

June 27, 1990

Bud Pazur
ALTC

RE: GEON 87349 WHITE 138 ISSUE 8

There are some ingredients in this compound which are either not acceptable, or for which I have no information as to their FDA status.

The colorants B-287 Golden TY-70 and B-296 Brown 7739 (used in 87333-000-3052) are not acceptable for food contact. Enclosed is a list of colorants that could be used. There may be others, also.

I have no information on the FDA status of Cenwax A (12-Hydroxystearic acid), although hydrogenated fatty acids from vegetable and animal sources are permitted for some uses. Likewise, I'm not sure if AC-316A polyethylene meets the specifications for oxidized PE as listed in 177.1620.

Loxiol G-70S (Pentaerythritol adipate-stearate) is limited to use conditions E, F & G in contact with foods except those containing more than 8% alcohol. Also, the total amount of ester (calculated as the free pentaerythritol) may not exceed 0.4% by weight of PVC.

In addition, Mark 1984 is limited to use conditions D, E, F and G in contact with all foods except liquid milk.

The temperature use conditions limitations and food use conditions described above would not exclude the compound from use as a refrigerator liner.

Since Geon 87349, White 138 is not acceptable for food contact use under FDA regulations, it would not be acceptable to the USDA.

If you have any questions, or I can be of further help, please call me at Ext. 3422.

W. C. Bachtel

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0627-1/jp

cc: P. Tully - CL-OTM-3

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BFG07536

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(vi) Colors (total not to exceed 10 percent by weight of rubber product).

Chrome oxide (Cr_2O_3).
C.I. pigment red 38, C.I. No. 21120.
Iron oxide. — *only shade*
Phthalocyanine.
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Titanium dioxide.
Ultramarine blue.
Zinc chromate.

(vii) Lubricants (total not to exceed 2 percent by weight of rubber product).

Polyethylene.
Sodium stearate.

(viii) Emulsifiers.

Fatty acid salts, sodium or potassium.
Naphthalene sulfonic acid-formaldehyde condensate, sodium salt.
Rosins and rosin-derivatives identified in § 175.105(c)(5) of this chapter.
Sodium decylbenzenesulfonate
Sodium dodecylbenzenesulfonate
Sodium lauryl sulfate.
Tall oil mixed soap (calcium, potassium, and sodium).

(ix) Miscellaneous (total not to exceed 5 percent by weight of rubber product).

Animal glue as described in § 178.3120 of this chapter.
Azodicarbonamide as chemical blowing agent.
2-Anthraquinone sulfonic acid sodium salt for use only as polymerization inhibitor in chloroprene polymers and not to exceed 0.03 percent by weight of the chloroprene polymers.
n-Butyllithium for use only as polymerization catalyst for polybutadiene.
4-tert-Butyl-o-thiocresol as peptizing agent.
tert-Butyl peracetate.
p-tert-Butylpyrocatechol.
Dialkyl (C_8 – C_{12}) dimethylammonium chloride for use only as a flocculating agent in the manufacture of silica.
Di- and triethanolamine.
Diethyl xanthogen disulfide.
4-(Diiodomethylsulfonyl) toluene, Chemical Abstracts Service Registry No. 20018-09-01, for use as an antifungal preservative at levels not to exceed 0.3 percent by weight of the sealants and caulking materials.
Dodecyl mercaptan isomers, single or mixed.
2-Ethoxyethanol.
Iodoform.
p-Menthane hydroperoxide.
 α -(p-Nonylphenyl)- ω -hydroxypoly (ox-ethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters, barium salt; the nonyl group is a propylene trimer isomer and the poly (ox-

ethylene) content averages 9 moles; for use only as residual polymerization emulsifier at levels not to exceed 0.7 percent by weight of ethylene-propylene-1,4-hexadiene copolymers identified under paragraph (c)(4)(i) of this section.

4,4'-Oxybis (benzenesulfonhydrazide) as chemical blowing agent.

Phenothiazine.

Potassium persulfate.

Sodium formaldehyde sulfoxylate.

Sodium polysulfide.

Sodium nitrite.

Sodium salt of ethylenediamine tetraacetic acid and glycine.

Sodium sulfide.

Styrene monomer.

Tall oil.

Thioxyleneis as peptizing agents.

Tridecyl mercaptan.

Zinc 4-tert-butylthiophenolate as peptizing agent.

(d) Rubber articles intended for use with dry food are so formulated and cured under conditions of good manufacturing practice as to be suitable for repeated use.

(e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.

(f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.

(g) In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

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(xii) Elastomers, as the basic poly-
mer.

Butadiene-acrylonitrile copolymer.
Butadiene-acrylonitrile-styrene copolymer.
Butadiene-styrene copolymer.
Butyl rubber.
Chlorinated rubber.
2-Chloro-1,3-butadiene (neoprene).
Natural rubber (natural latex or natural
latex solids, smoked or unsmoked).
Polyisobutylene.
Rubber hydrochloride.
Styrene-isobutylene copolymer.

