov>

8 Chemical / Physical Properties



8.1 Molecular Formula



$(C_2-F_4)X^-$

8.2 Molecular Weight



Molecular weight range is 400,000 to 10,000,000

Walker B, Stokes LD; Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012.

8.3 Color / Form (Complete)



White translucent to opaque solid

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Soft, waxy, milk-white solid

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19: 290 (1979)

White solid

Walker B, Stokes LD; Synthetic Polymers - Olefin, Diene Elastomers, and Vinyl Halides. Patty's Toxicology. 6th ed. (1999-2015). New York, NY: John Wiley & Sons, Inc. On-line Posting Date: Aug 17, 2012.

8.4 Melting Point



Melts to an extremely viscous gel at 327 °C

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

8.5 Density



2.2 g/cu cm

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Spun in molten state; density of threads about 2.3; breaking stress can reach 40 kg/sq mm with approx 30% elongation

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 39

8.6 Solubility (Complete)



No substance has been found which will dissolve the polymer at moderate temperatures

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

8.7 Other Experimental Properties (Complete)



Not wetted by water; subject to cold flow at high pressure

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Useful temp range cryogenic to +260 °C; Reverts to gaseous monomer at temperatures above 400 °C; Shore hardness 55-56; Tensile strength 3500-4500 psi; Flexural modulus about 80,000-90,000 psi at room temperature; Brittle point below -80 °C; Dielectric constant: 2.0-2.05 at 60 to 3X10+9 cycles

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Waxy, slippery feel

International Labour Office. Encyclopedia of Occupational Health and Safety. Volumes I and II. New York: McGraw-Hill Book Co., 1971., p. 1095

A highly stable thermoplastic tetrafluoroethylene homopolymer. Composed of at least 20,000 CF₂ monomer units linked into very long unbranched chains. Not affected by water, aqua regia, chlorosulfonic acid, acetyl chloride, boron fluoride, hot nitric acid, boiling solutions of sodium hydroxide and organic solvents.

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Low coefficient of friction; upon heating, weight loss varies from 0.001%/hr at 290 °C to 4%/hr at 450 °C

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19: 290 (1979)

Only alkali metals and fluorine under pressure attack Teflon below 300 °C

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 15

Does not carbonize in air at 700 °C; at 400 °C = 0.0002% weight loss/hr, at 500 °C = 0.0002% weight loss/hr; at 600 °C = 0.0002% weight loss/hr; at 680 °C = 0.001% weight loss/hr; at 734 °C = 0.006% weight loss/hr; at 788 °C = 0.09% weight loss/hr

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 205

Melts to an extremely viscous gel at 327 °C and reverts to the gaseous monomer at temperatures above 400 °C

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

9 Chemical Safety & Handling



9.1 Fire Potential



Under dynamic conditions...flow & pressure...Teflon /is/ ignited in fluorine-oxygen mixtures.

National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 491-89

The Combustion of Teflon in oxygen to give carbonyl fluoride is highly exothermic but a large ignition source is required. The minimum ignition temperature is 465 °C even under 7500 psi of oxygen gas.

National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 491-138

The ignition of Teflon tubing at -61 °C in supercritical oxygen at 900 psi required a hot nickel-chromium wire as an initiator.

National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 491-138

Teflon /is/ ignited @ 1,300 °F in a 5 psia /pounds per square inch absolute/ pure oxygen atmosphere, when used as a 20 AGW wire insulation.

National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 491-138

Sealing tape made of Teflon burned vigorously in contact with sodium-potassium alloy in a helium atmosphere.

National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 491-184

9.2 Fire Fighting Procedures (Complete)



Wear self contained breathing apparatus for fire fighting if necessary.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

9.3 Firefighting Hazards (Complete)



Carbon oxides, Hydrogen fluoride

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

9.4 Hazardous Reactivities and Incompatibilities (Complete)



Strong oxidizing agents

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

Incompatible with fluorine, sodium potassium alloy. Under the proper conditions it undergoes hazardous reactions with boron, magnesium, or titanium.

Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 3352

9.5 Personal Protective Equipment (PPE) (Complete)



Skin protection: Handle with gloves.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

Body Protection: Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

Respiratory protection: Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

9.6 Preventive Measures (Complete)



Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

The precautions that must be taken in the factory when polytetrafluoroethylene is worked below 300 °C can be summed up as removal of gases, fumes, & dust from work place & in addition specially good ventilation at dangerous places.

