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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F-0504]

**Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of the butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food. This action is in response to a petition filed by The Goodyear Tire and Rubber Co,

**DATES:** The regulation is effective (*insert date of publication in the Federal Register*); submit written objections and request for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 December 10, 1997 (62 FR 65084), FDA announced that a food additive petition (FAP 8B4561 ) had been filed by The Goodyear Tire and Rubber Co., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations

in § 178.2010 *Antioxidants and/or stabilizers* (21 CFR 178.2010) to provide for the expanded safe use of butylated reaction product of *p*-cresol and dicyclopentadiene for use as an antioxidant in acrylonitrile/butadiene/styrene copolymers in contact with food.

In the notice of filing for this additive, FDA announced that it had determined under § 25.32(i) (21 CFR 25.32(i)) that this action was of a type that did not individually or cumulatively have a significant effect on the human environment. Subsequently, during FDA's in-depth review of the petition, the agency determined that the proposed use of the subject additive was for both single service food-packaging materials and repeat use articles. Therefore, at the agency's request, the petitioner provided an amended claim of categorical exclusion from the requirement to prepare an environmental assessment under both § 25.32(i) (single service food packaging) and (j) (repeated use articles),

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 additive will achieve its intended technical effect, and (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 determined under § 25.32(i) and (j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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.

Any person who will be adversely affected by this regulation may at any time on or before *(inset-t date 30 days after date of publication in the* **Federal Register***)*. 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 redelegate 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:

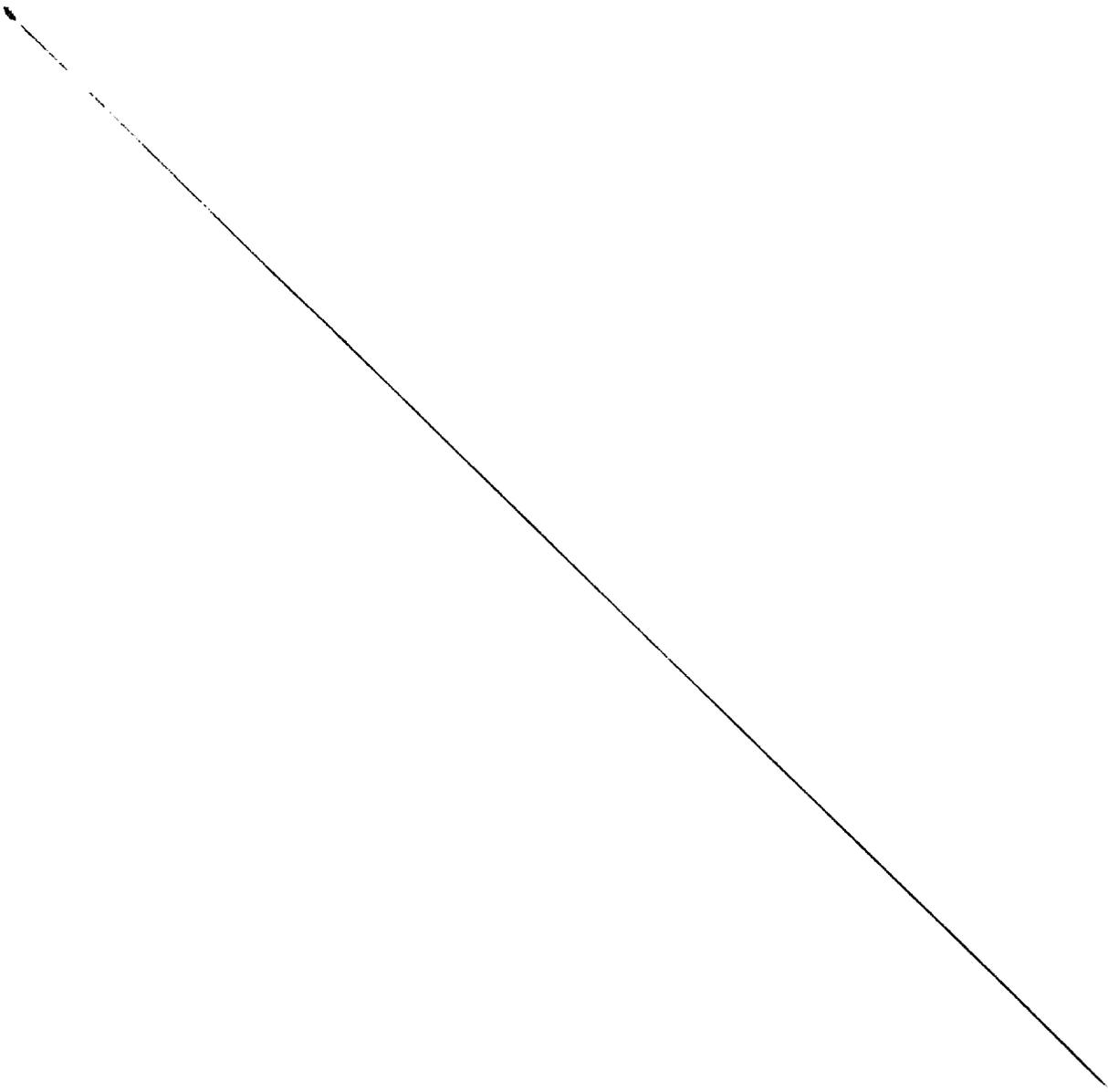
**Authority:** 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) in the entry for "Butylated reaction product of *p*-cresol and dicyclopentadiene" by revising the entry under the heading "Limitations" to read as follows:

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

\*     \*     \*     \*     \*

(b) \* \* \*

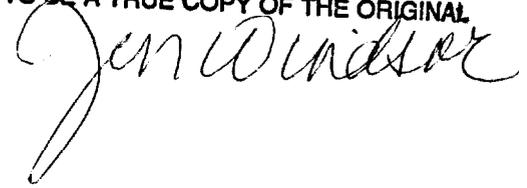


Substances	Limitations
<p>Butylated reaction product of <i>p</i>-cresol and dicyclopentadiene produced by reacting <i>p</i>-cresol and dicyclopentadiene in an approximate mole ratio of 1.5 to 1, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent</p>	<p>For use only:</p> <ol style="list-style-type: none"> <li>1. As components of nonfood articles complying with §§175.105 and 177.2600(c)(4)(iii) of this chapter.</li> <li>2. At levels not to exceed 10 percent by weight of acrylonitrile/butadiene/styrene copolymers. The finished copolymers may be used in contact with food of Types I, II, IV-B, VI-A, VI-B, 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, and with food of Types III, IV-A, V, VI-C, 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.</li> </ol>

Dated: 12/21/98  
 December 21, 1998



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

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**  


[FR Dec. 98-'? '???' Filed ??-? '98: 8:45am]

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