

BFGoodrich

EREF

The BFGoodrich Company
Geon Vinyl Division
6100 Oak Tree Boulevard
Cleveland, Ohio 44131
216-447-6000

AN 8315
deleted

December 22, 1992

Joel M. Mirsberger, C.P.M.
Oscar Mayer
Foods Corp.
P.O. Box 7188
910 Mayer Ave.
Madison, WI 53707

Dear Mr. Mirsberger:

This letter is in response to your request for information on the FDA status of the recipe for Geon experimental compound X1501 790 0809. Based on our evaluation of the recipe, the FDA clearance for this compound is limited to sections 21 CFR 175.300 (Resinous and polymeric coatings), 21 CFR 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods), 21 CFR 177.1200 (Cellophane), and 21 CFR 177.1210 (Closures and sealing gaskets for food containers).

Furthermore, this experimental compound must meet the extraction requirements as described under 21 CFR 178.2650 (b)(1).

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

Sincerely,

THE BFGOODRICH COMPANY

Connie N. Dillon
Connie N. Dillon
Regulatory and Data System Specialist

CND/rm
1222-1

cc: Bruce Doney

21678001

BFG15983

USERID: N50WBD1A
PTEFMID: PV120090

PAGE 1 OF 1

USP National Formulary
Twice / Indian Food Additive
GLAS

23/018

Dear Sonneters

DENA for 30
polymer thickener
units

1783740-1783741

178.2650 / must extract

12015

GRAS

175.105; 176.210; 177.315

✓ 178.3570

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C103D326
C103F326 GEON PROD

BFGOODRICH GEON VINYL DIVISION
RECIPE INQUIRY

USERID: NS0WBD1A
PTERMID: PV120090

PRODUCT NBR: X1501 790 0810 X15017900810P LDC: 15 DEPT: 5169 ISSUE: 001

SBC: 1311 EFFECTIVE DATE: 920916 INTERMEDIATE RM NBR:
TOTAL LBS RM: 160.830000 LBS PRODUCT: 160.830000 RECIPE TYPE: 2

PAGE 1 OF 1

SEQ	RAW MATL	DESCRIPTION	QUANTITY LC	PERCENT	COMMENTS
001	961-000498	110 X 450 FG	100.000000	62.1775	
002	931-710887	JAYFLEX 260	60.000000	37.3065	13.8% DINA
003	912-711557	THERMOLITE 890	0.400000	0.2487	
004	919-710858	VANILLIN NF REG	0.050000	0.0311	
005	943-711857	LOXIOL G-21	0.200000	0.1244	
006	943-710353	LOXIOL HDB 7111	0.150000	0.0933	
007	943-711619	LOXAMID EBS-F1	0.030000	0.0187	

NEXT RESPONSE:

NEXT KEY:

DC900016 RECIPE INQUIRY OK PF5-PROP PF6-RMKS PF9-SAFE PF10-INST
SR/LT-1 Aa

23/018

498:	PVC Resin	Prin Sorter
710887:	DENA4 DHP	178.3740; 175.300; 176.170; 177.1210; 177.2600
711557:	Stabilizer	178.2650; (must not select regeneration)
710858:	Benzaldehyde (C ₆ H ₅ CHO)	GRAS
711857:	Hardener Clear Oxide	175.105; 176.210; 178.3120; 178.3570;
710353:	Allyl Resin	177.1350; 175.300; 176.170; 177.1200; 177.1210
711619:	N. N'-Ethylenebis(2-chloroaniline) (Lubricant) Cat. No 110-30-5	175.105; 175.300; 177.1200; 177.1210; 177.1350; 177.2470; 177.2480

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Limitations

percent by weight of ethylene-propylene-5-polymer complying with § 177.1520 of this chapter, under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

0.1 percent by weight of olefin polymers of this chapter, under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

0.1 percent by weight of polystyrene and 0.1 percent by weight of rubber-modified polystyrene of this chapter, under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter.

0.5 percent by weight of elastomers used in this chapter.

0.5 percent by weight of nylon resins complying with § 177.1520 of this chapter.

0.5 percent by weight of polycarbonate resins of this chapter.

0.2 percent by weight of olefin polymers of this chapter, under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

0.2 percent by weight of ethylene-vinyl-acetate of this chapter, under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

0.2 percent by weight of olefin polymers of this chapter, under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.

0.5 percent by weight of acrylic and modified acrylic, complying with § 177.1010 of this chapter.

0.5 percent by weight of isobutylene copolymers complying with § 177.1420 of this chapter.

0.5 percent by weight of pressure sensitive adhesives complying with § 177.1520 of this chapter.

0.5 percent by weight of can end cement complying with § 177.1520 of this chapter.

0.5 percent by weight of side seam cement complying with § 177.1520 of this chapter.

0.5 percent by weight of petroleum alkyd resins complying with § 177.1520 of this chapter.