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 206

Workers are encouraged to wash their hands often to remove polytetrafluoroethylene dusts which can adhere to them. This advice is particularly directed to smokers who run a risk of breathing-in with the smoke of their contaminated tobacco the vapors given off by the ignited dusts. /PTFE dusts/

Lefaux, R. Practical Toxicology of Plastics. Cleveland: CRC Press Inc., 1968., p. 206

Smoking should be prohibited in areas where this material is being fabricated, or in general, where there may be dust from it.

Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 3352

...Because birds are very sensitive to fumes released by non-stick cookware, some organizations of pet bird owners recommend minimizing a bird's exposure to these fumes by keeping pet birds out of the kitchen or by increasing ventilation if non-stick cookware is used.

American Cancer Society; Teflon and Perfluorooctanoic Acid (PFOA); Available from, as of August 12, 2015: <https://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/teflon-and-perfluorooctanoic-acid--pfoa>

Provide appropriate exhaust ventilation at places where dust is formed.

9.7 Stability / Shelf Life (Complete)



Stable under recommended storage conditions.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

The finished polymerized compound is inert under ordinary conditions.

Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 3352

9.8 Storage Conditions (Complete)



Keep container tightly closed in a dry and well-ventilated place. Keep in a dry place.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

9.9 Cleanup Methods (Complete)



ACCIDENTAL RELEASE MEASURES; Personal precautions, protective equipment and emergency procedures: Avoid dust formation. Avoid breathing vapors, mist or gas. Environmental precautions: Do not let product enter drains. Methods and materials for containment and cleaning up: Sweep up and shovel. Keep in suitable, closed containers for disposal.

Sigma-Aldrich; Safety Data Sheet for Poly(tetrafluoroethylene). Product Number: 430935, Version 4.4 (Revision Date 06/29/2014). Available from, as of August 12, 2015:

<https://www.sigmaaldrich.com/safety-center.html>

9.10 Disposal Methods (Complete)



SRP: Recycle any unused portion of the material for its approved use or return it to the manufacturer or supplier. Ultimate disposal of the chemical must consider: the material's impact on air quality; potential migration in air, soil or water; effects on animal, aquatic and plant life; and conformance with environmental and public health regulations. If it is possible or reasonable use an alternative chemical product with less inherent propensity for occupational harm/injury/toxicity or environmental contamination.

Product: Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging: Dispose of as unused product.

10 Manufacturing / Use Information

10.1 Uses (Complete)

A major use for PTFE is in the chemical processing industry for structures, linings, seals, and hose or tubing. PTFE is also used for electrical wiring in the military and aerospace industries. Other electrical applications include coaxial cables, computer wire, electrical tape, and electrical components. Bearings, mechanical tapes, and coated glass fabrics are also produced from PTFE resins. Coated fabrics can be found in architectural applications and in food processing or conveying applications. Overbraided hose liners, thread sealant tapes, gaskets, pipe liners, fibers, and filaments are also produced. Highly porous fabric structures that can be used as membranes have been developed by exploiting the unique fibrillation capability of dispersion-polymerized PTFE.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

The major mechanical applications...are in seals & piston rings (...fluid transmission systems, hydraulic cylinders & nonlubricated compressors) & in machine bearings & bearing pads, & to a lesser extent, in mechanical tapes & impregnated glass fabrics.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 292

...For medical applications...(1) vascular grafts when fabricated into textiles; (2) knitted fabrics for treatment of aneurysms; (3) heart valves & aorta implants; (4) shunts in hemodialysis equipment; (5) bone replacements... (6) injections...for treatment of dysphonia.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 292

For hookup and hookup-type wire in electronic equipment; in computer wire, electrical tape, electrical components, spaghetti tubing. Seals and piston rings, basic shapes, bearings, mechanical tapes, coated glass fabrics. As tubing and sheets for chemical laboratory and process work; for lining reaction vessels; for gaskets and pump packings, sometimes mixed with graphite or glass fibers; as electrical insulator especially in high frequency applications; filtration fabrics; protective clothing. Prosthetic aid.