(xxii) Driers made by reaction of a
metal from paragraph (b)(3)(xxii)(a)
of this section with acid, to form the
salt listed in paragraph (b)(3)(xxii)(b)
of this section:

(a) Metals:

Aluminum.
Calcium.
Cerium.
Cobalt.
Iron.
Lithium.
Magnesium.
Manganese.
Zinc.
Zirconium.

(b) Salts:

Caprate.
Caprylate.
Isodecanoate.
Linoleate.
Naphthenate.
Neodecanoate.
Octoate (2-ethylhexoate).
Oleate.
Palmitate.
Resinate.
Ricinoate.
Soyate.
Stearate.
Tallate.

(xxiii) Waxes:

Paraffin, Type I.
Paraffin, Type II.
Polyethylene.
Sperm oil.
Spermaceti.

(xxiv) Plasticizers:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
Butyl phthalyl butyl glycolate.
Butyl stearate.
p-tert-Butyl phenyl salicylate.
Dibutyl sebacate.
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate.

Epoxydized soybean oil.
Irrum 14; oxirane epoxy-
Irrum), as the basic polymer.
Ethyl phthalyl ethyl glycolate.
2-Ethylhexyl diphenyl phosphite.
di-2-Ethylhexyl phthalate.
Glycerol.
Glycerol monooleate.
Glycerol triacetate.
Monoisopropyl citrate.
Propylene glycol.
Sorbitol.
Mono-, di-, and tristearyl citrate.
Triethyl citrate.
Triethylene glycol.
3-(2-Xenolyl)-1,2-epoxypropane.

(xxv) Release agents, as the basic
polymer, when applicable:

N, N'-Dioleoyl ethylenediamine (CAS Reg.
No. 110-31-8) for use only in ionomeric
resins complying with § 177.1330 of this
chapter and in ethylene vinyl acetate co-
polymers complying with § 177.1330 of
this chapter at a level not to exceed 0.0085
milligram per square centimeter (0.0085
milligram per square inch) in the finished
food-contact article.
N, N'-Distearoyl ethylenediamine.
Linoleic acid amide.
Oleic acid amide.
Palmitic acid amide.
Petrolatum.
Polyethylene wax.
Polyoxyethylene glycol monooleates (mol.
wt. of the polyoxyethylene glycol moiety
greater than 300).
Polytetrafluoroethylene.
Silicones (not less than 300 centistokes vis-
cosity): Dimethylpolysiloxanes and/or
methylphenylpolysiloxanes. The methyl-
phenylpolysiloxanes contain not more
than 2.0 percent by weight of cyclosilox-
anes having up to and including 4 silox-
ane units.
Silicones (not less than 100 centistokes vis-
cosity): Dimethylpolysiloxanes and/or
methylphenylpolysiloxanes limited to use
only on metal substrates. The methyl-
phenylpolysiloxanes contain not more
than 2.0 percent by weight of cyclosilox-
anes having up to and including 4 silox-
ane units.

(xxvi) Pigments and colorants:

Aluminum.
Aluminum hydroxide.
Aluminum and potassium silicate.
Aluminum oxide.
Aluminum silicate.
Barium sulfate.
Benzoate.
Benzoate, modified with stearic acid.
Carbon black.
Carbon black, modified with stearic acid.

Calcium silicate
Calcium sulfate
Carbon black (chromium protected)
Cobalt oxide-manganese oxide
Dispersed earth
Iron oxides
Magnesium oxide
Magnesium silicate (talc)
Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160).
Raw silica
Silica
Tartrazine lake (certified FD&C Yellow No. 5 only).
Titanium dioxide
Titanium dioxide-barium sulfate
Titanium dioxide-magnesium silicate
Zinc carbonate
Zinc oxide

(xxvii) Surface lubricants:

Cottonseed oil and other edible oils.
Dibutyl sebacate.
Diethyl sebacate.
Glyceryl monostearate.
Lanolin.
Mineral oil, white.
Palm oil.
Paraffin, Type I.
Paraffin, Type II.
Petrolatum.
Stearic acid.

(xxviii) Silicones and their curing catalysts:

(a) Silicones as the basic polymer:

Siloxane resins originating from methyl hydrogen polysiloxane, dimethyl polysiloxane, and methylphenyl polysiloxane.

(b) Curing (cross-linking) catalysts for silicones (the maximum amount of tin catalyst used shall be that required to effect optimum cure but shall not exceed 1 part of tin per 100 parts of siloxane resins solids):

Dibutyltin dilaurate.
Stannous oleate.
Tetrabutyl titanate.

(xxix) Surface active agents:

Ethylene oxide adduct of 2,4,7,9-tetramethyl-5-decyn-4,7-diol (CAS Reg. No. 9014-85-1).

Poly[2-(diethylamino) ethyl methacrylate] phosphate (minimum intrinsic viscosity in water at 25°C is not less than 9.0 deciliters per gram as determined by ASTM method D1243-79, "Standard Test Method for Dilute Solution Viscosity of Vinyl Chloride Polymers," which is incorporated by reference copies may be obtained from the American Society for Testing Materials, 1916 Race St., Philadelphia, PA 19106,

or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), for use only as a suspending agent in the manufacture of vinyl chloride copolymers and limited to use at levels not to exceed 0.1 percent by weight of the copolymers.

