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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 98F-0584]

Indirect Food Additives: Paper and Paperboard Components

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 monoisopropanolamine as a dispersant for pigments intended to be used either as fillers or colorants in food-contact paper and paperboard. This action is in response to a petition filed by DuPont Chemicals and White Pigments and The Dow Chemical Co.

DATES: This regulation is effective (*insert date of publication in the **Federal Register***); 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: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 31, 1998 (63 FR 40912), FDA announced that a food additive petition (FAP 8B4607) had been jointly filed by DuPont Chemicals and White Pigments, Edge Moor Plant, 104 Hay Rd., Wilmington, DE 19809, and The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposed to

amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of monoisopropanolamine as a dispersant for pigments intended to be used as fillers or colorants in food-contact paper and paperboard.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 176.170 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 rule as announced in the notice of filing for the petition. 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 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 *(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

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 176

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding a new entry under the headings ‘Lists of Substances’ and ‘Limitations’ to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

| List of Substances | Limitations |
|---|--|
| Monoisopropanolamine (CAS Reg. No. 78-96-6) | For use as a dispersant for titanium dioxide suspensions at a level not to exceed 0.68 percent by weight of titanium dioxide. The finished paper and paperboard will be used in contact with all food types under conditions of use E through G described in table 2 of paragraph (c) of this section. |

| List of Substances | Limitations |
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Dated: 5/7/99

May 7, 1999

L. Robert Lake

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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Michael W. Bell