

(1) \* \* \*

Food	Limita- tion (parts per mil- lion)	Use
* * *	* * *	* * *
Fava beans (cooked canned).	365 .....	Promote color retention.
* * *	* * *	* * *

\* \* \*

Dated: June 15, 1995.

**Janice F. Oliver,**Deputy Director for Systems and Support,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 95-15924 Filed 6-28-95; 8:45 am]

BILLING CODE 4160-01-F

**21 CFR Part 178****[Docket No. 93F-0033]****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 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane as an antioxidant for high density polyethylene intended for use in food-contact articles. This action is in response to a petition filed by Sumitomo Chemical America, Inc.

**DATES:** Effective June 29, 1995; written objections by July 31, 1995.

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

**FOR FURTHER INFORMATION CONTACT:** Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of

March 12, 1993 (58 FR 13604), FDA announced that a food additive petition (FAP 3B4358) had been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154. 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 3,9-bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane as an antioxidant for polyethylene complying with § 177.1520 *Olefin polymers* (21 CFR 177.1520) intended for use in food-contact articles.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that data in the petition support the safe use of the additive only in high density polyethylene with a minimum density of 0.94, and under limited use conditions. Therefore, the use of the additive has been limited in § 178.2010(b) consistent with these conditions.

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 July 31, 1995, 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 "Limitations" for the entry "3,9-Bis[2-{3-(3-*tert*-butyl-4-hydroxy-5-methylphenyl)propionyloxy}-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5.5]undecane" to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

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(b) \* \* \*