Teflon®/Tefzel®/Zonyl®

fluoropolymer resins and fluoroadditives

Teflon®/Tefzel® Fluoropolymer Resins and *Zonyl®* Fluoroadditives in Applications Regulated by the Food and Drug Administration

This data sheet pertains to the U.S. Federal Food and Drug Administration (FDA) regulations governing the use of fluoropolymers as articles or components of articles intended for use in contact with food.

Articles Intended to Contact Food

Reference: 21 CFR 177.1550 Perfluorocarbon Resins

Most *Teflon®* PTFE and FEP fluoropolymer resins may be used as articles or components of articles intended to contact food in compliance with this regulation. A partial list of resins that meet the requirements of this regulation is given in **Table 1**.

Teflon® PFA type fluoropolymer resins listed in **Table 1** have been approved by the FDA for repeated-use food contact articles such as tubing, hoses, components of valves, etc., as well as for coatings for articles intended for repeated food contact use in compliance with this regulation.

Some fluoropolymer resins are irradiated to facilitate grinding into fine powders for applications needing a very small particle size. Paragraph (c) specifies the allowable dose of radiation and maximum particle size for PTFE resins so processed and restricts their use to components of articles intended for repeated use in contact with food. **Table 1** shows the *Zonyl®* fluoroadditives that comply with this paragraph.

Processing Aids for Polyolefins

Reference: 21 CFR 177.1520 Olefin Polymers

Zonyl® fluoroadditives MP 1500J and MP 1600N; *Teflon®* PTFE and FEP resins listed in **Table 1**; and up to 2,000 ppm of *Zonyl®* fluoroadditives MP 1000, MP 1300, and MP 1400 may be used as extrusion aids for polyolefins in compliance with this regulation as long as the polyolefin resin complies with the regulation.

Components of Resinous and Polymeric Coatings

Reference: 21 CFR 175.300 Resinous and Polymeric Coatings

As indicated in **Table 1**, most *Teflon®* fluoropolymer resins and *Zonyl®* fluoroadditives may be used as release agents in compliance with this regulation as long as the finished coating meets the extractives limitations of the regulation. Both because of the small amount required for a release agent and its insolubility, the PTFE would be expected to contribute a negligible amount to the extractables, but it is the customer's responsibility to measure extractives on finished coating to ensure compliance.

Components of Paper and Paperboard

Reference: 21 CFR 176.170 Components of Paper and Paperboard in Contact with Aqueous and Fatty Foods

As indicated in **Table 1**, most *Teflon®* fluoropolymer resins and *Zonyl®* fluoroadditives may be used as release agents in compliance with this regulation as long as the finished coating meets the extractives limitations of this regulation. Both because of the small amount required for a release agent and its insolubility, the PTFE would be expected to contribute a negligible amount to the extractables, but it is the customer's responsibility to measure extractives on finished coating to ensure compliance.

Reference: 21 CFR 176.180 Components of Paper and Paperboard in Contact with Dry Food

As indicated in **Table 1**, most *Teflon*® fluoropolymer resins and *Zonyl*® fluoroadditives may be used as release agents in compliance with this regulation.

Lubricant for Rubber Articles

Reference: 21 CFR 177.2600 Rubber Articles Intended for Repeated Use

The *Teflon*® PTFE and FEP resins and the *Zonyl*® fluoroadditives indicated in **Table 1** can be used as lubricants for rubber articles intended for repeated use in contact with food in compliance with this regulation.

Components of Adhesives

Reference: 21 CFR 175.105 Adhesives

The *Teflon*® PTFE resins listed in **Table 1** and *Zonyl*® fluoroadditives MP 1000, MP 1300, MP 1400, MP 1500J, and MP 1600N may be used as components of adhesives in compliance with this regulation.

Tefzel® Fluoropolymers

Tefzel® 200, 210, 220, and 280 may be used as articles or components of articles intended for repeat-use food processing applications, in contact with all food types at temperatures up to 121°C (250°F) in compliance with the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Colorants in Polymers

Reference: 21 CFR 178.3297 Colorants for Polymers

This regulation permits certain colorants for use in polymers intended for food contact use. Included are TiO_2, iron oxides, all-gas channel black, and ultramarine colorants.

Housewares Exemption

Reference: Food Drug Cosmetic Law Journal, Vol. 42, No. 1, January 1987, p. 45

The housewares exemption holds that substances sold for use in housewares such as dinnerware or eating utensils need no FDA clearance. This exclusion flows from the legislative history of the 1958 Amendment to the FD&C Act, and FDA's position has been that it will not require Food Additives Amendment-type clearance of materials used to manufacture empty containers, utensils, or appliances sold to the consumer for home use.

USDA Acceptance

The United States Department of Agriculture (USDA) has accepted *Teflon*® PTFE, FEP, and PFA fluoropolymer resins that comply with 21 CFR 177.1550 as components of materials in direct contact with meat or poultry food products prepared under Federal inspection. Resins that comply with this regulation are shown in **Table 1**.

3-A Sanitary Standards

Teflon® PTFE, FEP, PFA, and *Tefzel*® fluoropolymer resins comply with the Criteria in "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-17," published by the 3-A Secretary, Dairy and Food Industries Supply Association, Inc.

US Pharmacopeia Class VI

Representative samples of *Teflon*® PTFE, FEP, PFA, and *Tefzel*® fluoropolymers have been tested in accordance with USP protocol, and all meet the requirements of a USP Class VI plastic. These tests on representative samples may not reflect results on articles made from these fluoropolymers, especially if other substances are added during fabrication. Testing of the finished article is the responsibility of the manufacturer or seller of the finished product if certification that it meets USP standards is required.

