



Elf Atochem North America Inc.
Three Parkway, Philadelphia, PA 19102
Tel: (215) 587-7000

19 February 1992

Ms. Connie Dillon
THE B.F. GOODRICH COMPANY
Dept 5458
6100 Oak Tree Blvd.
Independence, Ohio 44131
FAX: 216-447-6459

Dear Ms. Dillon,

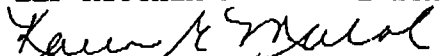
Per our conversation today, the Elf Atochem North America, Inc. product Thermolite* 890S is an octyltin stabilizer certified for use in food applications as specified in 21 CFR section 178.2650 *Organotin Stabilizers in vinyl chloride plastics* when used as specified for finished plastics meeting the restrictions set forth in section (b)(1).

The exact composition of this product is held as a Trade Secret by Elf Atochem North America, Inc.

If I can be of further assistance to you, please contact me at your convenience (215) 587-7917.

Very Truly Yours,

ELF ATOCHEM NORTH AMERICA, INC.


Karen E. Machol
Product Safety Specialist

cc: Steve Hulme
Tom Bole

FEB-19-92 WED 14:03

P. 01

elf atochem



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THIS DOCUMENT IS TO BE DELIVERED TO:

NAME: Connie Dutton - BFG 216-447-6450

DATE: 19 February 1992

FROM: Karen MacLeod

NUMBER OF PAGES (including cover): 2

COMMENTS: Per your request

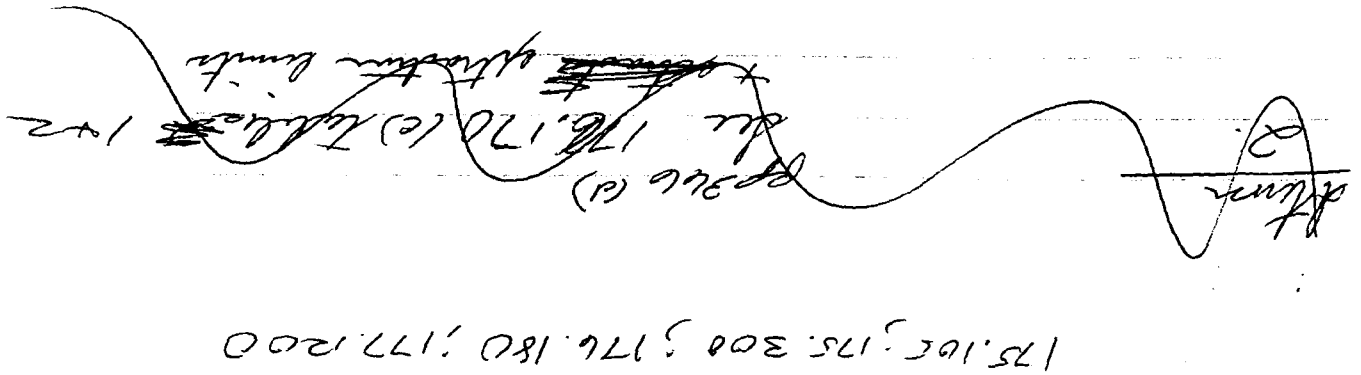
If there is a problem with the fax transmission, call (215) 587-7917.

BFG14969

21544018

Can we
confirm
the above?
How we get
confirmation on
above acids?
BT

The compound would be
acceptable for use under
21CFR 175.105 - 175.300; 176.180
and 177.1200 and is acceptable
for use in contact with food types
--- The finished food article ---
--- presented in Section 177.1010 (C) ~~system~~



§ 178.3800

Acrylonitrile.
Butadiene.
α-Methylstyrene.
Styrene.
Vinylidene chloride.

(iii) Polymers identified in paragraphs (a)(1) (i) and (ii) of this section containing no more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

Acrylic acid.
1,3-Butylene glycol dimethacrylate.
Divinylbenzene.
Methacrylic acid.

(iv) Mixtures of polymers identified in paragraph (a)(1) (i), (ii), and (iii) of this section; provided that no chemical reactions, other than addition reactions, occur when they are mixed.

(2) Polymers identified in paragraph (a)(1) of this section combined during their polymerization with butadiene-styrene copolymers; provided that no chemical reactions, other than addition reactions, occur when they are combined. Such combined polymers may contain 50 weight-percent or more of total polymer units derived from the butadiene-styrene copolymers.

(b) The polymer content of the finished plastic food-contact article consists of:

(1) Not less than 80 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section and not more than 5 weight-percent of polymer units derived from polymers identified in paragraph (a)(1) of this section and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers; or

(2) Not less than 50 weight-percent of polymer units derived from the vinyl chloride polymers identified in the introduction to this section, not more than 50 weight-percent of polymer units derived from homopolymers

21 CFR Ch. I (4-1-90 Edition)

and/or copolymers of ethyl acrylate and methyl methacrylate, and not more than 30 weight-percent of polymer units derived from copolymers of methyl methacrylate, α-methylstyrene and acrylonitrile and may optionally contain up to 15 weight-percent of polymer units derived from butadiene-styrene copolymers.

(c) No chemical reactions, other than addition reactions, occur among the vinyl chloride polymers and the modifying polymers present in the polymer mixture used in the manufacture of the finished plastic food-contact article.

(d) The finished plastic food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from Tables 1 and 2 of § 176.170(c) of this chapter, yields extracts not to exceed the limits prescribed in § 177.1010 (b) (1), (2), (3), and (4) of this chapter when tested by the methods prescribed in § 177.1010 (c) of this chapter.

