paragraph (b)(4) of this section. It is within the discretion of the concerned Fines, Penalties and Forfeitures Officer to grant or deny such requests.

(g) *Commencement of a formal investigation.* A formal investigation of a violation is considered to be commenced with regard to the disclosing party on the date recorded in writing by the Customs Service as the date on which facts and circumstances were discovered or information was received that caused the Customs Service to believe that a possibility of a violation existed. In the event that a party affirmatively asserts a prior disclosure (i.e., identified or labeled as a prior disclosure) and is denied prior disclosure treatment on the basis that Customs had commenced a formal investigation of the disclosed violation, and Customs initiates a penalty action against the disclosing party involving the disclosed violation, a copy of a ''writing'' evidencing the commencement of a formal investigation of the disclosed violation shall be attached to any required prepenalty notice issued to the disclosing party pursuant to 19 U.S.C. 1592 or 19 U.S.C. 1593a.

(h) *Scope of the disclosure and expansion of a formal investigation.* A formal investigation is deemed to have commenced as to additional violations not included or specified by the disclosing party in the party's original prior disclosure on the date recorded in writing by the Customs Service as the date on which facts and circumstances were discovered or information was received that caused the Customs Service to believe that a possibility of such additional violations existed. Additional violations not disclosed or covered within the scope of the party's prior disclosure that are discovered by Customs as a result of an investigation and/or verification of the prior disclosure shall not be entitled to treatment under the prior disclosure provisions.

(i) *Knowledge of the commencement of a formal investigation.*—(1) A disclosing party who claims lack of knowledge of the commencement of a formal investigation has the burden to prove that lack of knowledge. A person shall be presumed to have had knowledge of the commencement of a formal investigation of a violation if before the claimed prior disclosure of the violation a formal investigation has been commenced and:

(i) Customs, having reasonable cause to believe that there has been a violation of 19 U.S.C. 1592 or 19 U.S.C. 1593a, so informed the person of the type of or circumstances of the disclosed violation; or

(ii) A Customs Special Agent, having properly identified himself or herself and the nature of his or her inquiry, had, either orally or in writing, made an inquiry of the person concerning the type of or circumstances of the disclosed violation; or

(iii) A Customs Special Agent, having properly identified himself or herself and the nature of his or her inquiry, requested specific books and/or records of the person relating to the disclosed violation; or

(iv) Customs issues a prepenalty or penalty notice to the disclosing party pursuant to 19 U.S.C. 1592 or 19 U.S.C. 1593a relating to the type of or circumstances of the disclosed violation; or

(v) The merchandise that is the subject of the disclosure was seized; or

(vi) In the case of violations involving merchandise accompanying persons entering the United States or commercial merchandise inspected in connection with entry, the person has received oral or written notification of Customs finding of a violation.

(2) The presumption of knowledge may be rebutted by evidence that, notwithstanding the foregoing notice, inquiry or request, the person did not have knowledge that an investigation had commenced with respect to the disclosed information.

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by adding a new listing to the table in numerical order to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control No.
* * * * *		
§ 162.74	Prior disclosure	1515–0212
* * * * *		

Samuel H. Banks,

Acting Commissioner of Customs.

Approved: May 12, 1998.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 98–14154 Filed 5–27–98; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 97F–0283]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Monester of alpha-Hydro-omega-Hydroxy-Poly(Oxyethylene) Poly(Oxypropylene) Poly(Oxyethylene) (15 Mole Minimum) Blocked Copolymer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for safe use of monoester of alpha-hydro-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil as a component of defoaming agents used in the washing of sugar beets for processing into sugar. This action responds to a petition filed by Akzo Nobel Chemical, Inc.

DATES: The regulation is effective May 28, 1998; written objections and requests for a hearing by June 29, 1998.

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: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 11, 1997 (62 FR 37266), FDA announced that a food additive petition (FAP 6A4494) had been filed by Akzo Nobel Chemical, Inc., 5 Livingstone Ave., Dobbs Ferry, NY 10522–3407. The petition proposed to amend the food additive regulations in § 173.340 *Defoaming agents* (21 CFR 173.340) to provide for the safe use of monoester of α-hydro-ω-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene)(15 mole minimum) blocked copolymer derived from low erucic acid rapeseed (LEAR) oil as a component of defoaming agents used in the washing of sugar beets for processing into sugar. (Although the additive was named in the filing notice using the Greek symbols for alpha and omega, the agency has chosen to spell out the words in the listing of the additive to facilitate electronic searches.)

FDA has evaluated data in the petition and other relevant material. Based on this information the agency concludes that the proposed use of monoester of alpha-hydro-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer is safe, that the additive will achieve its intended technical effect, and therefore, 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 § 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 action, as announced in the notice of filing for FAP 6A4494 (62 FR 37266). 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 a environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. No comments were received during the 30-day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

Any person who will be adversely affected by this regulation may at any time on or before June 29, 1998 , 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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 173

Food additives.

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 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.340 is amended by revising paragraph (a)(4) and in the table in paragraph (a)(4) by revising the first heading and by alphabetically adding the entry for ''monoester of alpha-hydro-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil'' under the newly revised heading ''Substances'' to read as follows:

§ 173.340 Defoaming agents.

* * * * *

(a) * * *

(4) The substances listed in this paragraph (a) (4), provided they are components of defoaming agents limited to use in processing beet sugar only, and subject to the limitations imposed:

Substances	Limitations
* * *	* * * *
Monoester of alpha-hydro-omega-hydroxy-poly(oxyethylene) poly(oxypropylene) poly(oxyethylene) (15 mole minimum) blocked copolymer derived from low erucic acid rapeseed oil.	

* * * * *

Dated: May 19, 1998.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–14105 Filed 5–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0489]

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 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with *o*-xylene, as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. This action responds to a petition filed by Ciba Specialty Chemicals Corp.

DATES: The regulation is effective May 28, 1998. Submit written objections and request for a hearing by June 29, 1998.

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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), 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 January 2, 1997 (62 FR 100), FDA announced that a food additive petition (FAP 7B4529) 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 5,7-bis(1,1-dimethylethyl-3-hydroxy-2(3H)-benzofuranone, reaction products with *o*-xylene as an antioxidant and/or stabilizer for olefin polymers 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: (1) The proposed use of the additive is safe, (2) the food additive will achieve its intended technical effect, and therefore, (3) 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 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 June 29, 1998, 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *