食品安全委員会
Food Safety Commission

Fact Sheet
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Fluoropolymers: Overview

1. Fluoropolymers

A category of plastics, fluoropolymers are polymer compounds mainly comprising carbon and fluorine. Depending on the specific elemental composition, a fluoropolymer may be polytetrafluoroethylene (PTFE), perfluoroalkoxy alkane (PFA), a perfluoroethylene propene copolymer (FEP), or another variant. PTFE accounts for approximately 60 percent of all fluoropolymers. Fluoropolymers offer many advantageous properties, including thermal resistance, chemical resistance, low friction and nonadherence, which are leveraged for a wide range of applications in fields such as semiconductors, chemical plants, automobiles and beyond—even in coatings for cooking tools such as frying pans.

2. Effects on Humans

Based on a 1987 assessment by the International Agency for Research on Cancer (IARC), PTFE is classified as group 3: “The agent is not classifiable as to its carcinogenicity to humans.” No report can be found on the effects of orally ingesting fluoropolymers. It is believed that, even if small fragments of a fluoropolymer that break off from a cooking tool’s coating is absorbed by the human body, that substance will not cause any toxic response within the body. During animal testing, rats were provided with feed containing 25 percent PTFE for 90 days, and no toxic effect was observed. However, it has been reported that heating PTFE to an excessive degree will trigger thermal decomposition, and the resulting vapors are highly toxic if inhaled. If PTFE is heated at a temperature of between 315 and 375 degrees Celsius, it is believed that inhalation of the resulting toxic substance will produce influenza-type symptoms.

3. Overseas Study

In 2005, the German Federal Institute for Risk Assessment (BfR) publicized its “Selected questions and answers on cookware, ovenware and frying pans with a non-stick coating made of PTFE,” which states that toxic fumes occur when PTFE is heated to a temperature of 360 degrees Celsius or higher, triggering influenza-like symptoms upon inhalation. It also recommended that such cookware users avoid heating empty frying pans and other such tools for three minutes or longer as a means of preventing said phenomenon. In addition, the above Q&A states that frying pans and other such cookware pose no risk when used properly, and that fragments of coating which separate from such cookware will, if absorbed by the human body, pass through the body as-is without triggering a toxic response and thus cause no harm.

4. Domestic Studies

Although no fluoropolymer-based processing specifications have been established in Japan, standard specifications for synthetic resin cooking tools, containers and packaging used with food products apply in accordance with the Food Sanitation Act. Regarding efforts among industry groups, in 2002, member companies of the Japan Paper

Association (JPA) concluded an agreement to refrain from manufacturing high-fluorine-content greaseproof paper products and similar due to concerns over safety when used with food products.

In FY 2010, the Food Safety Commission of Japan proposed and deliberated on self-evaluations for fluoropolymers (from among all substances eluted from cooking tools). As a result of said deliberations, it was decided that information will be provided via fact sheets. This fact sheet provides a summary of relevant information based on the results of the FY 2011 General Study for Purposes of Ensuring Food Safety.

Fact Sheet:
Fluoropolymers

Category		Details	References
I. Substance name(s)		Fluoropolymers / fluorocarbon polymers (as general substance category names) Polytetrafluoroethylene (PTFE)	
II. Overview (usages, contamination incidents, food products with contamination potential, etc.)		A category of plastics, fluoropolymers are polymeric compounds mainly comprising carbon, fluorine, water and chlorine. Depending on the specific elemental composition, a fluoropolymer may be polytetrafluoroethylene (PTFE), perfluoroalkoxy alkane (PFA), a perfluoroethylene propene copolymer (FEP), or another variant. PTFE accounts for approximately 60 percent of all fluoropolymer demand. (2002, 2008)	1, 2
		Fluoropolymers offer many advantageous properties, including thermal resistance, chemical resistance, low friction and nonadherence, which are leveraged for a wide range of applications in fields such as semiconductors, chemical plants, automobiles and beyond—even in coatings for cooking tools such as frying pans. (2002, 2008)	1, 2
III. Reason(s) for increase in attention received by this substance		In January 2005, the United States Environmental Protection Agency (EPA) Science Advisory Board (SAB) declared that perfluorooctanoic acid (PFOA), which is used as an auxiliary agent when manufacturing the PTFE utilized widely in cookware products, is "likely to be carcinogenic to humans," which drew greater attention to the potential hazards of PTFE. The EPA released a public statement conveying that, although the specific risks are uncertain, they are concerned that PFOA may pose a risk to human health. No definite conclusion has been reached regarding this assessment; it remains in the draft phase.	3, 4
IV. Scientific opinions regarding toxicity (in Japan, from international institutions, and in other countries/regions)			
A. Toxicity within the body (in metabolic processes from intake to expulsion)		Even if a person ingests a coating fragment which has separated from a product coating, said fragment will pass through the body without being absorbed, and thus trigger no toxic response in the body. (2005)	5
		PTFE's molecular weight is large (400,000–10,000,000), and therefore most PTFE content will not decompose in response to solvents. (2000)	6
B. Toxicity	1. Acute toxicity	No information available.	
	2. Genetic toxicity (mutagenicity)	No information available.	
	3. Carcinogenicity	Based on an assessment by the IARC, PTFE is classified as group 3: "The agent is not classifiable as to its carcinogenicity to humans." (1987)	7
	4. Reproductive and/or developmental toxicity	No information available.	