0.5 percent by weight of petroleum alkyd resins or their hydrogenated products complying with § 177.1520 of this chapter.

0.5 percent by weight of resins and polymers of this chapter.

0.5 percent by weight of rosin and rosin derivatives complying with § 177.1520 of this chapter.

0.5 percent by weight of closures complying with § 177.1520 of this chapter.

0.5 percent by weight of petroleum and rosin and rosin derivatives complying with § 177.1520 of this chapter.

Substances	Limitations
Tris[2-methyl-4-hydroxy-5-tert-butylphenyl]butane (CAS Reg. No. 1843-08-4)	21. At levels not to exceed 0.5 percent by weight of reinforced wax complying with § 178.3850. 22. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.3. The finished polymers may be used in contact with food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. For use only: 1. At levels not to exceed 0.25 percent by weight of polymers used as provided in § 176.180 of this chapter. 2. At levels not to exceed 0.25 percent by weight of the following polymers when used in articles that contact food of Types I, II, IV-B, VI-B, VII-B, and VIII described in Table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 178.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 3. At levels not to exceed 0.1 percent by weight of the following polymers when used in articles that contact food of Types III, IV-A, V, VI-A, VI-C, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter: Olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, or 4 or complying with other sections in Parts 174, 175, 176, 177, 178 and § 178.45 of this chapter; vinyl chloride polymers; and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. 4. As provided in § 175.105 of this chapter. 5. At levels not to exceed 0.2 percent by weight of polystyrene and/or modified polystyrene polymers identified in § 177.1640 of this chapter. 6. At levels not to exceed 0.25 percent by weight of acrylonitrile-butadiene-styrene copolymers used in contact with nonalcoholic foods. 7. At levels not to exceed 1 percent by weight of closure-sealing gasket compositions complying with § 177.1210(b) of this chapter. For use only: 1. At levels not to exceed 0.2 percent by weight of isobutyleneisoprene copolymers complying with § 177.1420 of this chapter. Provided, That the finished copolymers contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Types V, VII, VIII, and IX. 2. At levels not to exceed 0.02 percent by weight of polypropylene polymers complying with § 177.1520(c), item 1.1 of this chapter.
Zinc dibutyldithiocarbamate (CAS Reg. No. 136-23-2)	For use only in rigid polyvinyl chloride and/or in rigid vinyl chloride copolymers complying with § 177.1980 of this chapter. Provided, That total salicylates (calculated as the acid) do not exceed 0.3 percent by weight of such polymers.
Zinc palmitate	
Zinc stearate	

¹ Copies are available from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

[42 FR 14609, Mar. 15, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 178.2010, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 178.2550 4-Hydroxymethyl-2,6-di-tert-butylphenol.

4-Hydroxymethyl-2,6-di-tert-butylphenol may be safely used as an antioxidant in articles intended for use in contact with food, in accordance with the following prescribed conditions:

- The additive has a solidification point of 140°-141°C.
- The concentration of the additive and any other permitted antioxidants in the finished food-contact article does not exceed a total of 0.5 milligram per square inch of food-contact surface.

§ 178.2650 Organotin stabilizers in vinyl chloride plastics.

The organotin chemicals identified in paragraph (a) of this section may be safely used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in vinyl chloride homopolymers and copolymers complying with the provisions of § 177.1950 or § 177.1980 of this chapter and that are identified for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonal-

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coholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, except for the organotin chemical identified in paragraph (a)(3) of this section, which may be used in contact with food of types I through IX at temperatures not exceeding 75 °C (167 °F), and further that the organotin chemicals identified in paragraphs (a) (5) and (6) of this section may be used in contact with food of types I through IX at temperatures not exceeding 66 °C (150 °F), conditions of use D through G described in table 2 of § 176.170(c) of this chapter, and further that dodecyltin chemicals identified in paragraph (a)(7) of this section which may be used in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter at temperatures not exceeding 71 °C (160 °F), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the organotin chemicals are those listed in paragraphs (a) (1), (2), (3), (4), (5), (6), and (7) of this section.

(1) Di(*n*-octyl)tin *S,S'*-bis(isooctylmercaptoacetate) is an octyltin chemical having 15.1 to 16.4 percent by weight of tin (Sn) and having 8.1 to 8.9 percent by weight of mercapto sulfur. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin oxide. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. Di(*n*-octyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of di(*n*-octyl)tin dichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride. Di(*n*-octyl)tin oxide has an organotin composition that is not less than 95 percent by weight of di(*n*-octyl)tin oxide and not more than 5 percent by weight of bis[tri(*n*-octyl)tin] oxide, and/or mono *n*-octyltin oxide.