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

§ 178.3800 Preservatives for wood.

Preservatives may be safely used on wooden articles that are used or intended for use in packaging, transporting, or holding raw agricultural products subject to the provisions of this section:

(a) The preservatives are prepared from substances identified in paragraph (b) of this section and applied in amounts not to exceed those necessary to accomplish the technical effect of protecting the wood from decay, mildew, and water absorption.

(b) The substances permitted are as follows:

List of substances	Limitations
Copper-8-quinolinate	Used singly or in combination so as to constitute not less than 50% of the solids.
Mineral spirits	
Paraffin wax	

Food and Drug

Petroleum hydrocarbon copolymerization of alkyd, and monomer of cracked petroleum. Pentachlorophenol and

Rosins and rosin derivatives. Zinc salt of sulfonated

§ 178.3850 Reinforced

Reinforced wax as an article or intended for use in manufacturing, packaging, or holding provisions of the

(a) Reinforced petroleum wax to certain optional its production, sired physical c

(b) The quantity of or a does not exceed required tended physical any limitation

(c) Any substance production of ing any option: subject of a r 175, 176, 177, chapter, confo tion in such re

(d) The substance production of wax include:

(1) Substance as safe in food.

(2) Substance for use in accord or approval.

(3) Substance paragraph and tions provided

Enucamide (erucylamide). N,N-Dioctylethylenedi

Limitations

Percent by weight of ethylene-propylene-5-mers complying with § 177.1520 of this chapter, except such polymers in the form of not exceed 0.005 inch.

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

Percent by weight of polystyrene and polystyrene and rubber-modified polystyrene conditions described in § 176.170(c) under conditions of use E through G.

Percent by weight of elastomers used in § 177.2600 of this chapter.

Percent by weight of nylon resins complying with § 177.1640 of this chapter. Provided, That the finished polymer conditions of use E, F, and G described in this chapter.

Percent by weight of polycarbonate resins in this chapter.

Percent by weight of polystyrene and polymers complying with § 177.1640 of this chapter. Provided, That the finished polymer contacts food only under conditions of use E, F, and G described in Table 2 of this chapter.

5 percent by weight of olefin polymers of this chapter, item 1.1, 1.2, or 1.3.

Percent by weight of olefin polymers of this chapter, item 2.1, 2.2, 2.3, 3.1, or 3.2, or complying with item 2.1, 2.2, or 2.3 having a thickness of not more than 0.005 inch, shall contact food only under conditions of use E, F, and G described in Table 2 of this chapter.

Percent by weight of ethylene-vinyl-acetate 177.1350 of this chapter, and that are food only under conditions of use E, F, and G described in Table 2 of this chapter. The polymers in the form in which they contact food shall not exceed 0.004 inch.

Percent by weight of olefin polymers of this chapter, item 4. The finished material shall not exceed 0.005 inch (0.002 inch), conditions of use E, F, and G described in this chapter.

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

0.1 percent by weight of isobutylene 177.1420 of this chapter.

§ 175.105 of this chapter.

Percent by weight of pressure sensitive adhesives of this chapter.

Percent by weight of can end cement § 175.300(b)(3) (can) of this chapter.

Percent by weight of side seam cement § 175.300(b)(3) (can) of this chapter.

Percent by weight of petroleum alkyd with § 175.320(b)(3) of this chapter.

Percent by weight of petroleum alkyd hydrogenated products complying with § 175.320(b)(3) of this chapter.

Percent by weight of resins and polymers in this chapter.

Percent by weight of rosin and rosin 177.1210 of this chapter.

5 percent by weight of closures with § 177.1210 of this chapter.

0.5 percent by weight of petroleum and rosin derivatives complying with § 177.1210 of this chapter.

Substances	Limitations
Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane (CAS Reg. No. 1843-03-4).	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 § 179.45 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 § 179.45 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 salicylate	
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:

(a) The additive has a solidification point of 140°-141°C.

(b) 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-

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), 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 $[(C_8H_{17})_2SnC_4H_6O_4]_n$ (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) C₁₅₋₁₈-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'-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-carbobutoxyethyl)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-carbobutoxyethyl)tin dichloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols. The bis(beta-carbobutoxyethyl)tin dichloride has an organotin composition that is not less than 95 percent by weight of bis(beta-carbobutoxyethyl)tin dichlo-

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2/28/92

to: Ron Miller
AVKTC

Experiments

Subject: FDA Status on Compounds X 150-168-061-01 through 03
X-150-168-061-02
X-150-168-061-03

I reviewed the above experimental compounds for their current FDA Status. Compounds X 150-168-061-01 and 02 look okay. All the ingredients have FDA clearance. Experimental compound X 150-168-061-03 has one ingredient (L-21/Stearic Acid) which has no FDA clearance.

~~Report was sent to FDA for review~~
~~Report and findings to be submitted~~

Code No. L-21

Copies of BFG's hair material specifications and current FDA ^(not for supply) requirements on Stearic acid were sent to Wistar and encouraged their review and response on whether they can provide in a Stearic acid that meets both BFG and FDA requirements.

~~I am collecting copies of both Wistar's and BFG's responses to our request. For well~~
~~note that BFG's response was copied on Wistar's response. Copy of BFG's response.~~

Wistar informed us they cannot accept the limits on % ~~Terminator~~ at 440/550 of 93/99 min. and the narrower Titer value of 55.0 + 0.5. They would