

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 176**

[Docket No. 95F-0016]

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 silver chloride-coated titanium dioxide as a preservative in polymer latex emulsions used in the coating of food-contact paper and paperboard. This action is in response to a petition filed by Johnson Matthey Chemicals.

DATES: Effective December 5, 1995; written objections and requests for a hearing by January 4, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, 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 February 13, 1995 (60 FR 8243), FDA announced that a food additive petition (FAP 5B4442) had been filed by Johnson Matthey Chemicals, c/o 1000 Potomac St. NW., Washington, DC 20007. 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 silver chloride-coated titanium dioxide as a preservative in polymer

latex emulsions used in the coating of food-contact paper and paperboard.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive in paper and paperboard products in contact with food is safe and 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 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 January 4, 1996, 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 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: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (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 "List of Substances" and "Limitations" to read as follows:

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

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(a) * * *

(5) * * *

List of Substances	Limitations
* * * * *	* * * * *
Silver chloride-coated titanium dioxide	For use only as a preservative in polymer latex emulsions at a level not to exceed 2.2 parts per million (based on silver ion concentration) in the dry coating.
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