(2) Di(*n*-octyl) tin maleate polymer is an octyltin chemical having the formula $[(C_8H_{17})_2SnC_4H_4O_2]_n$ (where *n* is between 2 and 4 inclusive), having 25.2 to 26.6 percent by weight of tin (Sn) and having a saponification number of 225 to 255. It is made from di(*n*-octyl)tin dichloride or di(*n*-octyl)tin

oxide meeting the specifications prescribed for di(*n*-octyl) tin dichloride or di(*n*-octyl) tin oxide in paragraph (a)(1) of this section.

(3) *C₁₂-*n*-Alkyl mercaptoacetates* reaction products with dichlorodioctylstannane and trichlorooctylstannane (CAS Reg. No. 83447-69-2) is an organotin chemical mixture having 10.8 to 11.8 percent by weight of tin (Sn) and having 8.0 to 8.6 percent by weight of mercapto sulfur. It is made from a mixture of di(*n*-octyl)tin dichloride and (*n*-octyl)tin trichloride which has an organotin composition that is not less than 95 percent by weight di(*n*-octyl)tin dichloride/(*n*-octyl)tin trichloride, and not more than 1.5 percent by weight of tri(*n*-octyl)tin chloride. The alkyl radical in the mercaptoacetate is derived from a mixture of saturated *n*-alcohols which has a composition that is not less than 50 percent by weight tetradecyl alcohol, and that is not more than 50 percent by weight total of decyl alcohol and/or dodecyl alcohol, and/or hexadecyl alcohol.

(4) (*n*-Octyl)tin *S,S,S'*-tris(isooctylmercaptoacetate) is an octyltin chemical having the formula $n-C_8H_{17}Sn(SCH_2CO_2C_8H_{17})_3$ (CAS Reg. No. 26401-86-5) having 13.4 to 14.8 percent by weight of tin (Sn) and having 10.9 to 11.9 percent by weight of mercapto sulfur. It is made from (*n*-octyl)tin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process isooctyl alcohol. The (*n*-octyl)tin trichloride has an organotin composition that is not less than 95 percent by weight of (*n*-octyl)tin trichloride and not more than 5 percent by weight of tri(*n*-octyl)tin chloride.

(5) Bis(*beta*-carboboxyethyl)tin bis(isooctylmercaptoacetate) (CAS Reg. No. 63397-60-4) is an estertin chemical having 14.0 to 15.0 percent by weight of tin (Sn) and having 7.5 to 8.5 percent by weight of mercapto sulfur. It is made from bis(*beta*-carboboxyethyl)tin dichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols. The bis(*beta*-carboboxyethyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of bis(*beta*-carboboxyethyl)tin dichlo-

ride and n weight of tin trichloride content of tin) dichloride percent.

(6) tris(isooctyl) Reg. No. (chemical (by weight (to 11.5 perc sulfur. It is toxyethylth radical in (rived from alcohol. Th trichloride tion that is weight of trichloride cent total (diestertin cl

(7) The mixture of of tris(isooctyl) Reg. No. 67 cent by weight di(isooctyl)tin No. 84030-6 cent by weight 8 to 9 perc sulfur. It is dodecyltin di(dodecyl)tin not more th of dodecyltin than 2 perc butyltin diol 3 percent by chloride. Th mercaptoacet process prin

(b) The v tainers, film form in wh food, shall i tions:

(1) The f for contact listed in this with the sol izing those mined from this chapter reflecting the as determin extraction t

ride and not more than 5 percent by weight of bis(beta-carbobutoxyethyltin) trichloride. The triestertin chloride content of bis(beta-carbobutoxyethyltin) dichloride shall not exceed 0.02 percent.

(6) *Beta-carbobutoxyethyltin tris(isooctylmercaptoacetate)* (CAS Reg. No. 63438-80-2) is an estertin chemical having 13.0 to 14.0 percent by weight of tin (Sn) and having 10.5 to 11.5 percent by weight of mercapto sulfur. It is made from *beta*-carbobutoxyethyltin trichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohol. The *beta*-carbobutoxyethyltin trichloride has an organotin composition that is not less than 95 percent by weight of *beta*-carbobutoxyethyltin trichloride and not more than 5 percent total of triestertin chloride and diestertin chloride.

(7) The dodecyltin stabilizer is a mixture of 50 to 60 percent by weight of *n*-dodecyltin *S,S,S'*-tris(isooctylmercaptoacetate) (CAS Reg. No. 67649-65-4) and 40 to 50 percent by weight of di(*n*-dodecyl)tin *S,S'*-di(isooctylmercaptoacetate) (CAS Reg. No. 84030-61-5) having 13 to 14 percent by weight of tin (Sn) and having 8 to 9 percent by weight of mercapto sulfur. It is made from a mixture of dodecyltin trichloride and di(dodecyl)tin dichloride which has not more than 0.2 percent by weight of dodecyltin trichloride, not more than 2 percent by weight of dodecylbutyltin dichloride and not more than 3 percent by weight of tri(dodecyl)tin chloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols.

(8) The vinyl chloride plastic containers, film or panels in the finished form in which they are to contact food, shall meet the following limitations:

(i) The finished plastics intended for contact with foods of the types listed in this section shall be extracted with the solvent or solvents characterizing those types of foods as determined from Table 2 of § 176.170(c) of this chapter at the temperature reflecting the conditions of intended use as determined therein. Additionally, extraction tests for acidic foods shall

be included and simulated by 3-percent acetic acid at temperatures specified for water in Table 2 of § 176.170(c) of this chapter. The extraction tests shall cover at least three equilibrium periodic determinations, as follows:

(i) The exposure time for the first determination shall be at least 72 hours for aqueous solvents, and at least 6 hours for heptane.

(ii) Subsequent determinations shall be at a minimum of 24-hour intervals for aqueous solvents, and 2-hour intervals for heptane. These tests shall yield total octyltin stabilizers not to exceed 0.5 parts per million as determined by analytical method entitled "Atomic Absorption Spectrometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, p. 1090-1093 (1977), which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW, Washington, DC 20408.

(iii) Subsequent determinations for the dodecyltin mixture described in paragraph (a)(7) of this section shall be at a minimum of 24-hour intervals for aqueous solvents and 2-hour intervals for heptane. These tests shall yield di(*n*-octyl)tin *S,S'*-bis(isooctylmercaptoacetate), or di(*n*-octyl)tin maleate polymer, or (C₁₀-C₁₈)-alkylmercaptoacetate reaction products with dichlorodioctylstannane and trichlorooctylstannane, or *n*-octyltin *S,S,S'*-tris(isooctylmercaptoacetate), tris(isooctylmercaptoacetate) and di(*n*-dodecyl)tin bis(isooctylmercaptoacetate) or any combination thereof, not to exceed 0.5 parts per million as determined by an analytical method entitled "Atomic Absorption Spectrophotometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, pp. 1090-1093 (1977), which is incorporated by reference in accordance with

§ 178.3010

5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

(2) In lieu of the tests prescribed in paragraph (b) (1) of this section, the finished plastics intended for contact with foods only of Types II, V, VI-A (except malt beverages), and VI-C may be end-tested with food-simulating solvents, under conditions of time and temperature, as specified below, whereby such tests shall yield the octyltin residues cited in paragraph (b)(1) of this section not in excess of 0.5 ppm:

	Food-simulating solvent	Time (hours)	Temperature (degrees Fahrenheit)
Type II	Acetic acid, 3 pct	48	135
Type V	Heptane	2	100
Type VI-A	Ethyl alcohol, 8 pct	24	120
Type VI-C	Ethyl alcohol, 50 percent	24	120

[42 FR 14609, Mar. 15, 1977, as amended at 47 FR 11847, Mar. 19, 1982; 48 FR 7170, Feb. 18, 1983; 48 FR 42972, Sept. 21, 1983; 48 FR 51612, Nov. 10, 1983; 49 FR 8432, Mar. 7, 1984; 50 FR 62, Jan. 2, 1985; 50 FR 3510, Jan. 25, 1985; 50 FR 37998, Sept. 19, 1985; 50 FR 47212, Nov. 15, 1985; 54 FR 24898, June 12, 1989]

Subpart D—Certain Adjuvants and Production Aids

§ 178.3010 Adjuvant substances used in the manufacture of foamed plastics.

The following substances may be safely used as adjuvants in the manufacture of foamed plastics intended for use in contact with food, subject to any prescribed limitations:

List of substances	Limitations
Azodicarbonamide	For use as a blowing agent in polystyrene complying with item 2.1 in § 177.1520(c) of this chapter at a level not to exceed 5 percent by weight of finished foamed polystyrene.
Isopentane	For use as a blowing agent in polystyrene.
n-Pentane	Do.

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—Continued

List of substances	Limitations
1,1,2,2-Tetrachloroethylene	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.3 percent by weight of finished foamed polystyrene intended for use in contact with food only of the types identified in § 178.170(c) of this chapter, Table 1, under Categories I, II, VI, and VIII.
Toluene	For use only as a blowing agent adjuvant in polystyrene at a level not to exceed 0.35 percent by weight of finished foamed polystyrene.

[47 FR 22090, May 21, 1982]

§ 178.3120 Animal glue.

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

(a) Animal glue consists of the proteinaceous extractives obtained from hides, bones, and other collagen-rich substances of animal origin (excluding diseased or rotted animals), to which may be added other optional adjuvant substances required in its production or added to impart desired properties.

(b) The quantity of any substance employed in the production of animal glue does not exceed the amount reasonably required to accomplish the intended physical or technical effect nor any limitation further provided.