Sodium dioctyl sulfosuccinate.

Sodium dodecylbenzenesulfonate

Sodium lauryl sulfate.

2,4,7,9-Tetramethyl-5-decyn-4,7-diol (C.A.S. Reg. No. 126-86-3), for use only in can coatings which are subsequently dried and cured at temperatures of at least 193°C (380°F) for 4 minutes.

(xxx) Antioxidants:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Gum guaiac.
Dilauryl thiodipropionate.
Nordihydroguaiaretic acid.
Propyl gallate.
Distearyl thiodipropionate.
Thiodipropionic acid.
2,4,5-Trihydroxybutyropheneone.

(xxxi) Can end cements (sealing compounds used for sealing can ends only): In addition to the substances listed in paragraph (b) of this section and those listed in § 177.1210(b)(5) of this chapter, the following may be used:

Butadiene-styrene-divinylbenzene copolymer (CAS Reg. No. 26471-45-4) for use only at levels not to exceed 23.8 percent by weight of the cement solids in can end cements.

Butadiene-styrene-fumaric acid copolymer.

4,4'-Butylidenebis (6-tert-butyl-m-cresol).

Dibenzamido phenyl disulfide.

Di-β-naphthyl phenylenediamine.

Dipentamethylene thiuram tetrasulfide.

Isobutylene-isoprene-divinylbenzene copolymers for use only at levels not to exceed 15 percent by weight of the dry cement composition.

Naphthalene sulfonic acid-formaldehyde condensate, sodium salt, for use only at levels not to exceed 0.6 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium decylbenzene sulfonate.

Sodium nitrite for use only at levels not to exceed 0.3 percent by weight of the cement solids in can end cements for containers having a capacity of not less than 5 gallons.

Sodium pentachlorophenate for use as a preservative at 0.1 percent by weight in can-sealing compounds on containers having a capacity of 5 gallons or more.

Sodium phenylphenate.

Styrene-maleic methyl and butyl use only at level percent of the cement formul
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6/26/90

To: W. Bachtel

From: Bud Payer

Re: Gen 87349 White 138 Issue 8

Pat Tully is interested in pursuing the refrigerator door and liner market with this compound, specifically at GE. GE wants to use an "FDA compound" for this application.

Can you please tell me the FDA status of this compound, assuming we switched from Mark 1900 to Mark 1984 (710493). Which additives or levels would limit food contact? Also, could you please comment on USDA status?

Thanks
Bud

cc: P. Tully

20860005

ROUTE TO: CHUCK PURKS

* GEON VINYL TECHNICAL DOCUMENT *

CUSTOMER NO / DESC: TRAYCO

RI: 150

GEON VINYL RECIPE

03/16/90 10:30:39

GEON 87349 WHITE 138

OSHA WARNING LABEL: A

COMMODITY NO.: 87349 000 1380

LOC: 12 DEPT: 5667 ISSUE: 008

SBC NBR: 1306

EFFECTIVE DATE: 03/15/90

LAB REF: 40-12-65

DELETE FLAG: NO

CMPR: A.S.PAZUR/DB

BASED ON: 87349 WHITE 138, ISSUE 7, 3/13/90

APPLICATION: THERMOFORMED SANITARYWARE

PARTS	INGREDIENTS	SEQ	LOC	PERCENT
100.00000	961 000475 86X1 FG	110	12	70.361
12.00000	942 710849 PARALOID BTA 733	210		8.443
1.50000	941 00K006 PARALOID K-120N	220		1.035
1.00000	941 709120 PARALOID K-175	230		.704
3.00000	912 000006 MARK 1900 (710498)			2.111
2.00000	931 00P075 DIOCTYL PHTHALATE	320		1.467
4.50000	935 00P031 EPOXY SOYA	410		3.165
12.00000	925 710356 ULTRAFLEX H-6403	510		8.443
3.50000	924 00B123 TI-PURE R-100 T:02	610		2.463
.01400	961 000405 87333-000-2102	620		.010
.00500	921 00B287 GOLDEN TY-70	630		.004
.00500	961 000534 87333-000-3052	640		.004
1.00000	943 710889 LOKIOL G-70S	710		.704
1.00000	943 710339 GLYCOLUBE 825 BEADS	720		.704
.40000	943 00L029 CENWAX A	730		.281
.20000	943 710867 AC-316A POLYETHYLENE	740		.141
142.12400	TOTAL			100.000

SPECIFIC GRAVITY:

TYPE SAMPLE: USE PREVIOUS ISSUE

MATCHED TO: GEON 87341 WHITE 138

ISSUED: TO ADD 710867

MARKETING APPROVAL:

HARDNESS: TED

COLOR: 1

87333-000-2102

110X377-64.1

708675 Sapulley 200-28.2 - ca 003

B-2 Black Room 10.26% Iron Oxide

87333-000-2102

110X377-60.664

Sapulley 200-30.768

87333-000-2102 110X377-60.664

L-29- 12-Hydroxy stearic acid CAS #106-16-5

20860006

BFG07541