	5. Other toxicity types (short and long term)	No toxic effect was observed during a test in which rats were provided with feed containing 25 percent PTFE for 90 days. (2000)	6
countries/regions	1. European Union		
	2. United States		
	3. Others		

VI. Exposure information (in Japan, from international institutions, and in other countries/regions)		
A. Estimated daily intake amounts	No information available.	
B. Transfers from materials that come into contact with food products	No information available on material-transfer contamination. For reference: the normal amount of PTFE used for a frying pan's coating is 3 grams. (2008)	1
VII. Risk assessments (based on ADI, TDI, ARfD, MOE, etc.)		
A. In Japan	No information available.	
B. International Agency for Research on Cancer (IARC)	PTFE has been assessed as group 3: "The agent is not classifiable as to its carcinogenicity to humans." (1987)	7
C. International institutions	No information available.	

D. Other countries/regions	1. European Union	The BfR publicized its “Selected questions and answers on cookware, ovenware and frying pans with a non-stick coating made of PTFE,” which includes the following information: (2005) □Even if a person ingests a coating fragment which has separated from a product coating, said fragment will pass through the body without being absorbed, and thus trigger no toxic response in the body. Therefore, said coating fragments have no harmful effect. □PTFE, which is frequently used in non-stick coatings on cooking implements, emits toxic fumes when excessively heated (to a temperature of 360°C or higher). However, there is no risk if the material is used properly. □Inhaling toxic fumes generated due to heating to 360°C or higher leads to influenza-like symptoms. However, such symptoms have not been reported in home-use environments, but instead in PTFE production plants where contaminant concentrations are high.	5

Category		Details	References
	2. United States	In January 2005, the EPA SAB declared that PFOA, which is used as an auxiliary agent when manufacturing the PTFE utilized widely in cookware products, is “likely to be carcinogenic to humans.” The EPA released a public statement conveying that, although the specific risks are uncertain, they are concerned that PFOA may pose a risk to human health. No definite conclusion has been reached regarding this assessment; it remains in the draft phase.	3, 4
	3. Others	No information available.	
VIII. Risk management measures (standard values)			
A. In Japan		Based on the Food Sanitation Act, standard specifications have been established for synthetic resin cooking tools, containers and packaging used with food products. There are no specific standards for fluoropolymer-based processing.	1, 10
B. International institutions		No information available.	
C. Other countries/regions	1. European Union	No information available.	
	2. United States	No information available.	
	3. Others	No information available.	
IX. Risk management measures (excluding standard values; including contamination prevention measures, risk mitigation methods, etc.)			
A. In Japan		Based on the Food Sanitation Act, standard specifications have been established for synthetic resin cooking tools, containers and packaging used with food products. There are no specific standards for fluoropolymer-based processing.	1, 10
		Regarding efforts among industry groups, in 2002, member companies of the JPA concluded an agreement to refrain from manufacturing high-fluorine-content greaseproof paper products and similar due to concerns over safety when used with food products.	11
B. International institutions		No information available.	
	1. European	The BfR publicized its “Selected questions and answers on cookware, ovenware and frying pans with a non-stick coating made of PTFE.” (2005) In regard to contamination prevention measures, risk mitigation methods and similar, the following information is included: In order to prevent overheating, refrain from heating any empty	5