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

Vet: in prosthetic reconstructive work; component of polytetrafluoroethylene paste for injection

Rossoff, I.S. *Handbook of Veterinary Drugs*. New York: Springer Publishing Company, 1974., p. 467

IN MECHANICAL TAPES & GLASS FIBERS; IN CABLE CONNECTORS, CIRCUIT BREAKERS, & STAND-OFF INSULATORS; POLYMER FOR PARTS USED IN HANDLING LIQUIDS, SEALS, PISTON RINGS, & BEARINGS; POLYMER FOR RODS, SHEETS, TUBES, WIRE & CABLE INSULATION, ANTI-STICK COATINGS IN CONSUMER APPLICATIONS; IN LUBRICANT POWDERS, FIBERS, & IMPREGNATED FABRICS

SRI

High-temperature industrial plastics

HAWLEY. *CONDENSED CHEM DICTNRY 10TH ED* 1981 p.997

10.2 Manufacturers



Teflon - Manufacture and Production Data (2012)

Company PPG Industries Inc
Site PPG Industries Inc, Lake Charles Plant
Address PO Box 1000, Lake Charles LA 70602
Manufacture No
Import CBI
Company Marubeni America Corp
Site Marubeni Specialty Chemicals Inc - Tampa Div
Address 8675 Hidden River Pkwy, Tampa FL 33637
Manufacture No
Import Yes

US EPA; *Chemical Data Reporting (CDR)*. Non-confidential 2012 Chemical Data Reporting information on chemical production and use in the United States. Available from, as of Sept 22, 2015:

https://java.epa.gov/oppt_chemical_search/

10.3 Methods of Manufacturing (Complete)



In aqueous medium, TFE /tetrafluoroethylene/ is polymerized by two different procedures. When little or no dispersing agent is used and vigorous agitation is maintained, a precipitated resin is produced, commonly referred to as granular resin. In another procedure, called aqueous dispersion polymerization, a sufficient dispersing agent is employed and mild agitation produces small colloidal particles dispersed in the aqueous reaction medium; precipitation of the resin particles is avoided. The two products are distinctly different, even though both are high molecular weight PTFE polymers. The granular product can be molded in various forms, whereas the resin produced by the aqueous dispersion cannot be molded, but is fabricated by dispersion coating or conversion to powder for paste extrusion with a lubricant medium. Granular resin cannot be paste extruded or dispersion coated.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

Granular PTFE is made by polymerizing TFE /tetrafluoroethylene/ alone or in the presence of trace amounts of comonomers. An initiator, a small amount of dispersing agent, and other additives may be present; an alkaline buffer is occasionally used. In the early stages of polymerization, an unstable dispersion is formed, but lack of dispersing agent and vigorous agitation cause the polymer to partially coagulate; the remainder of the process is fairly complex. The polymerized product is stringy, irregular, and variable in shape. The dried granular polymer is ground to different average particle sizes, depending on the product requirements, eg, the flow and other properties. Coarser fabrication of particles leaves a higher void in the sintered article. A better balance between handleability and moldability (ability to mold and sinter in the absence of voids) is achieved by agglomerating the finely divided resin to ca 400-800 μm . For ram extrusion of granular resin into long tubes and rods, a partially presintered resin is preferred.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

Fine powder resins are made by polymerizing TFE /tetrafluoroethylene/ in an aqueous medium with an initiator and emulsifying agents. ... The rate of polymerization and the particle shape are influenced by the amount of the emulsifying agent. The particle structure can be influenced by the polymerization process. Most of the particles are formed in the early stages of the polymerization process and the particles grow as the batch progresses; hence, the radial variation in molecular weight and polymer composition within the dispersion particle can be achieved by controlling the polymerization variables, including ingredients and operating conditions. Polymer is isolated from the dispersion with mechanical agitation and, optionally, the addition of electrolyte. The thin dispersion rapidly thickens into a gelled matrix and coagulates into a water-repellent agglomeration that floats on the aqueous medium as the mechanical agitation is continued. The agglomeration is dried gently; shearing must be avoided.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

Dispersion is made by the polymerization process used to produce fine powders. Differences lie in the average particle sizes for dispersion products. The most common dispersion has an average particle size of about 0.2 μm , probably the optimum particle size for most applications. ... Efforts have been made to reduce the amount of fluorinated emulsifying agents in the dispersion and to recover these agents for reuse. The raw dispersion is stabilized with a nonionic or anionic surfactant and concentrated to 60-65 wt% solids by electrodecantation, evaporation, or thermal concentration. The concentrated dispersion can be further modified with chemical additives. Fabrication characteristics of these dispersions depend on polymerization conditions and additives.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

Prepared by polymerization of tetrafluoroethylene: Plunkett, USA patent 2230654 (1941 to Kinetic Chem.); Brubaker, USA patent 2393967; Joyce, USA patent 2394243 (both to du Pont).

