DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F–0567]

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 expanded safe use of ethylene-octene-1 copolymers, containing not less than 50 weight-percent of polymer units derived from ethylene, as articles or components of food-contact articles. This action is in response to a petition filed by The Dow Chemical Co.

DATES: This rule is effective March 28, 2000. Submit written objections and requests for a hearing by April 27, 2000.

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

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 28, 1998 (63 FR 40297), FDA announced that a petition (FAP 8B4601) had been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to expand the safe use of ethylene-octene-1 copolymers as articles or components of articles contacting food by lowering the required level of polymer units derived from ethylene to not less than 50 weight-percent.

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 therefore, (3) 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 § 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 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 April 27, 2000. 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 are to be submitted and are to 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: 21 U.S.C. 321, 342, 348, 379(e).

2. Section 177.1520 is amended by adding paragraph (a)(3)(i)(*a*)(*4*), and in the table in paragraph (c) by adding item ''3.2c'' in numerical order to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(a) * * *

(3) * * *

(i) * * *

(*a*) * * *

(*4*) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.

* * * * *

(c) * * *

Olefin polymers	Density	Melting Poing (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of the polymer in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
* *	*	*	*	* *
3.2c Olefin copolymers described in paragraph (a)(3)(i)(*a*)(*4*) of this section have a melt flow index no greater than 50 grams per 10 minutes as determined by the method described in paragraph (d)(7) of this section. Articles manufactured using these polymers may be used with all types of food under conditions of use C through H as described in table 2 of § 176.170(c) of this chapter.	0.85–0.92			
* *	*	*	*	* *

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Dated: February 29, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–7540 Filed 3–27–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–0126]

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 for the safe use of N,N′″–1,2-ethanediylbis [N–[3–[[4,6-bis [butyl (1,2,2,6,6-pentamethyl-4-piperidinyl) amino] -1,3,5-triazin-2-yl]amino]propyl]- N′,N″-dibutyl-N′,″-bis (1,2,2,6,6-pentamethyl-4-piperidinyl) -1,3,5-triazine-2,4,6-triamine] as a light/thermal stabilizer in olefin polymers intended for use in contact with food. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

DATES: This rule is effective March 28, 2000. Submit written objections and requests for a hearing by April 27, 2000.

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: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 3, 1999 (64 FR 5299), FDA announced that a food additive petition (FAP 9B4639) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. 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 N,N′″–[1,2-ethanediylbis [[[4,6-bis [butyl (1,2,2,6,6-pentamethyl-4-piperidinyl) amino] -1,3,5-triazin-2-yl]imino] -3,1-propanediyl]] bis[N′,N″-dibutyl-N′,N″-bis (1,2,2,6,6-pentamethyl-4-piperidinyl) -1,3,5-triazine-2,4,6-triamine] as a light/thermal stabilizer in olefin polymers intended for use in contact with food. After further evaluation, the agency has determined that the correct name for the subject additive is N,N′″–1,2-ethanediylbis[N–[3-[[4,6-bis[butyl(1,2,2,6,6-pentamethyl-4-piperidinyl)amino]-1,3,5-triazin-2-yl]amino]propyl]-N′,N″-dibutyl-N′,N″-bis(1,2,2,6,6-pentamethyl-4-piperidinyl)-1,3,5-triazine-2,4,6-triamine] (CAS Reg. No. 106990–43–6) in accordance with the Chemical Abstracts Service (CAS) 9th Collective Index. This latest CAS name will be used in the regulation.

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 as a light/thermal stabilizer in olefin polymers intended for use in contact with food is safe, and (2) the additive will have the intended technical effect. 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 potential environmental effects of this rule as announced in the notice of filing for FAP 9B4639 (64 FR 5299). 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