USP testing was done to support use of these fluoropolymers in pharmaceutical processing and food processing applications. While USP Class VI certification is not required for pharmaceutical processing, many pharmaceutical customers seeking ISO-9000 certification have requested it.

Medical Use

Caution: Do not use *Teflon*® or *Tefzel*® fluoropolymers or Zonyl® fluoroadditives in medical applications involving permanent implantation in the human body. For other medical applications, see "DuPont Medical Caution Statement," H-50102.

DuPont does not make surgical or medical grades of *Teflon*® or *Tefzel*® resins and does not guarantee continuity of process in our manufacturing operations as changes may occur from time to time.

Table 1
Summary of DuPont Fluoropolymer Resins and Fluoroadditives Complying with FDA Regulations[1]

Products	21 CFR 177.1550	21 CFR 177.1520	21 CFR 177.2600	21 CFR 175.300	21 CFR 175.105	21 CFR 176.170	21 CFR 176.180
Teflon® PTFE Granular Resins 7A, 7C, 8, 8A, 8B, 9B, 701N, 703N, 801N, 807N, 809N, 850A, 901N, L129, TG70J, TG170J	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Teflon® PTFE Fine Powders 6C, 6CN, 60, 62, 62N, 636N, 637N, 669N, 669RFFN, K-10, 67 CFP6000, CFP6000N	Yes	Yes	Yes	Yes	Yes	Yes	Yes
DuPont PTFE 65, 65J, 65N	Yes	Yes	Yes	Yes	Yes	Yes	Yes
DuPont PTFE Dispersions[2] 30, 30B, 30N, K-20	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Teflon® FEP Resins 100, 100N, 100J, 140, 140N, 140J, 160, 160N, 4100, 4100N, 5100	Yes	Yes	Yes	Yes	Yes	Yes	Yes
DuPont FEP Dispersions[2] 120, 121A	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Teflon® PFA Resins 440HP, 450HP	Yes[3]	No	No	Yes[3]	Yes[3]	Yes[3]	Yes[3]
Zonyl® Fluoroadditives MP 1000, MP 1300	No	2000 ppm maximum	No	Yes	Yes	Yes	Yes
Zonyl® Fluoroadditives MP 1400	Yes[3]	2000 ppm maximum	Yes	Yes	Yes	Yes	Yes
Zonyl® Fluoroadditives MP 1500J, MP 1600N	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tefzel® Fluoropolymers 200, 210, 220, 280	See accompanying text.						

[1]See accompanying text and the FDA regulations for any limitations or conditions of use. It is the customer's responsibility to test finished articles to ensure compliance with the extractives limitations of applicable regulations.
[2]Articles made from dispersions sintered at high temperatures common to the industry should comply (see Note 1). Articles made from unsintered dispersions do not comply.
[3]Limited to articles or components of articles for repeated use in contact with food.

For more information on Fluoroproducts: (302) 479-7731

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Teflon®
fluoropolymer resin

Zonyl® fluoroadditives are part of the DuPont family of fluoropolymers. Customers who wish to use the *Teflon*® trademark in connection with *Zonyl*® fluoroadditive products under license from DuPont should contact (800) 262-2745.

CAUTION: Do not use in medical applications involving permanent implantation in the human body. For other medical applications, see "DuPont Medical Caution Statement," H-50102.

(12/96) 196199F Printed in U.S.A.
[Replaces: H-22779-4]
Reorder No.: H-22779-5

DuPont Fluoroproducts

Material Data Sheet

Material	High Purity PFA ASTM D3307-type V	MC228

Description	Pfa (perfluoroalkoxy) Fluoropolymer translucent virgin grade This grade of material is compliant with US FDA regulation 21 CFR 177.1550 § (a) (1) and (b) as finished articles.

Application	This material has excellent chemical inertness, heat resistance and low coefficient of friction

Temperature	Low temperature service limit –76F (–60 C). Upper temperature continuous service limit 500F (+260 C).

Products	Jacket material for our range of Encapsulated O Rings & Gaskets

Physical Properties

General		
Specific Gravity	ASTM D792	2.15
Hardness shore D	ASTM D2240	55
Elongation % 23C	ASTM D638	300
250C		500
Tensile strength 23C PSI (Mpa)	ASTM D638	4063(28)
250C PSI (Mpa)		1741(12)
Flexural modulus 23C PSI (Mpa)	ASTM D790	90711(625)
250C PSI (Mpa)		100145(69)
MIT folding endurance (0.18-0.20mm film) cycles	ASTM 2176	200,000
Thermal		
Melting point F (C)	D2116	580-590 (302-310)
Coefficient of linear thermal expansion	D696	
(21-100C) K^{-1}		140.10^{-6}
(100-150C) K^{-1}		180.10^{-6}
(150-200C) K^{-1}		200.10^{-6}
Environmental		
Water absorption % 24 hrs	D570	< 0,03
Weathering		excellent

Information

The above information corresponds to our current knowledge and is offered solely to provide possible suggestions for your own experimentations. It is not intended to substitute any testing you may need to conduct to determine suitability of our products for your end use. Northern Engineering reserves the right to revise this information as new knowledge and experience becomes available. Northern Engineering makes no warranties and assumes no liability in connection with any use of the above information.

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