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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F-0285]

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 expanded safe use of bis(*p*-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food. This action responds to a petition filed by Mitsui Toatsu Chemicals, Inc. (now Mitsui Chemicals, Inc.).

DATES: 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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-216), 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 August 10, 1992 (57 FR 35595), FDA announced that a food additive petition (FAP 2B4330) had been filed by Mitsui Toatsu Chemicals, Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the expanded safe use of bis(*p*-ethylbenzylidene)

sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food. Subsequent to the filing of the petition, Mitsui Toatsu Chemicals, Inc., merged with Mitsui Chemicals, Inc. Therefore, the current name of the petitioner is Mitsui Chemicals, Inc.

FDA has evaluated 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 that therefore the regulations in § 178.3295 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.

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 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 178.3295 is amended in the table by revising the entry for “Bis(*p*-ethylbenzylidene) sorbitol” to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
Bis(<i>p</i> -ethylbenzylidene) sorbitol (CAS Reg. No. 79072-96-1).	For use only as a clarifying agent at a level not to exceed 0.35 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.2a, or 3.2b, where the copolymers complying with items 3.1a, 3.2a, or 3.2b contain not less than 85 weight percent of polymer units derived from propylene.

Dated: 5/3/99
May 3, 1999



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

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