DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 90F–0435]

Indirect Food Additives: Polymers

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 isobutylene-butene copolymers as a plasticizer in polypropylene intended for use in contact with food. This action responds to a food additive petition filed by Amoco Chemical Co.

DATES: The regulation is effective July 2, 1998. Submit written objections and requests for a hearing by August 3, 1998.

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: Julius Smith, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–215), 200 C St. SW., Washington, DC 20204,202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 11, 1991 (56 FR 1197), FDA announced that a petition (FAP 1B4238) had been filed by Amoco Chemical Co., Chicago, IL 60601. The petition proposed to amend the food additive regulations in § 177.1430 *Isobutylene-butene copolymers* (21 CFR 177.1430) to provide for the safe use of isobutylene-butene copolymers as components of food-contact articles and as plasticizers in polypropylene in contact with food complying with 21 CFR 177.1520. Upon further review of the petition, the agency has determined that the petitioner is proposing only the use of isobutylene-butene copolymers as a plasticizer in polypropylene.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive in polypropylene articles is safe, (2) the additive will have the intended technical effect, and therefore, (3) the regulations in § 177.1430 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 August 3, 1998, 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.

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.

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

2. Section 177.1430 is amended in the table in paragraph (b) by revising item ''2.'' under the heading ''Isobutylene-butene copolymers'' to read as follows:

§ 177.1430 Isobutylene-butene copolymers.

* * * * *

(b) * * *

Isobutylene-butene copolymers	Molecular weight (range)	Viscosity (range)	Maximum bromine value
* * *	*	*	* *
2. Used as plasticizers in polyethylene or polypropylene complying with § 177.1520, and in polystyrene complying with § 177.1640.			
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Dated: June 23, 1998.

L. Robert Lake,

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

[FR Doc. 98–17543 Filed 7–1–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0468]

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 tris(2,4-di-*tert*-butylphenyl)phosphite by removing the restrictions on the temperature of use in low-density polyethylene films of thickness greater than 0.051 millimeter (mm) (0.002 inch (in)), provided that the film does not contain a total of tris(2,4-di-*tert*-butylphenyl)phosphite in excess of 0.062 milligram (mg) per square inch (in^2) of the food-contact surface. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

DATES: This regulation is effective July 2, 1998. Written objections and requests for a hearing by August 3, 1998.

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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), 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 November 28, 1997 (62 FR 63350), FDA announced that a food additive petition (FAP 8B4563) had been filed by Ciba Specialty Chemicals Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. 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 tris(2,4-di-*tert*-butylphenyl)phosphite by removing the restriction on the temperature of use in low-density polyethylene films of thickness greater than 0.051 mm (0.002 in), provided that the film does not contain a total of tris(2,4-di-*tert*-butylphenyl)phosphite in excess of 0.062 mg per in^2 of the food contact-surface.

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 that therefore, 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4563 (62 FR 63350). FDA has concluded that the action is of a type that does not individually or cumulatively have a significant effect on the human environment, and that therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before August 3, 1998, 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 objection 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.

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

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 revising the entry for ''tris(2,4-di-*tert*-butylphenyl)phosphite'' in item ''6.'' under the heading ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

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(b) * * *