C. Other countries/regions	Union	cooking implement for three minutes or longer. If any food product is inside the frying pan or similar cooking implement during overheating, a burnt smell will occur to indicate overheating to the user, which makes overheating itself unlikely. And because coatings are susceptible to flaking, users should use wooden or plastic cooking utensils.	
	2. United States	In regard to perfluorocarbons and fluorocarbons, the United States Food and Drug Administration (FDA) has established standards for tools and packaging that come into contact with food products, as well as elution-related specifications and similar.	12, 13
	3. Others	No information available.	
X. Reference information (containing PTFE references)			
A. Material name (IUPAC)		Poly(difluoromethylene)	
B. CAS name and number		Ethene, 1,1,2,2-tetrafluoro-, homopolymer / 9002-84-0	
C. Molecular/structural formula		$(CF_2\text{-}CF_2)n$ Atomic weight: 400,000–10,000,000 (average for commercially available granular resin products)	6
D. Physical properties			
1. Form(s)		Granular, fine powder, aqueous dispersion	6
2. Melting point (Celsius)		327°C–342°C (327°C)	6

Category	Details	References
3. Boiling point (Celsius)	No information available.	
4. Specific gravity (g/cm^3)	2.1–2.7	6
5. Solubility	Insoluble	6
E. Effects of formulation, processing, and cooking	Emits toxic fumes when excessively heated (to a temperature of 360°C or higher). However, there is no risk in the case of frying pans and similar products when the product is used properly.	5
F. References		

Reference materials

1. *Fusso Jushi Seihin Toriatsukai Manyuaru* (Fluoropolymer Product Handling Manual). Edited by the Japan Fluoropolymers Industry Association Environmental Committee, 8th edition.
   Japan Fluoropolymers Industry Association, 2008.
2. *Shitteimashita ka? Fusso Jushi no Koto* (Did You Know? About Fluoropolymers). Japan Fluoropolymers Industry Association, 2002.
3. *Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers / Risk Assessment.* United States Environmental Protection Agency, updated 29 April 2010, http://www.epa.gov/oppt/pfoa/pubs/pfoarisk.html.
4. *Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Acid and Its Salts.* United States Environmental Protection Agency, 2005.

5. “Frequently Asked Questions about cookware and roastware with a non-stick coating.” German Federal Institute for Risk Assessment, 2005, https://www.bfr.bund.de/en/selected_questions_and_answers_on_cookware__ovenware_and_frying_pans_with_a_non_stick_coating_made_of_ptfe-60855.html.
6. Naito, Hiroshi. *Kagaku Busshitsu Dokusei Handobukku Dai-V-Maki* (Chemical Substance Toxicity Handbook Volume Five). Maruzen Publishing, Translation supervision by Noriko Yokote, 2000, pp. 200–06.
7. “Agents Classified by the IARC Monographs.” International Agency for Research on Cancer [IARC], http://monographs.iarc.fr/ENG/Classification/index.php.
8. *The Guide to the Safe Handling of Fluoropolymer Resins.* The Society of the Plastics Industry, fourth Edition, 2005, pp. 76–77.
9. Johnston et al. *Toxicology and Applied Pharmacology.* “Pulmonary Effects Induced by Ultrafine PTFE Particles,” 168: 2000, pp. 208–215.
10. *Shokuhin, Tenkabutsu Nado no Kikaku Kijun (Showa 34-nen Kyu-Koseisho Kokuji Dai-370-go)* (Specifications and Standards for Food Products, Additives and Similar (1959 Former Ministry of Health and Welfare Report No. 370)). Japanese Ministry of Health, Labour and Welfare, http://www.mhlw.go.jp/topics/bukyoku/iyaku/kigu/dl/4.pdf.
11. Japan Paper Association meeting, 18 October 2011.
12. Code of Federal Regulation Title 21 “Food and Drugs,” Part 177 “Indirect Food Additives: Polymers,” Section 177.1550 “Perfluorocarbon resins,” http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=177.1550.
13. Code of Federal Regulation Title 21 “Food and Drugs,” Part 177 “Indirect Food additives: Polymers,” Section 177.1380 “Fluorocarbon resins,” www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=177.1380.

Note: All webpages cited were last accessed on 31 May 2012. URLs may have been changed by the hosting organizations during the interval.

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Revisions:

- Changes were made to “3. Overseas Study” following careful examination