

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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21 CFR Part 178

[Docket No. 99F-1457]

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 4,5-dichloro-2-((5-hydroxy-3-methyl-1-(3-sulfohenyl)-1H-pyrazol-4-yl)azo)benzenesulfonic acid, calcium salt(1:1), (C.I. Pigment Yellow 183) as a colorant in high density polyethylene and polypropylene resins intended for use in contact with food. This action responds to a petition filed by BASF Corp.

DATES: This regulation is effective *[insert date of publication in the Federal Register]*. Submit written objections and requests 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: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), 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 May 27, 1999 (64 FR 28825), FDA announced that a food additive petition (FAP 9B4664) had been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828-1234. The petition proposed to

amend the food additive regulations to provide for the safe use of 4,5-dichloro-2-((4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazol-4-yl)azo)benzenesulfonic acid, calcium salt(1: 1), (C.I. Pigment Yellow 183) as a colorant in high density polyethylene and polypropylene resins intended for use in contact with food.

During review of the petition, it was determined that the colorant exists in two tautomeric forms: Keto and enol. As indicated by its infrared spectrum, the colorant exists chiefly in its enol form. It was decided, therefore, that the colorant (C.I. Pigment Yellow 183) should be identified in the regulation by the enol nomenclature and the CAS number. The colorant is listed, accordingly, in the codified section of this document as 4,5-dichloro-2-((5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl)azo)benzenesulfonic acid, calcium salt(1: 1), (C.I. Pigment Yellow 183, CAS Reg. No. 652 12-77-3).

FDA has evaluated the 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 therefore, (3) that the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 17 1.1(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 (address above) by appointment with the information contact person listed above. As provided in 21 CFR 17 1.1(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 environmental effects of this rule as announced in the notice of filing for FAP 9B4664 (64 FR 28825, May 27, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection 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 anytime on or before *[insert date 30 days after date of publication in the **Federal Register**]* file with the Dockets Management Branch (address above) written objection 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 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 objection 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:

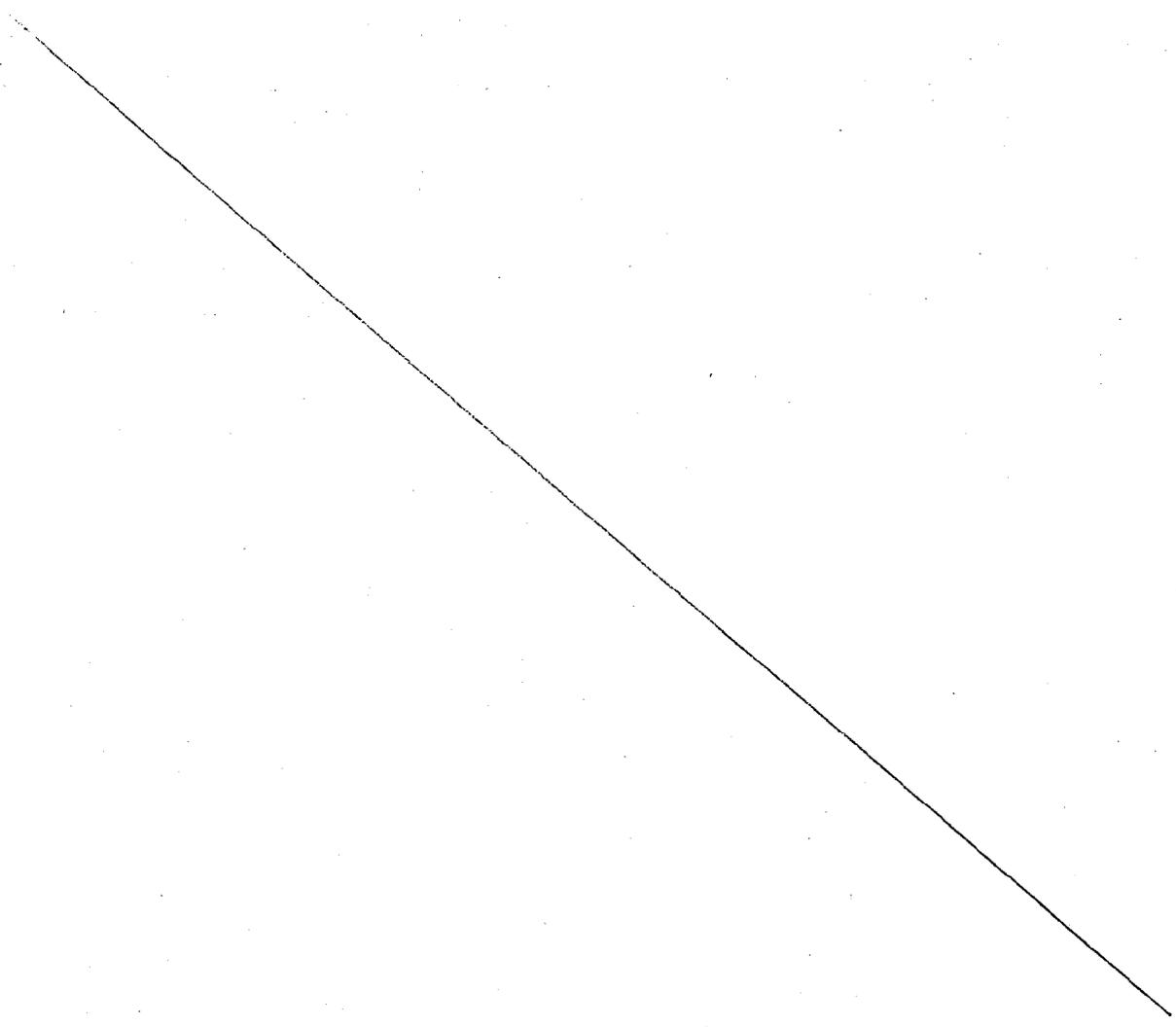
Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding an entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *



Substances	Limitations
<p>* * *</p> <p>4,5-Dichloro-2-((5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl)azo)benzenesulfonic acid, calcium salt(1:1), (C.I. Pigment Yellow 183, CAS Reg. No, 65212-77-3).</p> <p>* * *</p>	<p>* * *</p> <p>For use only:</p> <p>1. At levels not to exceed 1 percent by weight of polypropylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 1.2, 1.3, 3.1a, 3.1b, 3.1c, 3.2a, 3.2b, 3.4, or 3.5. The finished articles are to contact food only under conditions of use E through G, as described in Table 2 of § 176.170(c) of this chapter.</p> <p>2. At levels not to exceed 1 percent by weight of high density polyethylene polymers and copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.1c, 3.2a, 3.2b, 3.6 (density not less than 0.94 grams per cubic centimeter), or 5. The finished articles are to contact food only under conditions of use E through G, as described in Table 2 of § 176.170(c) of this chapter.</p> <p>* * *</p>

Dated: 12/17/99

December 17, 1999



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

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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