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WRITER'S DIRECT DIAL NUMBER

March 26, 1993

(202) 434-4120

VIA FACSIMILE

Ms. Connie Dillon
The Geon Company
6100 Oak Tree Boulevard
Cleveland, Ohio 44131

Re: FDA Regulatory Status of Mark 1900;
Our File No. BF4567

Dear Ms. Dillon:

The purpose of this letter is to respond to your request for written confirmation of your March 1, 1993 telephone conference with Dr. Lester Borodinsky regarding the status of Witco Corporation's (Witco's) Mark 1900 under the laws and regulations administered by the Food and Drug Administration (FDA). You specifically inquired as to its regulatory status when used as a stabilizer for polyvinyl chloride (PVC) compounds that, in turn, are used in possible food-contact applications, such as drainage hoses in food compartments of refrigerators.

As Les indicated, Mark 1900 meets the compositional requirements outlined in the Food Additive Regulation applicable to its use in food-contact PVC, namely, 21 C.F.R. § 178.2010, "Antioxidants and/or stabilizers for polymers." Therefore, provided the specifications of Section 178.2010 are met, we have no hesitation in advising that Mark 1900 may be used as a stabilizer in PVC food-contact articles, including drainage hoses in food compartments of refrigerators, and that such use may properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable Food Additive Regulations, including Section 178.2010.

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By way of background, Section 201(s) of the Act defines a food additive, in pertinent part, as any substance that is reasonably expected to become a component of food under the intended conditions of its use, and is neither generally recognized as safe (GRAS) nor prior sanctioned. Under Section 409(a)(2), a food additive is "unsafe" and, therefore, subject to regulatory action unless it is used in conformity with a regulation prescribing its safe use. Therefore, a food-contact material, or a component thereof, that is reasonably expected to become a component of food must be the subject of a regulation, GRAS, or prior sanctioned. If a substance is not reasonably expected to become a component of food under its intended conditions of use, then it is not a food additive.

We understand that The Geon Company (Geon) uses Mark 1900, a methyltin-based stabilizer manufactured by Witco, in the base formulation of several compounds. In letters dated March 17, 1993, November 20, 1992, and May 20, 1991, Witco has informed you of the following two points: (i) Mark 1900 is not certified as conforming to FDA's requirements; and (ii) its composition is somewhat different than Witco's FDA-grade stabilizer, Mark 1984. Specifically, Witco has indicated that its Mark 1900 is based on 2-ethylhexyl thioglycolate while the Mark 1984 stabilizer is derived from isooctyl thioglycolate. You asked whether the difference in formulation and Witco's failure to certify Mark 1900 as FDA-compliant renders Mark 1900 unacceptable for use in the formulation of food-contact products. As explained more fully below, the difference in the formulation of Mark 1900 is inconsequential from a regulatory standpoint, as is the lack of certification from Witco as to Mark 1900's compliance with the applicable regulatory specifications.

As you know, the list of substances permitted for use as stabilizers in Section 178.2010 includes dimethyltin/monomethyltin isooctylmercaptoacetates. Section 178.2010 specifies that this stabilizer compound must consist of 71 to 81 percent by weight of dimethyltin bis(isooctylmercaptoacetate), 19 to 29 percent by weight of monomethyltin tris(isooctylmercaptoacetate), and no more than 0.4 percent by weight of trimethyltin compounds. In addition, the tin content must be between 18.7 and 19.7 percent, the mercaptosulfur content must fall between 11.5 and 12.5 percent, the isooctyl radical in the mercaptoacetate must be "derived from" oxo process isooctyl alcohol, and other alkyltin compounds may not exceed 20 parts per million (ppm). Such methyltin stabilizer compounds may be used at levels up to 2.0 weight percent in rigid PVC used to manufacture pipes intended for contact with water in food-processing plants, and at the same level in rigid PVC and rigid PVC copolymers complying with 21 C.F.R. § 177.1950 or § 177.1980 for use in contact with

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all food types, except liquid milk, for hot-filled or pasteurized applications below 150°F.^{1/}

It is our opinion that Witco's Mark 1900 complies with the compositional requirements of Section 178.2010 for dimethyltin/monomethyltin isooctylmercaptoacetates. The term "isooctyl" refers to one or more isomeric branched hydrocarbon radicals composed of eight carbon atoms. 2-Ethylhexyl is one of these isomeric radicals, and is frequently a predominant component when isooctyl is a mixture of isomers. Thus, 2-ethylhexyl, the radical used in Witco's Mark 1900, is encompassed by the isooctyl component of "isooctylmercaptoacetates." Furthermore, 2-ethylhexyl is derived from oxo process isooctyl alcohol, namely, 2-ethylhexyl alcohol. Therefore, as Witco has assured you that Mark 1900 meets the other compositional requirements of Section 178.2010 for this type of stabilizer, it may properly be said that Mark 1900 complies with Section 178.2010's compositional requirements for dimethyltin/ monomethyltin isooctylmercaptoacetates.