O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013., p. 1412

10.4 General Manufacturing Information (Complete)



TM /trade mark/ for tetrafluoroethylene (TFE) fluorocarbon polymers available as molding and extrusion powders, aqueous dispersion, film, finishes, and multifilament yarn or fiber. The name also applies to fluorinated ethylene-propylene (FEP) resins available in the same form. The no-stick cookware finishes may be of either type. Fibers are monofilaments made from copolymer of TFE and FEP.

Lewis, R.J. Sr.; Hawley's Condensed Chemical Dictionary 15th Edition. John Wiley & Sons, Inc. New York, NY 2007., p. 1209

By altering the surface properties of polytetrafluoroethylene (PTFE) substrates using a special PIII technique, mesenchymal stem cells (MSCs) proliferation and osteogenesis can be promoted in culture without osteogenic supplements. The structures are created intrinsically in the PTFE for no risk of materials delamination. Large-scale features and locally different functions can also be readily produced on the same substrate by this technique.

PMID:22628263

Wang H et al; Adv Mater. 24 (25): 3315-24 (2012)

Polytetrafluoroethylene has been degraded at various temp, & following compd were detected: (1) at 450 °C, tetrafluoroethylene; (2) at 460 °C, hexafluoropropylene; (3) at 475 °C, perfluoroisobutylene; (4) between 500-650 °C, carbonyl fluoride; (5) above 650 °C, carbon tetrafluoride & carbon dioxide.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 290

...Avail in 3 forms: (1) granular, for molded parts & extruding thick-walled tubing & rods; (2) coagulated dispersions (also referred to as fine powders), for extruding thin sections; & (3) aq dispersions, for coating, impregnation & prepn of fibers & films.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 290

Filled polymers are also avail; these are generally made by mixing fillers such as glass fiber, graphite, molybdenum disulfide, metal oxides or ceramics & finely-divided granular polytetrafluoroethylene. Reprocessed scrap & off-grade material is also used.

IARC. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 290

10.5 Formulations / Preparations (Complete)



Available forms: Extrusion and molding powders, aqueous dispersion, film, multifilament fiber.

Lewis, R.J. Sr.; Hawley's Condensed Chemical Dictionary 15th Edition. John Wiley & Sons, Inc. New York, NY 2007., p. 1019

High molecular weight polytetrafluoroethylene is manufactured and sold in three forms: granular, fine powder, and aqueous dispersion; each requires a different fabrication technique. Granular resins are manufactured in a wide variety of grades to obtain a different balance between powder flows and end-use properties. Fine powders that are made by coagulating aqueous dispersions are also available in various grades. Differences in fine powder grades correspond to their usefulness in specific applications and to the ease of fabrication. Aqueous dispersions are sold in latex form and are available in different grades. A variety of formulation techniques are used to tailor these dispersions for specific applications.

Gangal SV, Brothers PD; Perfluorinated Polymers. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). John Wiley & Sons, Inc. Online Posting Date: September 25, 2015

10.6 Consumption Patterns (Complete)



POLYMER, OF WHICH 36% IS USED IN PARTS TO HANDLE LIQUIDS, 25% IN VARIOUS MECHANICAL APPLICATIONS, 20% IN VARIOUS ELECTRICAL APPLICATIONS, AND 19% FOR CONSUMER ANTI-STICK COATINGS, FIBERS, IMPREGNATED FABRICS, AND LUBRICANT POWDERS (1974)

SRI

10.7 U.S. Production (Complete)



(1972) 6.02X10+9 GRAMS

SRI

(1975) 5.92X10+9 GRAMS

SRI

(1984) 1.29X10+10 g

USITC. SYN ORG CHEM-U.S. PROD/SALES 1984 p.136

Non-confidential 2012 Chemical Data Reporting (CDR) information on the production and use of chemicals manufactured or imported into the United States. Chemical: Ethene, 1,1,2,2-tetrafluoro-, homopolymer. National Production Volume: Withheld.