(c) Any substance employed in the production of animal glue and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Optional adjuvant substances employed in the production of animal glue include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in animal glue and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

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petroleum wax is permitted in Subchapter B of this chapter as a component of articles intended to contact food, provided that the synthetic petroleum wax meets the definition and specifications prescribed in § 172.888 of this chapter.

§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed in compliance with §§ 561.310 and 561.340 of this chapter, or that are intended for use in contact with dried food in compliance with §§ 193.60 and 193.390 of this chapter.

§ 178.3740 Plasticizers in polymeric substances.

Subject to the provisions of this regulation, the substances listed in paragraph (b) of this section may be safely used as plasticizers in polymeric substances used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technological effect.

(b) List of substances:

Limitations

used in §§ 175.105 and 176.180 of this chapter.

For substances used in food-contact articles complying with § 175.320, or § 176.170 of this chapter: *Provided*, That the vinyl phthalate contains not more than 1 percent by weight of phthalate.

For substances used in other permitted food-contact articles: That the butyl benzyl phthalate contains not more than 1 percent by weight of dibenzyl phthalate; and *Provided further*, That the food-contact article, when extracted with the solvent or characterizing the type of food and under the conditions of temperature characterizing the conditions of its intended use, as determined by the methods prescribed in § 175.300(d) of this chapter, net chloroform-soluble extractives not to exceed 0.5 mg. per g., as determined by the methods prescribed in § 175.300(e) of this chapter.

At levels not exceeding 33 percent by weight of polyvinyl copolymers used in contact with food (except foods that are more than 8 percent of alcohol) at temperatures not to exceed 100°C. The average thickness of such homopolymers in which they contact food shall not exceed 0.004 inch.

Substances	Limitations
(1) C ₁₂ -C ₁₈ alkyl adipate, in which the C ₁₂ -C ₁₈ alkyl groups are derived from linear alpha olefins by the oxo process.	For use only under the conditions listed below, and excluding use as a component of resinous and polymeric coatings described in § 175.300 of this chapter. - At levels not to exceed 24 percent by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not to exceed 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymer in the form in which they contact food shall not exceed 0.002 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
(2) Alkyl adipate made from C ₁₂ -C ₁₈ (predominately C ₁₂ and C ₁₄) or C ₁₂ -C ₁₈ synthetic fatty alcohols complying with § 172.854 of this chapter.	For use only: - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter, with fatty foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in which they contact food shall not exceed 0.002 inch.
Dicyclohexyl phthalate	For use only: - As provided in §§ 175.105, 176.170, 176.180, and 177.1200 of this chapter. - Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1980 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid.
D(2-ethylhexyl) adipate	For use only: - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.
Diisononyl adipate	For use only: - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact under conditions of use F and G described in Table 2 of § 176.170(c) of this chapter with fatty, nonalcoholic foods having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch. - At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic foods. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch.

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Substances	Limitations
Diisononyl phthalate	4. At levels not exceeding 35 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use, and G described in Table 2 of § 176.170(c) of this chapter with fatty nonalcoholic foods having a fat and oil content not exceeding a total of 40 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.002 inch. For use only at levels not exceeding 43 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, and VIII, at temperatures not exceeding room temperature. The average thickness of such polymers in the form in which they contact food shall not exceed 0.005 inch.
Di(2-ethylhexyl) azelate	For use only: 1. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact with nonfatty, nonalcoholic food. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch. 2. At levels not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use, and G described in Table 2 of § 176.170(c) of this chapter, with fatty nonalcoholic food having a fat and oil content not exceeding a total of 30 percent by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Di-n-hexylazelate	For use only: 1. In polymeric substances used in contact with nonfatty food. 2. In polymeric substances used in contact with fatty food and limited to use at levels not exceeding 15 pct by weight of such polymeric substance except as provided under limitation 3. 3. At levels greater than 15 but not exceeding 24 pct by weight of permitted vinyl chloride homo- and/or copolymers used in contact, under conditions of use F or G described in Table 2 of § 176.170(c) of this chapter, with fatty food having a fat and oil content not exceeding a total of 30 pct by weight. The average thickness of such polymers in the form in which they contact food shall not exceed 0.003 inch.
Dihexyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. In articles that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI-B, and VIII.
Diphenyl phthalate	For use only: 1. As provided in § 175.105 of this chapter. 2. Alone or in combination with other phthalates, in plastic film or sheet prepared from polyvinyl acetate, polyvinyl chloride, and/or vinyl chloride copolymers complying with § 177.1590 of this chapter. Such plastic film or sheet shall be used in contact with food at temperatures not to exceed room temperature and shall contain no more than 10 pct by weight of total phthalates, calculated as phthalic acid. Iodine number, maximum 5; oxirane oxygen, minimum 7.8 pct. Iodine number, maximum 5; oxirane oxygen, minimum 9-pct. For use only: 1. In polymeric substances used in contact with non-fatty food. 2. In polyethylene complying with § 177.1520 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking. 3. In polystyrene complying with § 177.1640 of this chapter and used in contact with fatty food, provided that the hydrogenated polybutene is added in an amount not to exceed 5 pct by weight of the polystyrene, and further provided that such plasticized polystyrene shall not be used as a component of articles intended for packing or holding food during cooking.
Epoxidized butyl esters of linseed oil fatty acids	For use in polyethylene complying with § 177.1520 of this chapter, provided that the polyisobutylene is added in an amount not exceeding 0.5 pct by weight of the polyethylene, and further provided that such plasticized polyethylene shall not be used as a component of articles intended for packing or holding food during cooking.
Epoxidized linseed oil	
Mineral oil, white	
Polybutene, hydrogenated (minimum viscosity at 99° F, 39 Saybolt Universal seconds, as determined by ASTM methods D445-82 ("Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity)") and D2161-82 ("Standard Method for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity"), and bromine number of 3 or less, as determined by ASTM method D1492-78 ("Standard Test Method for Bromine Index of Aromatic Hydrocarbons by Coulometric Titration"), which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.	
Polyisobutylene (mol weight 300-5,000)	

