

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 177**

[Docket No. 95F-0365]

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 ethylene/pentene-1 copolymers containing not less than 90 percent of polymer units derived from ethylene as components of articles intended for use in contact with food. This action is in response to a petition filed by Sasol Alpha Olefins.

DATES: Effective November 22, 1996; written objections and requests for a hearing by December 23, 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: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3084.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 15, 1995 (60 FR 57434), FDA announced that a food additive petition (FAP 5B4482) had been filed by Sasol Alpha Olefins, P.O. Box 5486, Johannesburg 2000, Republic of South Africa. The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of ethylene/pentene-1 copolymers containing not less than 90 percent of polymer units derived from ethylene as components of articles 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 food additive use is safe, that it will achieve its intended technical effect, and therefore, that the regulations in § 177.1520 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 December 23, 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 177.1520 is amended by adding a new paragraph (a)(3)(i)(a)(3), and in the table in paragraph (c) by revising item 3.1a and by adding a new item 3.1c to read as follows:

§ 177.1520 Olefin polymers.

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(a) * * *

(3) * * *

(i) * * *

(a) * * *

(3) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.

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(c) * * *

Olefin polymers	Density	Melting point (MP) or softening point (SP) (Degrees Centigrade)	Maximum extractable fraction (expressed as percent by weight of polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
3.1a Olefin copolymers described in paragraph (a)(3)(i) of this section for use in articles that contact food except for articles used for packing or holding food during cooking; except olefin copolymers described in paragraph (a)(3)(i)(a)(3) of this section and listed in item 3.1c of this table and olefin copolymers described in paragraph (a)(3)(i)(e) of this section and listed in item 3.1b of this table.	0.85–1.00	5.5 pct at 50 °C	30 pct at 25 °C
3.1c Olefin copolymers described in paragraph (a)(3)(i)(a)(3) of this section for use in contact with food only under conditions of use B, C, D, E, F, G, and H described in § 176.170(c) of this chapter, Table 2; except that such copolymers when used in contact with food of the types identified in § 176.170(c), Table 1, under types III, IVA, V, VIIA, and IX, shall be used only under conditions of use D, E, F, and G described in § 176.170(c) of this chapter, Table 2.	Not less than 0.92

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Dated: November 18, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–29874 Filed 11–21–96; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 250

RIN 1076–AD68

Indian Fishing—Hoopa Valley Indian Reservation

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Indian Affairs is eliminating 25 CFR Part 250 as mandated by Executive Order 12866 to streamline the regulatory process and enhance the planning and coordination of new and existing regulations. The necessity for this rule no longer exists.

EFFECTIVE DATE: November 22, 1996.

FOR FURTHER INFORMATION CONTACT: Gary Rankel, Chief, Branch of Fish, Wildlife

and Recreation, Office of Trust Responsibilities, Bureau of Indian Affairs, Department of the Interior, 1849 C St. NW, Mail Stop 4513–MIB, Washington, DC 20240, Telephone (202) 208–4088.

SUPPLEMENTARY INFORMATION: On May 2, 1996, at 61 FR 19600, the Bureau published a proposed rule to eliminate 25 CFR Part 250, Indian Fishing—Hoopa Valley Indian Reservation. The purpose for which this rule was promulgated has been fulfilled and the rule is no longer required. Both the Hoopa Valley Tribe and the Yurok Tribe have established regulations to protect the fishery resources and fishing rights of Indians of the Hoopa Valley and Yurok Indian Reservations. With tribal fishing regulations now in place, 25 CFR Part 250 is no longer necessary. We received no comments in response to the proposed rule.

Evaluation and Certification

The Department has certified to the Office of Management and Budget (OMB) that this rule meets the applicable standards provided in Sections 2(a) and 2(b)(2) of Executive Order 12778.

The Office of Management and Budget has determined that this rule is not a

significant regulatory action under Executive Order 12866.

There will be no economic effect on each tribal government and tribal organization under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) and no additional outlays will be required of tribal governments, tribal organizations, and the Federal Government.

In accordance with Executive Order 12630, the Department has determined that this rule does not have significant “takings” implications. The rule does not pertain to “taking” of private property interests, nor does it affect private property.

The Department has determined that this rule will not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

This rule has been examined under the Paperwork Reduction Act of 1995 and has been found to contain no information collection documents.

Drafting Information

The primary author of this document is Gary Rankel, Bureau of Indian Affairs.

List of Subjects in 25 CFR Part 250

Indians, Indian-fishing rights.