

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: Vir Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 8, 1991 (56 FR 37712), FDA announced that a food additive petition (FAP 1B4274) had been filed by Atochem North America, Inc., c/o 1150 17th St. NW., Washington, DC 20036 (presently, 1001 G St. NW, suite 500 West, Washington, DC 20001). The petition proposed that the food additive regulations be amended in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of β , 3(or 4)-bis(octadecylthio)cyclohexylethane as an antioxidant in polymeric articles intended for food-contact uses. The agency reviewed the nomenclature of the additive and has determined that to ensure unambiguous identification of the compound, a synonym compatible with the Chemical Abstract Service nomenclature, namely, 1-[(beta-(octadecylthio)ethyl)-3(or 4)-(octadecylthio)cyclohexane, should be included in this final rule.

Upon further review of the petition, the agency noted that the petitioner had requested use of the additive for general use in polymers rather than as an additive for paper and paperboard. In a notice published in the **Federal Register** of September 11, 1991 (56 FR 46323), FDA amended the filing notice of August 8, 1991, to state that the petitioner had requested that the food additive regulations be amended in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the use of β ,

3(or 4)-bis(octadecylthio)cyclohexylethane as an antioxidant for general use in polymeric food-contact articles.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe and that 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 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 March 17, 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 alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *
(b) * * *

Substances	Limitations
*	*
β , 3(or 4)-Bis(octadecylthio)cyclohexylethane (CAS Reg. No. 37625-75-5); CAS synonym: 1-[(beta-(octadecylthio)ethyl)-3(or 4)-(octadecylthio)cyclohexane.	For use only: 1. At levels not to exceed 0.3 percent by weight of all polymers for use in contact with foods of Types I, II, IV-B, VI, VII-B, and VIII under conditions of use B through H as described in Tables 1 and 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.3 percent by weight of polyolefins complying with § 177.1520 of this chapter, for use in contact with food of types III, IV-A, V, VII-A, and IX under conditions of use C through G as described in Tables 1 and 2 of § 176.170(c) of this chapter.
*	*