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PRODUCTION RECIPE INQUIRY

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USERID: N50CND1A
TERMID: PV120069

PRODUCT NO. 00110 450 FG00 LOC 80 DEPT E120 ISSUE S92
DESCRIPTION 110X450FG00 SBC 111B INT. RM. 961000816

CO. CODE E

TEM	RM NUMBER	DESCRIPTION	QUANTITY	USE
010	968 000094	06611 E00	100.024561	
020	953 710760	LUPERSOL 225M60	.061093	
030	953 00G098	METHOCEL F50 PRE	.031744	
040	957 00W013	PVA, 88%	.040030	
050	911 00A030	BHT DISPERSION	.061093	
060	911 00A028	DTAHQ DISPERSION	.037634	
080	953 710689	ALCOTEX 55-002H	.144246	

175.300, 177.2, 178.5, 179.8, 181.1, 182.4, 183.7, 185.0, 186.3, 187.6, 188.9, 190.2, 191.5, 192.8, 194.1, 195.4, 196.7, 198.0, 199.3, 200.6, 201.9, 203.2, 204.5, 205.8, 207.1, 208.4, 209.7, 211.0, 212.3, 213.6, 214.9, 216.2, 217.5, 218.8, 220.1, 221.4, 222.7, 224.0, 225.3, 226.6, 227.9, 229.2, 230.5, 231.8, 233.1, 234.4, 235.7, 237.0, 238.3, 239.6, 240.9, 242.2, 243.5, 244.8, 246.1, 247.4, 248.7, 250.0, 251.3, 252.6, 253.9, 255.2, 256.5, 257.8, 259.1, 260.4, 261.7, 263.0, 264.3, 265.6, 266.9, 268.2, 269.5, 270.8, 272.1, 273.4, 274.7, 276.0, 277.3, 278.6, 279.9, 281.2, 282.5, 283.8, 285.1, 286.4, 287.7, 289.0, 290.3, 291.6, 292.9, 294.2, 295.5, 296.8, 298.1, 299.4, 300.7, 302.0, 303.3, 304.6, 305.9, 307.2, 308.5, 309.8, 311.1, 312.4, 313.7, 315.0, 316.3, 317.6, 318.9, 320.2, 321.5, 322.8, 324.1, 325.4, 326.7, 328.0, 329.3, 330.6, 331.9, 333.2, 334.5, 335.8, 337.1, 338.4, 339.7, 341.0, 342.3, 343.6, 344.9, 346.2, 347.5, 348.8, 350.1, 351.4, 352.7, 354.0, 355.3, 356.6, 357.9, 359.2, 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546.4, 547.7, 549.0, 550.3, 551.6, 552.9, 554.2, 555.5, 556.8, 558.1, 559.4, 560.7, 562.0, 563.3, 564.6, 565.9, 567.2, 568.5, 569.8, 571.1, 572.4, 573.7, 575.0, 576.3, 577.6, 578.9, 580.2, 581.5, 582.8, 584.1, 585.4, 586.7, 588.0, 589.3, 590.6, 591.9, 593.2, 594.5, 595.8, 597.1, 598.4, 599.7, 601.0, 602.3, 603.6, 604.9, 606.2, 607.5, 608.8, 610.1, 611.4, 612.7, 614.0, 615.3, 616.6, 617.9, 619.2, 620.5, 621.8, 623.1, 624.4, 625.7, 627.0, 628.3, 629.6, 630.9, 632.2, 633.5, 634.8, 636.1, 637.4, 638.7, 640.0, 641.3, 642.6, 643.9, 645.2, 646.5, 647.8, 649.1, 650.4, 651.7, 653.0, 654.3, 655.6, 656.9, 658.2, 659.5, 660.8, 662.1, 663.4, 664.7, 666.0, 667.3, 668.6, 669.9, 671.2, 672.5, 673.8, 675.1, 676.4, 677.7, 679.0, 680.3, 681.6, 682.9, 684.2, 685.5, 686.8, 688.1, 689.4, 690.7, 692.0, 693.3, 694.6, 695.9, 697.2, 698.5, 699.8, 701.1, 702.4, 703.7, 705.0, 706.3, 707.6, 708.9, 710.2, 711.5, 712.8, 714.1, 715.4, 716.7, 718.0, 719.3, 720.6, 721.9, 723.2, 724.5, 725.8, 727.1, 728.4, 729.7, 731.0, 732.3, 733.6, 734.9, 736.2, 737.5, 738.8, 740.1, 741.4, 742.7, 744.0, 745.3, 746.6, 747.9, 749.2, 750.5, 751.8, 753.1, 754.4, 755.7, 757.0, 758.3, 759.6, 760.9, 762.2, 763.5, 764.8, 766.1, 767.4, 768.7, 770.0, 771.3, 772.6, 773.9, 775.2, 776.5, 777.8, 779.1, 780.4, 781.7, 783.0, 784.3, 785.6, 786.9, 788.2, 789.5, 790.8, 792.1, 793.4, 794.7, 796.0, 797.3, 798.6, 799.9, 801.2, 802.5, 803.8, 805.1, 806.4, 807.7, 809.0, 810.3, 811.6, 812.9, 814.2, 815.5, 816.8, 818.1, 819.4, 820.7, 822.0, 823.3, 824.6, 825.9, 827.2, 828.5, 