USEPA/Pollution Prevention and Toxics; 2012 Chemical Data Reporting Database. Ethene, 1,1,2,2-tetrafluoro-, homopolymer (9002-84-0). Available from, as of August 31, 2015:

https://java.epa.gov/oppt_chemical_search/

10.8 U.S. Imports (Complete)



(1972) 6.22X10+8 GRAMS

SRI

(1975) No Data

SRI

(1986) No Data

10.9 U.S. Exports (Complete)



(1972) No Data

SRI

(1975) No Data

SRI

(1984) 1.47X10+9 g

BUREAU OF THE CENSUS. U.S. EXPORTS, SCHEDULE E, 1984 p.2-123

11 Laboratory Methods



11.1 Analytic Laboratory Methods (Complete)



IR spectrometry & scanning electron microscopy were used for detecting teflon particles in aIR of a workshop for hot teflon coating. This monitoring was used for controlling teflon-fume fever, a pulmonary complaint.

CARTON B ET AL; CAH NOTES DOC 90: 57 (1978)

...Differential thermal analysis, & mass spectrometry has been used in identification & analysis of polytetrafluoroethylene.

IARC. *Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work). Available at: <https://monographs.iarc.fr/ENG/Classification/index.php>, p. V19 292

Hydrolyzable fluoride (hydrogen fluoride, inorganic fluoride, carbonyl fluoride and other organic forms of fluoride, which are hydrolyzed in alkaline solution) has been used as a marker of the decomposition products of fluorocarbon polymers. The quantification uses fluoride-ion-selective electrode or ion chromatography. Fluorinated hydrocarbons can be monitored by gas chromatography.

The Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals 124. Thermal Degradation Products of Polyethylene, Polypropylene, Polystyrene, Polyvinylchloride and Polytetrafluoroethylene in the Processing of Plastics. p. 35 (1998); Available from, as of August 11, 2015: https://www.inchem.org/documents/kemi/kemi/ah1998_12.pdf

12 Special References



12.1 Special Reports (Complete)



Waritz RS; An industrial approach to evaluation of pyrolysis and combustion hazards. *Environ Health Perspect* 11: 197-202 (1975); Review of Teflon toxicity due to pyrolysis written by the former DuPont toxicologist.[Waritz RS; *Environ Health Perspect* 11: 197-202 (1975) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1475183/pdf/envhper00495-0189.pdf>]

13 Synonyms and Identifiers



Synonyms

9002-84-0

TEFLON

ALGLOFLON

BALFON 7000

CHROMOSORB T

DIXON 164

ETHENE, TETRAFLUORO-, HOMOPOLYMER

ETHYLENE, TETRAFLUORO-, POLYMERS

FBF 74D

FLUON

FLUON L 169

FLUON CD 1

FLUON CD 023

FLUON CD 042

FLUON G4
FLUOROFLEX
FLUOROLON 4
FLUOROPLAST 4
FLUOROPLAST 4B
FLUOROPLAST 4D
FLUOROPLAST 4M
FTORLON F-4MB
FTORLON 4
FTOROPLAST F-4
FTOROPLAST 4
FTOROPLAST 4D
HALON G 80
HALON G 183
HALON G 700
HALON TFEG 180
HEYDEFLOX
PERFLUOROETHYLENE POLYMER
POLY(ETHYLENE TETRAFLUORIDE)
POLYFENE
POLYFLON
POLYFLON D 1
POLYTEF
POLYTETRAFLUOROETHENE
POLYTETRAFLUOROETHYLENE
POLYTETRAFLUOROETHYLENE RESIN
PROPLAST
PTFE
PTFE-GM3
SOREFLON 5A
TEFLON 110
TEFLON 30
TEFLON 5
TEFLON 6
TEFLON 6C
TEFLON K
TEFLON T 30

TEFLON T 6
TEFLON T 5
TEFLON TFE
TETRAFLUOROETHENE HOMOPOLYMER
TETRAFLUOROETHENE POLYMER
TETRAFLUOROETHYLENE HOMOPOLYMER
TETRAFLUOROETHYLENE POLYMER
TETRAN 30
UNON P
VALFLON
VELFLON
Zitex H 662-124
Zitex K 223-122
UNII-E1NC1JVS3O

13.1 Related HSDB Records



7708 [PERFLUOROISOBUTYLENE] (degradation product)

13.2 Substance Title



TEFLON

13.3 Associated Chemicals (Complete)



Trifluoroacetate; 14477-72-6

14 Administrative Information



14.1 Hazardous Substances DataBank Number



833

14.2 Last Revision Date



20170414

14.3 Last Review Date





14.4 Update History

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Complete Update on 02/21/1997, 1 field added/edited/deleted.

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