

305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of December 20, 1995 (60 FR 65658), FDA announced that a food additive petition (FAP 6B4489) had been filed by Registration and Consulting Co., Ltd., on behalf of Peroxid-Chemie GmbH, c/o Bruce A. Schwemmer, Bruce EnviroExcel Group, Inc., 94 Buttermilk Bridge Rd., Washington, NJ 07882 (formerly 55 River Dr. South No. 1808, Jersey City, NJ 07310). The petition proposed to amend the food additive regulations in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) to provide for the safe use of di(4-methylbenzoyl) peroxide as an accelerator for silicone polymers and elastomers complying with § 177.2600 for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that it will achieve its intended technical effect, and that the regulations in § 177.2600 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 21 CFR 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1996, 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 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.2600 is amended in paragraph (c)(4)(ii)(b) by alphabetically adding a new entry for "Di(4-methylbenzoyl) peroxide" to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(b) * * *

Di(4-methylbenzoyl) peroxide (CAS Reg. No. 895-85-2) for use only as a crosslinking agent in silicone polymers and elastomers identified under paragraph (c)(4)(i) of this section at levels not to exceed 1 percent by weight of such polymers and elastomers where the total of all accelerators does not

exceed 1.5 percent by weight of rubber product.

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Dated: August 22, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-22482 Filed 9-3-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 96F-0092]

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 for use as an antioxidant and/or stabilizer at levels not to exceed 0.05 percent by weight of olefin polymers intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K. K.

DATES: Effective September 4, 1996; written objections and requests for a hearing by October 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of March 25, 1996 (61 FR 12075), FDA announced that a food additive petition (FAP 6B4498) had been filed by Asahi Denka Kogyo K. K., 2-13 Shirahata 5-Chome, Urawa City, Saitama 336, 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 as an antioxidant and/or stabilizer at levels not to exceed 0.05 percent by weight of olefins complying with 21 CFR 177.1520 intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material.

Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1996, 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 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (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 neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester" under the heading "Substances" and by adding a new entry "2." 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 complying with § 177.1520 of this chapter. * * * 2. At levels not to exceed 0.05 percent by weight of polymers complying with § 177.1520(c) of this chapter, item 3.1 or 3.2, and with a maximum thickness of 100 micrometers (0.004 inch) for use with all food types under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter.
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Dated: August 20, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

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21 CFR Part 178

[Docket No. 96F-0027]

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 bis(2,4-di-*tert*-butyl-6-methylphenyl) ethyl phosphite as a

processing stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective September 4, 1996; written objections and requests for a hearing by October 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and