Of course, Section 178.2010 also requires that the methyltin stabilizer compound comply with the specifications described above, such as the tin content and weight of the trimethyltin compounds. To date, Witco has not certified that its Mark 1900 meets these specifications. While we generally recommend obtaining the supplier's certification of compliance since it may serve to limit your liability, compliance may be established by determining that the regulatory requirements are satisfied regardless of manufacturer certification. Thus, if Mark 1900 meets the specifications set forth in Section 178.2010, it is irrelevant whether or not Witco has so certified, and it can be used as intended in full compliance with the Act and FDA's regulations.^{2/}

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1/ Specifically, the regulation states that the described substance may be used in contact with Food Types I, II, III, IV (except liquid milk), V, VI, VII, VIII, and IX, as described in Table 1 of 21 C.F.R. § 176.170(c), under Conditions of Use D, E, F, and G, as described in Table 2 of 21 C.F.R. § 176.170(c).

2/ For purposes of the application of current interest, which we understand to be drainage hoses for food compartments in refrigerators, the stabilizer does not need to be cleared under Section 178.2010 because it is not reasonably expected to become a component of food and, therefore, is not a food additive. However, if your customer requires your assurance that Mark 1900 is cleared for use in your PVC compounds under Section 178.2010, (continued...)

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We trust that this letter is fully responsive to your request for our written opinion on the FDA status of Mark 1900. Should you have any questions, or if we may be of assistance in any other way, please do not hesitate to contact us.

Cordially yours,


Ralph A. Simmons

2/(...continued)
you will need to establish (either through Witco or by independent testing) that the stabilizer complies with the specifications in the regulation, in addition to meeting the compositional requirements discussed above.

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Substances	Limitations
Dicetyl thiodipropionate having a melting point of 59°-62° C as determined by ASTM method E324-79, "Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals," and a saponification value in the range 176-183 as determined by ASTM method D1962-67 (Reapproved 1979), "Standard Test Method for Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids," 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, DC 20408.	The concentration of this additive and any other permitted antioxidants in the finished food-contact article shall not exceed a total of 0.5 milligram per square inch of food-contact surface.
Didodecyl-1,4-dihydro-2,6-dimethyl-3,5-pyridinedicarboxylate (CAS Reg. No. 36265-41-5).	For use only at levels not to exceed 0.3 percent by weight in rigid polymer articles modified in accordance with § 176.3790 that contact food, under conditions of use E, F, and G described in Table 2 of § 176.170 of this chapter.
2,6-Di(o-methyl benzyl)-4-methyl phenol [Chemical Abstracts Service Registry No. 1817-68-1].	For use only at levels not to exceed 0.2 percent by weight of olefin polymers complying with item 3.4 in § 177.1520(c) of this chapter, provided that such olefin polymers are limited to use at a level not to exceed 25 percent by weight in other olefin polymers complying with § 177.1520 of this chapter; and the total amount in such finished olefin polymers not to exceed 0.05 percent by weight, including the level that may be contributed by its presence at 6 percent in the item "butylated, styrenated cresols" listed in this paragraph; and further provided that the finished olefin polymers are intended for contact with foods, except those containing more than 8 percent alcohol.
Dimethyl succinate polymer with 4-hydroxy-2,2,6,6-tetramethyl-1-piperidineethanol (CAS Reg. No. 65447-77-0).	For use only: 1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520 of this chapter and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.
Dimethyltin/monomethyltin isooctylmercaptosuccinate consisting of 71 to 81 percent by weight of dimethyltin bis(isooctylmercaptosuccinate) (CAS Reg. No. 26636-01-1), 19 to 29 percent by weight of monomethyltin tris(isooctylmercaptosuccinate) (CAS Reg. No. 54849-38-6), and no more than 0.4 percent by weight of trimethyltin compounds, and having the following specifications: Tin content (as Sn) in the range of 18.7 to 19.7 percent and mercaptosulfur content in the range of 11.5 to 12.5 percent. The isooctyl radical in the mercaptosuccinate is derived from oxo process isooctyl alcohol. Other alkyltin compounds are not to exceed 20 ppm.	For use only at levels not to exceed 2.0 percent by weight: 1. In rigid polyvinyl chloride used in the manufacture of pipes intended for contact with water in food-processing plants, and 2. In rigid polyvinyl chloride and in rigid vinyl chloride copolymers complying with § 177.1950 of this chapter or § 177.1980 of this chapter for use in contact with food of Types I, II, III, IV (except liquid milk), V, VI, VII, VIII, and IX described in Table 1 of § 176.170(c) of this chapter under conditions of use D, E, F, and G described in Table 2 of § 176.170(c) of this chapter.
Dimyristyl thiodipropionate having a melting point of 48°-52° C as determined by ASTM method E324-79, "Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals," and a saponification equivalent in the range 280-290 as determined by ASTM method D1962-67 (Reapproved 1979), "Standard Test Method for Saponification Value of Drying Oils, Fatty Acids, and Polymerized Fatty Acids," 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, DC 20408.	Finished food-contact articles containing this additive shall meet the extractives limitations prescribed in § 176.170(c) of this chapter.
Di(n-octyl)tin bis(2-ethylhexyl maleate) (CAS Reg. No. 10039-33-5) having 12.5 to 15.0 percent by weight of tin (Sn) and having a saponification number of 260 to 280. The additive is made from di(n-octyl)tin oxide meeting the specifications of § 176.2650(a)(1).	For use only at levels not to exceed 0.5 percent by weight of acrylonitrile copolymers complying with §§ 177.1020 and 177.1030 of this chapter and used in contact with all food types under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.
N,N-Diphenylthiourea	For use only: