

Fluoropolymers in Applications Regulated by the Food and Drug Administration

Technical Information

This information pertains to the U.S. Federal Food and Drug Administration (FDA) amendments that provide for the use of Viton fluoropolymers as a processing aid in the production of extruded olefin polymers.

Extrusion Aid for Polyolefins

References: 21 CFR 177.1520 Olefin Polymers FR, Vol. 55, No. 86, 18596, 5/3/90

The regulation permits the use of Viton™ FreeFlow™ products as processing aids in the production of extruded olefin polymers (e.g., polyethylene, polypropylene, and certain copolymers as specified in the regulation) at the levels indicated in Table 1. The finished polymers may be used in contact with food under conditions specified in the regulation (maximum use temperature 100 °C [212 °F]).

Table 1. FDA Food Contact Levels

Product	No Restrictions, ppm	Below 100 °C (212 °F), ppm
Viton™ FreeFlow™ Z-200	1,500	1,500*
Viton™ FreeFlow™ Z-100	950	3,800
Viton™ FreeFlow™ 40	500	2,000
Viton™ FreeFlow™ 10	500	2,000
Viton™ FreeFlow™ GB	1,000	4,000
Viton™ FreeFlow™ RC	2,000	8,000

The FDA has issued a nonobjection letter stating that the ethylene homopolymers and copolymers complying with 21 CFR 177.1520 containing levels of Viton FreeFlow products (as shown in Table 1) can be safely used in contact with all types of food (no temperature restrictions), subject to meeting the limits of extraction tests specified in the regulation.

Other Countries

The use of Viton™ FreeFlow™ in polyolefins intended for food contact is permissible in many countries. For specific information, contact Chemours.

Handling Precautions

Under ordinary handling conditions, Viton™ fluoroelastomer polymers and products based on them present no health hazards of which Chemours is aware. However, there are potential hazards that result from the use of certain compounding ingredients or from high-temperature processing and service conditions. Before proceeding with any compounding or processing work, consult and follow label directions and handling precautions from suppliers of all ingredients.

For a complete review of handling precautions and the health- and hazard-related information on Viton FreeFlow, refer to Chemours Safety Data Sheet (SDS) and follow the recommendations in the Chemours technical bulletin, "Guide for Concentrate Preparation and Handling of Viton, FreeFlow, PPAs."



Viton[™] FreeFlow[™] Fluoroelastomers

For more information, visit Viton.com

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