829.8, 831.1, 832.4, 833.7, 835.0, 836.3, 837.6, 838.9, 840.2, 841.5, 842.8, 844.1, 845.4, 846.7, 848.0, 849.3, 850.6, 851.9, 853.2, 854.5, 855.8, 857.1, 858.4, 859.7, 861.0, 862.3, 863.6, 864.9, 866.2, 867.5, 868.8, 870.1, 871.4, 872.7, 874.0, 875.3, 876.6, 877.9, 879.2, 880.5, 881.8, 883.1, 884.4, 885.7, 887.0, 888.3, 889.6, 890.9, 892.2, 893.5, 894.8, 896.1, 897.4, 898.7, 900.0, 901.3, 902.6, 903.9, 905.2, 906.5, 907.8, 909.1, 910.4, 911.7, 913.0, 914.3, 915.6, 916.9, 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1416.1, 1417.4, 1418.7, 1420.0, 1421.3, 1422.6, 1423.9, 1425.2, 1426.5, 1427.8, 1429.1, 1430.4, 1431.7, 1433.0, 1434.3, 1435.6, 1436.9, 1438.2, 1439.5, 1440.8, 1442.1, 1443.4, 1444.7, 1446.0, 1447.3, 1448.6, 1450.0, 1451.3, 1452.6, 1453.9, 1455.2, 1456.5, 1457.8, 1459.1, 1460.4, 1461.7, 1463.0, 1464.3, 1465.6, 1466.9, 1468.2, 1469.5, 1470.8, 1472.1, 1473.4, 1474.7, 1476.0, 1477.3, 1478.6, 1479.9, 1481.2, 1482.5, 1483.8, 1485.1, 1486.4, 1487.7, 1489.0, 1490.3, 1491.6, 1492.9, 1494.2, 1495.5, 1496.8, 1498.1, 1499.4, 1500.7, 1502.0, 1503.3, 1504.6, 1505.9, 1507.2, 1508.5, 1509.8, 1511.1, 1512.4, 1513.7, 1515.0, 1516.3, 1517.6, 1518.9, 1520.2, 1521.5, 1522.8, 1524.1, 1525.4, 1526.7, 1528.0, 1529.3, 1530.6, 1531.9, 1533.2, 1534.5, 1535.8, 1537.1, 1538.4, 1539.7, 1541.0, 1542.3, 1543.6, 1544.9, 1546.2, 1547.5, 1548.8, 1550.1, 1551.4, 1552.7, 1554.0, 1555.3, 1556.6, 1557.9, 1559.2, 1560.5, 1561.8, 1563.1, 1564.4, 1565.7, 1567.0, 1568.3, 1569.6, 1570.9, 1572.2, 1573.5, 1574.8, 1576.1, 1577.4, 1578.7, 1580.0, 1581.3, 1582.6, 1583.9, 1585.2, 1586.5, 1587.8, 1589.1, 1590.4, 1591.7, 1593.0, 1594.3, 1595.6, 1596.9, 1598.2, 1599.5, 1600.8, 1602.1, 1603.4, 1604.7, 1606.0, 1607.3, 1608.6, 1609.9, 1611.2, 1612.5, 1613.8, 1615.1, 1616.4, 1617.7, 1619.0, 1620.3, 1621.6, 1622.9, 1624.2, 1625.5, 1626.8, 1628.1, 1629.4, 1630.7, 1632.0, 1633.3, 1634.6, 1635.9, 1637.2, 1638.5, 1639.8, 1641.1, 1642.4, 1643.7, 1645.0, 1646.3, 1647.6, 1648.9, 1650.2, 1651.5, 1652.8, 1654.1, 1655.4, 1656.7, 1658.0, 1659.3, 1660.6, 1661.9, 1663.2, 1664.5, 1665.8, 1667.1, 1668.4, 1669.7, 1671.0, 1672.3, 1673.6, 1674.9, 1676.2, 1677.5, 1678.8, 1680.1, 1681.4, 1682.7, 1684.0, 1685.3, 1686.6, 1687.9, 1689.2, 1690.5, 1691.8, 1693.1, 1694.4, 1695.7, 1697.0, 1698.3, 1699.6, 1700.9, 1702.2, 1703.5, 1704.8, 1706.1, 1707.4, 1708.7, 1710.0, 1711.3, 1712.6, 1713.9, 1715.2, 1716.5, 1717.8, 1719.1, 1720.4, 1721.7, 1723.0, 1724.3, 1725.6, 1726.9, 1728.2, 1729.5, 1730.8, 1732.1, 1733.4, 1734.7, 1736.0, 1737.3, 1738.6, 1739.9, 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2066.2, 2067.5, 2068.8, 2070.1, 2071.4, 2072.7, 2074.0, 2075.3, 2076.6, 2077.9, 2079.2, 2080.5, 2081.8, 2083.1, 2084.4, 2085.7, 2087.0, 2088.3, 2089.6, 2090.9, 2092.2, 2093.5, 2094.8, 2096.1, 2097.4, 2098.7, 2099.9, 2101.2, 2102.5, 2103.8, 2105.1, 2106.4, 2107.7, 2109.0, 2110.3, 2111.6, 2112.9, 2114.2, 2115.5, 2116.8, 2118.1, 2119.4, 2120.7, 2122.0, 2123.3, 2124.6, 2125.9, 2127.2, 2128.5, 2129.8, 2131.1, 2132.4, 2133.7, 2135.0, 2136.3, 2137.6, 2138.9, 2140.2, 2141.5, 2142.8, 2144.1, 2145.4, 2146.7, 2148.0, 2149.3, 2150.6, 2151.9, 2153.2, 2154.5, 2155.8, 2157.1, 2158.4, 2159.7, 2161.0, 21

