

2. Section 177.2600 is amended in paragraphs (c)(4)(ii)(a) and (c)(4)(ii)(b) by alphabetically adding new entries for "Diisopropyl xanthogen polysulfide" to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(a) * * *

Diisopropyl xanthogen polysulfide (a 1:2:1 mixture of O,O-di(1-methylethyl)trithio-bis-thioformate, O,O-di(1-methylethyl)tetrathio-bis-thioformate, and O,O-di(1-methylethyl)pentathio-bis-thioformate) for use as a cross linking agent in the vulcanization of natural rubber, styrene-butadiene copolymer, acrylonitrile-butadiene copolymer, and ethylene-propylene terpolymers identified under paragraph (c)(4)(i) of this section and limited to use at levels not to exceed 2.4 percent by weight of such copolymers.

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(b) * * *

Diisopropyl xanthogen polysulfide (a 1:2:1 mixture of O,O-di(1-methylethyl)trithio-bis-thioformate, O,O-di(1-methylethyl)tetrathio-bis-thioformate, and O,O-di(1-methylethyl)pentathio-bis-thioformate).

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Dated: July 22, 1995.

Janice F. Oliver,

*Deputy Director for Systems and Support,
Center for Food Safety and Applied Nutrition.
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21 CFR Part 178

[Docket No. 94F-0423]

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 4-chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, calcium salt (1:1) (C. I. Pigment Yellow 191) as a colorant for all polymers intended for use in contact with food. This action is in response to a petition filed by Hoechst Celanese Corp.

DATES: Effective August 3, 1995; ; written objections and request for a hearing by September 5, 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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December 29, 1994 (59 FR 67301), FDA announced that a food additive petition (FAP 5B4441) had been filed by Hoechst Celanese Corp., 500 Washington St., Coventry, RI 02816. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of benzenesulfonic acid, 4-chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methyl-, calcium salt (1:1) (C. I. Pigment Yellow 191) as a colorant in all polymers intended for use in contact with food. In this final rule the agency is using the alternative name 4-chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, calcium salt (1:1) (C. I. Pigment Yellow 191).

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 § 178.3297 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 September 5, 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 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows: