PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

1. The authority citation for 21 CFR Part 81 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86–618; sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note); 21 CFR 5.10.

§ 81.1 [Amended]

2. Section 81.1 *Provisional lists of color additives* is amended in the table of paragraph (b) for the entry "D&C Red No. 36" by revising the closing date to read "February 27, 1989."

§ 81.27 [Amended]

3. Section 81.27 *Conditions of provisional listing* is amended in the table, appearing in the introductory text in paragraph (d), by revising the closing date for the entry "D&C Red No. 36" to read "February 27, 1989."

Dated: December 22, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88–29704 Filed 12–22–88; 11:54 am]

BILLING CODE 4160–01–M

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21 CFR Part 175

[Docket No. 88F–0053]

Indirect Food Additives; Adhesives and Components of Coatings

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene, as adhesives in the manufacture of multilayer structures intended to contact food. This action is in response to a petition filed by The Dow Chemical Co.

DATES: Effective December 27, 1988; written objections and requests for a hearing by January 26, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 17, 1988 (53 FR 8805), FDA announced that a food additive petition (FAP 8B4066) had been filed by The Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, proposing that § 175.105 *Adhesives* (21 CFR 175.105) of the food additive regulations be amended to provide for the safe use of ethylene-octene-1 copolymers as adhesives in multilayer structures intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency finds that the additive is more specifically identified as "ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene." The agency further concludes that the proposed use of this food additive is safe, and that the regulations 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before January 26, 1989 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 175

Adhesives, 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, Part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR Part 175 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry in the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Ethylene-octene-1 copolymers containing not less than 70 weight percent ethylene (CAS Reg. No. 26221–73–8)	
* * * * *	

Dated: December 15, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–29573 Filed 12–23–88; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 178

[Docket No. 87F-0321]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,2'-(2,5-thiophenediyl)-bis(5-*tert*-butylbenzoxazole) as an optical brightener for polyoxymethylene homopolymer intended to contact food. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective December 27, 1988; written objections and requests for a hearing by January 26, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 12, 1987 (52 FR 43399), FDA announced that a food additive petition (FAP 7B4027) had been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 2,2'-(2,5-thiophenediyl)-bis(5-*tert*-butylbenzoxazole) as an optical brightener for polyoxymethylene homopolymer intended to contact food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of this food additive is safe, and that the regulations should be amended in 21 CFR 178.3297(e) 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an environmental assessment under 21 CFR 25.31a(b)(1).

Any person who will be adversely affected by this regulation may at any time on or before January 26, 1989 file with the Dockets Managment 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, 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(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.3297 is amended in the table of paragraph (e) by adding a new entry under the heading "Limitations" for "2,2'-(2,5-Thiophenediyl)-bis(5-*tert*-butylbenzoxazole) (CAS Reg. No. 7128-64-5)" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * * * *	
2,2'-(2,5-Thiophenediyl)-bis(5-*tert*-butylbenzoxazole) (CAS Reg. No. 7128-64-5).	For use as an optical brightener only: * * * 4. At levels not to exceed 0.01 percent by weight of polyoxymethylene homopolymer complying with § 177.2480 of this chapter.
* * * * *	

Dated: December 15, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-29572 Filed 12-23-88; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 87F-0183]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Antioxidants and/or Stabilizers for Polymers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the permitted use of tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant and stabilizer in 4-methylpentene-1 copolymers intended to contact food. This action responds to a petition filed by the Ciba-Geigy Corp.

DATES: Effective December 27, 1988; written objections and requests for a hearing by January 26, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF-335),

Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 2, 1987 (52 FR 25075), FDA announced that a petition (FAP 7B3999) had been filed by the Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant and thermal stabilizer for poly(methylpentene) intended to contact food. Subsequently, in an amended filing notice published in the **Federal Register** of November 9, 1987 (52 FR 43122), FDA announced that the petitioner was amending the petition to provide for expanded use of tris(2,4-di-*tert*-butylphenyl) phosphite as an antioxidant and stabilizer only in 4-methylpentene-1 copolymers complying with 21 CFR 177.1520(c), item 3.3. The amended filing notice stated that the expanded uses include an increased use level and an increased temperature of use (including microwave use).

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the additive is safe for its requested use in 4-methylpentene-1 copolymers. The requested uses include an increase in the use level from 0.2 percent to 0.5 percent, deletion of the thickness limitations on the 4-methylpentene-1 copolymer, and an increase in the permitted temperature of use from the currently specified limit of room temperature use to high temperature (above 100 °C (212 °F)) heat-sterilized use.

The agency, however, is not adopting the petitioner's specific request to include microwave oven reheating use in the text of the regulation, as this use is included in use condition H, specified in the regulation. (Condition H is identified in 21 CFR 176.170(c), Table 2, as "Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in the container at time of use.") The petitioner has amended its petition to withdraw the request for a specific mention of microwave reheating.

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 and 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. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before January 26, 1989 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 of the Center for Food Safety and Applied Nutrition, 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(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.2010 is amended in the table of paragraph (b) in the entry for "Tris(2,4-di-*tert*-butylphenyl)phosphite" by revising item 8 and by adding a new item 22 under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* *	* *
Tris(2,4-di-*tert*-butylphenyl)phosphite (CAS Reg. No. 31570-04-4).	For use only: * * * 8. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 4. The finished polymers having a thickness greater than 0.051 millimeter (0.002 inch), shall contact food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. * * * 22. At levels not to exceed 0.5 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.3. The finished polymers may be used in contact with food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.
* *	* *

Dated: December 15, 1988.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–29574 Filed 12–23–88; 8:45 am]

BILLING CODE 4160–01–M