FDA

A-30 654231 175.105, 176.170, 177.2600

AKRON DISPERSIONS - YES 175.105, 176.170, 177.2600

AMERICAN DISPERSIONS - YES 175.105, 175.125, 175.300, 176.170,
176.180, 176.210, 177.1200, 177.1210,
177.1650, 177.2600, 178.3120

NEXT RESPONSE: REGCINQ NEXT KEY:
PRESS PF8 TO PAGE FORWARD AND PF7 TO PAGE BACK

BFG15993

21678011

001R71 BF GOODRICH COMPANY MESSAGE SERVICE 12:12:11
 DM: P103R360 TO: CLEVMAIN DOCUMENT: 020002 47 LINES 09/02/92

ROUTE TO: DILLON, CONNIE N

 * LAPORTE T E C H N I C A L D O C U M E N T *

R103360 LAPORTE RECIPE 09/02/92 12:12:09

GEON RESIN 110X450FG LOC: 80 DEPT: E120 ISSUE: 392
 COMMODITY NO.: 00110 450 FG00 EFFECTIVE DATE: 01/01/92
 SBC NBR: 111B DELETE FLAG: NO
 LAB REF: CMPR:
 BASED ON:
 APPLICATION:

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
100.02456	968 000094 06611 E00	010		99.626
.06109	953 710760 LUPERSOL 225M60	020		.061
.03174	953 00G098 METHOCEL F50 PREMIUM	030		.032
.04003	957 00W013 PVA, 88%	040		.040
.06109	911 00A030 BHT DISPERSION	050		.061
.03763	911 00A028 DTAHQ DISPERSION	060		.037
.14424	953 710689 ALCOTEX 55-002H 40%	080		.144
100.40040		TOTAL		100.000

TYPE SAMPLE:
 ISSUED:
 MARKETING APPROVAL:

BFG15994

21678012

C617D096
C617F096

INVENTORY NO / CAS INQUIRY
GEON PROD

USERID: N50CND1A
PTERMID: PV120103

INVENTORY NUMBER : 912 / 71 / 1557

CAS NO.	CONCT PCT.	DESCRIPTION
15571-58-1	075.0000	
27107-89-7	040.0000	

NEXT RESPONSE: RMCASINQ NEXT KEY:
NO MORE CAS NUMBERS TO BE DISPLAYED

21678013

BFG15995