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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F-0213]

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 expanded safe use of phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester as an antioxidant in polypropylene homopolymer and copolymers not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: The regulation 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: Hortense S. Macon, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-206), 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 9, 1997 (62 FR 31433), FDA announced that a petition (FAP 7B4542) had been filed by Asahi Denka Kogyo K.K., Shirahata 5-Chome, Urawa City, Saitama 366, Japan. 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 expanded safe use of phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester for use: (1) At levels not to exceed 0.25 percent by weight of olefin copolymers complying with § 177.1520 (21 CFR 177.1520) in contact with foods of types I, II, III, IV–B, VI–B, and VIII, as described in Table 1, and under conditions of use B through H, described in Table 2 of § 176.170(c) (21 CFR 176.170(c)), of this chapter, and with foods types IV–A, V, VI–A, VI–C, VII–A, and IX, under conditions of use C through G, as described in § 176.170(c), Tables 1 and 2, respectively; and (2) at levels not to exceed 0.10 percent by weight of either olefin copolymers or polypropylene complying with § 177.1520 which may be used in contact with foods of types IV–A, V, VI–C, VII–A, and IX, under conditions of use H, as described in § 176.170(c) of this chapter, Tables 1 and 2 respectively. When the petition was filed on June 9, 1997, it contained an environmental assessment (EA). In the notice of filing, the agency announced that it was placing the EA on display at the Dockets Management Branch for public review and comment. No comments were received.

Subsequent to filing of the petition, the petitioner requested that the petition be amended to permit use of the subject additive as an antioxidant in polypropylene homopolymer and copolymers, at a use level not to exceed 0.25 percent by weight, for all food types described in Table 1 under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. Therefore, in a notice published in the **Federal Register** of August 28, 1998 (63 FR 46053), FDA announced that the filing notice of June 9, 1997, was amended to include the petitioned additive, phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester for use as an antioxidant in polypropylene homopolymer and copolymers for all food types under conditions of use B through H.

In the amended filing notice of August 28, 1998, the agency incorrectly stated that it was placing the EA for the petition on display at the Dockets Management Branch for public review and comment. Instead, the original EA was maintained at the Dockets Management Branch. On

October 15, 1998, the petitioner submitted a claim of categorical exclusion under new § 25.32(i) (21 CFR 25.32(i)), in accordance with the procedures in 21 CFR 25.15(a) and (d). Because the agency had not completed the review of an EA for the use of the subject additive that was described in the amended filing notice, the agency reviewed the claim of categorical exclusion under § 25.32(i) for this final rule.

FDA has evaluated 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 therefore, (3) that the regulations in § 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 determined under § 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is 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 on or before *(insert date 30 days after date of publication in the **Federal Register**)*, file with the Dockets Management Branch (address above) written objections thereto. 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 to read 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 revising the entry for “phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester” in item “1.” under the heading “Limitations” to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
Phosphorous acid, cyclic neopentetetrayl bis(2,6-di- <i>tert</i> -butyl-4-methylphenyl)ester (CAS Reg. No. 80693-00-1).	For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers complying with § 177.1520 of this chapter, for use with all food types described in table 1 of § 176.170(c) of this chapter only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.

Dated: 3/1/99
March 1, 1999



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

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