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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 94F-0334]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of methyltin-2-mercaptoethylolate sulfide used alone or in combination with several optional substances as a heat stabilizer for use in rigid poly(vinyl chloride) (PVC) and rigid vinyl chloride copolymers intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants. This action is in response to a petition filed by Morton International, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

SUPPLEMENTARY INFORMATION:

NFR2

In a notice published in the **Federal Register** of October 21, 1994 (59 FR 53193), FDA announced that a food additive petition (FAP 4B4430) had been filed by Morton International, Inc., 2000 West St., Cincinnati, OH 45215. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of methyltin-2-mercaptoethylolate sulfide mixtures as heat stabilizers for use in PVC pipes intended for transporting water for food contact.

Subsequent to the filing of the petition, FDA determined that methyltin-2-mercaptoethylolate sulfide is a complex mixture. In addition, FDA determined that the petition also proposed that methyltin-2-mercaptoethylolate sulfide may be used in combination with certain optional substances. Therefore, in a notice published in the **Federal Register** of September 7, 1999 (64 FR 48655), FDA announced that it was amending the filing notice of October 21, 1994, to indicate that the petitioner requests that the food additive regulations be amended to provide for the safe use of methyltin-2-mercaptoethylolate sulfide as a heat stabilizer for use in rigid PVC and rigid vinyl chloride copolymers, complying with §§ 177.1950 and 177.1980 (21 CFR 177.1950 and 177.1980), respectively, intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants. For these purposes, methyltin-2-mercaptoethylolate sulfide is defined as one or more of the following:

1. 9-Octadecenoic acid (Z)-, 2-mercaptoethyl ester, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 68442-12-6); or
2. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, 2-mercaptoethyl decanoate, 2-mercaptoethyl octanoate, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 151436-98-5); or
3. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 201687-57-2).

In addition, FDA announced in the September 7, 1999, notice that it was amending the filing notice of October 21, 1994, to indicate that the petitioner requested that the food additive regulations be amended to provide for the safe use of methyltin-2-mercaptoethyleate sulfide as a heat stabilizer for use in rigid PVC and rigid vinyl chloride copolymers, complying with §§ 177.1950 and 177.1980, respectively, intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants, in combination with the following optional substances:

1. 2-Mercaptoethyl oleate (CAS Reg. No. 59118-78-4), or 2-mercaptoethyl tallate (CAS Reg. No. 68440-24-4), or 2-mercaptoethyl octanoate (CAS Reg. No. 57813-59-9), or 2-mercaptoethyl decanoate (CAS Reg. No. 68928-33-6), alone or in combination;
2. 2-Mercaptoethanol (CAS Reg. No. 60-24-2);
3. Mineral oil (CAS Reg. No. 8012-95-1); or
4. Butylated hydroxytoluene (CAS Reg. No. 128-37-0).

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in 21 CFR 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 4B4430 (64 FR 48655). No new information or comments have

been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings “Substances” and “Limitations” to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
<p>Methyltin-2-mercaptoethylolate sulfide, which is defined as one or more of the following:</p> <ol style="list-style-type: none"> 1. 9-Octadecenoic acid (Z)-, 2-mercaptoethyl ester, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 68442-12-6); 2. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, 2-mercaptoethyl decanoate, 2-mercaptoethyl octanoate, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 151436-98-5); or 3. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 201687-57-2); and which has the following specifications: Tin content (as Sn) 5 to 21 percent by weight; mercaptosulfur content 5 to 13 percent by weight; acid value no greater than 4. <p>Methyltin-2-Mercaptoethylolate sulfide may also be used with one or more of the following optional substances:</p> <ol style="list-style-type: none"> 1.1a 2-Mercaptoethyl oleate (CAS Reg. No. 59118-78-4), 1.1b 2-Mercaptoethyl tallate (CAS Reg. No. 68440-24-4), 1.1c 2-Mercaptoethyl octanoate (CAS Reg. No. 57813-59-9), 1.1d 2-Mercaptoethyl decanoate (CAS Reg. No. 68928-33-6), alone or in combination; not to exceed 40 percent by weight of the stabilizer formulation; 2.1 2-Mercaptoethanol (CAS Reg. No. 60-24-2): Not to exceed 2 percent by weight of the stabilizer formulation. 3.1 Mineral oil (CAS Reg. No. 8012-95-1): Not to exceed 40 percent by weight of the stabilizer formulation. 4.1 Butylated hydroxytoluene (CAS Reg. No. 128-37-0): Not to exceed 5 percent by weight of the stabilizer formulation. <p>The total of the optional substances (1.1a through 4.1) shall not exceed 60 percent by weight of the stabilizer formulation.</p>	<p>For use only in rigid poly(vinyl chloride) and rigid vinyl chloride copolymers complying with §§ 177.1950 and 177.1980 of this chapter, respectively, used in the manufacture of pipes and pipe fittings intended for contact with water in food processing plants, at levels not to exceed:</p> <ol style="list-style-type: none"> 1. 1.0 percent by weight in pipes, and 2. 2.0 percent by weight in pipe fittings.

Dated: 2/29/00
February 29, 2000



L. Robert Lake
Director
Office of Policy, Planning and Strategic Initiatives
Center for Food Safety and Applied Nutrition

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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