BFGoodrich

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April 5, 1993

Marty Vistins
Becton Dickinson Worldwide Medical Gloves
14300 Winchester Blvd.
Los Gatos, CA 95030-1888

Dear Mr. Vistins:

At the request of Ralph Purtell I am providing you with some general information on the FDA status of Geon E-10 and a determination of the clearance of this PVC resin under 21CFR177.2600, rubber articles intended for repeated use. It is my understanding that you are interested in using Geon E-10 in a glove application intended for repeated use in contact with food.

Geon E-10 is a polyvinyl chloride (PVC) homopolymer. This resin is "prior sanctioned" for use in general food contact applications, both flexible and rigid. The "prior sanctioned" status of Geon E-10 is based on an article by A. J. Lehman, from the FDA (Journal of the Association of Food and Drug Officials, July, 1951), on the use of PVC in food contact applications and compliance with Good Manufacturing Practice (GMP) specifications (maximum volatility of 3.0%, 1 hour at 105° C, and an inherent viscosity of not less than 0.35 by ASTM D-1243-79) which were established in 1963 by a knowledgeable group of industry representatives under the auspices of the Society of Plastics Industries, Inc.

Because of its "prior sanctioned" status, Geon E-10 is acceptable for use, not only under those sections where PVC is specifically listed, but under those sections which allow the use of "prior sanctioned" materials. One example of such clearance is 21CFR 177.2600 (rubber articles intended for repeated use). This section states that "Substances employed in the preparation of rubber articles include, subject to any limitations prescribed, substances used in accordance with the provisions of a prior sanction or approval."

Please contact me at (216) 447-7831 if you have any further questions.

Sincerely,

Connie N. Dillon

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Regulatory and Data System Specialist

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bcc: Mike Marshall
Tom Moore
Ralph Purtell
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ject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. (NOTE: In testing the finished food-contact article, use a separate test sample for each required extracting solvent.)

(c) In accordance with good manufacturing practice, finished food-contact articles containing the polyvinylidene fluoride resins shall be thoroughly cleansed prior to their first use in contact with food.

§ 177.2550 Reverse osmosis membranes.

Substances identified in paragraph (a) of this section may be safely used as reverse osmosis membranes intended for use in processing bulk quantities of liquid food to separate permeate from food concentrate or in purifying water for food manufacturing under the following prescribed conditions:

(a) *Identity.* For the purpose of this section, reverse osmosis membranes may consist of either of the following formulations:

(1) A cross-linked high molecular weight polyamide reaction product of 1,3,5-benzenetricarbonyl trichloride with 1,3-benzenediamine (CAS Reg. No. 83044-99-9) or piperazine (CAS Reg. No. 110-85-0). The membrane is on the food-contact surface, and its maximum weight is 62 milligrams per square decimeter (4 milligrams per square inch) as a thin film composite on a suitable support.

(2) A cross-linked polyetheramine (CAS Reg. No. 101747-84-6), identified as the copolymer of epichlorohydrin, 1,2-ethanediamine and 1,2-dichloroethane, whose surface is the reaction product of this copolymer with 2,4-toluenediisocyanate (CAS Reg. No. of the final polymer is 99811-80-0) for use as the food-contact surface of reverse osmosis membranes used in processing liquid food. The composite membrane is on the food-contact surface and its maximum weight is 4.7 milligrams per square decimeter (0.3 milligrams per square inch) as a thin film composite on a suitable support. The maximum weight of the 2,4-toluenediisocyanate component of the thin film composite is 0.47 milligrams per square decimeter (0.03 milligrams per square inch).

(3) For the purpose of this section, the reverse osmosis membrane consists of a polyaramide identified as 2,4-diaminobenzenesulfonic acid, calcium salt (2:1) polymer with 1,3-benzenediamine, 1,3-benzenedicarbonyl dichloride, and 1,4-benzenedicarbonyl dichloride (CAS Reg. No. 39443-76-0). The membrane is the food contact surface and may be applied as a film on a suitable support. Its maximum weight is 512 milligrams per square decimeter (33 milligrams per square inch).

(4) A cross-linked high molecular weight polyamide reaction product of poly(*N*-vinyl-*N*-methylamine) (CAS Reg. No. 31245-56-4), *N*,*N*'-bis(3-aminopropyl)ethylenediamine (CAS Reg. No. 10563-26-5), 1,3-benzenedicarbonyl dichloride (CAS Reg. No. 99-63-8) and 1,3,5-benzenetricarbonyl trichloride (CAS Reg. No. 4422-95-1). The membrane is the food-contact surface. Its maximum weight is 20 milligrams per square decimeter (1.3 milligrams per square inch) as a thin film composite on a suitable support.

(b) *Optional adjuvant substances.* The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic polymer. These optional adjuvant substances may include substances permitted for such use by regulations in Parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) *Supports.* Suitable supports for reverse osmosis membranes are materials permitted for such use by regulations in Parts 170 through 186 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(d) *Conditions of use.*

(1) Reverse osmosis membranes described in paragraphs (a)(1), (2), and (3) of this section may be used in contact with all types of liquid food at temperatures up to 80 °C (176 °F).

(2) Reverse osmosis membranes described in paragraph (a)(4) of this section may be used in contact wit all types of liquid food, except food containing more than 8 percent alcohol, at temperatures up to 80 °C (176 °F).

(3) Reverse osmosis membranes shall be maintained in a sanitary manner in accordance with current good manufacturing practice so as to prevent microbial adulteration of food.

(4) To assure their safe use, reverse osmosis membranes and their supports shall be thoroughly cleaned prior to their first use in accordance with current good manufacturing practice.

[49 FR 49448, Dec. 20, 1984, as amended at 52 FR 29668, Aug. 11, 1987; 53 FR 31835, Aug. 22, 1988; 53 FR 32215, Aug. 24, 1988; 55 FR 8139, Mar. 7, 1990]

§ 177.2600 Rubber articles intended for repeated use.

Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section.

(b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food.

(c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed:

(1) Substances generally recognized as safe for use in food or food packaging.

(2) Substances used in accordance with the provisions of a prior sanction or approval.

(3) Substances that by regulation in Parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation.

(4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specific[illegible]on in such regu tion.

(i) *Elastomers.*

Acrylonitrile-butadiene copolymer.

Butadiene-acrylonitrile-ethylene glycol methacrylate copolymers containing more than 5 weight percent of poly units derived from ethylene glycol methacrylate.

Butadiene-acrylonitrile-methacrylic acid polymer.

Butadiene-styrene-methacrylic acid cop mer.

Chloroprene polymers.

Chlorotrifluoroethylene-vinylidene fluo copolymer.

Ethylene-propylene copolymer elaston which may contain not more tha weight-percent of total polymer units rived from 5-methylene-2-norborn and/or 5-ethylidine-2-norbornene.

Ethylene-propylene-dicyclopentadiene polymer.

Ethylene-propylene-1,4-hexadiene cop mers containing no more than 8 wei percent of total polymer units deri from 1,4-hexadiene.

Isobutylene-isoprene copolymer.

Polybutadiene.

Polyester elastomers derived from the r tion of dimethyl terephthalate, 1,4-bu ediol, and α-hydro-Ω-hydroxypoly (ox tramethylene). Additionally, trimethyl mellitate may be used as a reactant. polyester elastomers may be used onl contact with foods containing not m than 8 percent alcohol and limited to in contact with food at temperatures exceeding 150 °F.

Polyisoprene.

Polyurethane resins derived from reacti of diphenylmethane diisocyanate adipic acid and 1,4-butanediol.

Rubber, natural.

Silicone basic polymer as described ASTM method D1418-81, "Standard P tice for Rubber and Rubber Latices— menclature," which is incorporated by erence. Copies may be obtained from American Society for Testing Mater 1916 Race St., Philadelphia, PA 19103 may be examined at the Office of the F eral Register, 1100 L St. NW., Wash ton, DC 20408.

Silicone (Si) elastomers containing me groups.

Silicone (Psi) elastomers contain methyl and phenyl groups.

Silicone (Vsi) elastomers contain methyl and vinyl groups.

Silicone (Fsi) elastomers contain methyl and fluorine groups.

Silicone (PVsi) elastomers contain phenyl, methyl, and vinyl groups.

Styrene-butadiene copolymer.

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