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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.

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(b) * * *

Substances	Limitations
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5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with <i>o</i> -xylene (CAS Reg. No. 181314-48-7).	<p>For use only:</p> <ol style="list-style-type: none"> At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter. The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI-A, VI-B, VII-B, and VIII, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. At levels not to exceed 0.02 percent by weight of propylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 3.1a, 3.2a, 3.2b, 3.4, or 3.5, and ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, or 3.6 (where the density of each of these polymers is at least 0.94 gram per cubic centimeter), or 5. The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter; provided that the finished food-contact articles have a volume of at least 18.9 liters (5 gallons). At levels not to exceed 0.02 percent by weight of ethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, or 3.6 (where the density of each of these polymers is less than 0.94 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter; provided that the average thickness of such polymers in the form in which they contact food shall not exceed 50 micrometers (0.002 inch).
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Dated: May 11, 1998.

L. Robert Lake,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Diego; 98-011]

RIN 2115-AA97

Safety Zone; Oceanside, CA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the navigable waters of the Pacific Ocean adjacent to Oceanside, California, for the 2nd Annual Oceanside Grand Prix Powerboat Race on 31 May 1998. The race zone will encompass the water from the Oceanside harbor entrance and the southerly city limits of Oceanside,

approximately .5 miles from the shoreline and running approximately parallel thereto, in an area more particularly described as follows: beginning at a point located at latitude 33°09'87" N, longitude 117°22'81" W; thence northeast to a point located at latitude 33°10'14" N, longitude 117°22'33" W; thence northwest to a point located at latitude 33°11'49" N, longitude 117°23'36" W; thence north to a point located at latitude 33°11'64" N, longitude 117°23'36" W; thence southeast to the point of the beginning.

This safety zone is established to protect the lives and property of the race participants and spectators by establishing an exclusionary zone around the race course. Entry into, transit through, or anchoring within this zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation becomes effective at 1:30 p.m. (DST) on May 31, 1998, and continues until 2:45 p.m. (DST) on May 31, 1998, unless cancelled earlier by the Captain of the Port.

ADDRESSES: Marine Safety Office San Diego, 2716 N. Harbor Drive, San Diego, CA 92101-1064.

FOR FURTHER INFORMATION CONTACT: LT Mike Arguelles, U.S. Coast Guard Marine Safety Office San Diego at (619) 683-6484.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publication of a notice of proposed rulemaking and delay of its effective date would be contrary to the public interest since immediate action is necessary to ensure the safety of vessels operating in the area of the race. The safety zone boundaries and 2nd Annual Oceanside Grand Prix arrangements were not finalized until a date fewer than 30 days prior to the event date. Following normal rulemaking procedures in this case would be impracticable.

Drafting Information

The drafters of this regulation are Lieutenant Mike Arguelles, Project Officer, U.S. Coast Guard Marine Safety Office San Diego, and LTJG Derek A. D'Orazio, Project Attorney, Maintenance