

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier C. WMS-DIV

21 CFR Part 177

[Docket No. 93F-0151]

Indirect Food Additives: Polymers

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 Nylon MXD-6 as nonfood-contact layers of multilayer films and rigid plastic containers composed of polypropylene food-contact and exterior layers. This action is in response to a petition filed on behalf of Mitsubishi Gas Chemical Co., Inc.

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 May 19, 1993 (58 FR 29230), FDA announced that a food additive petition (FAP 3B4372) had been filed on behalf of Mitsubishi Gas Chemical Co., Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 177.1390 *Laminate* cf98152

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structures for use at temperatures of 250 °F and above (21 CFR 177.1390) and § 177.1500 *Nylon resins* (21 CFR 177.1500) to provide for the safe use of Nylon MXD-6 as a nonfood-contact component in laminated articles for use in contact with food. However, the petition was subsequently amended to restrict the use of the subject additive to nonfood-contact layers of: (1) Multilayer films and (2) rigid plastic containers composed of polypropylene food-contact and exterior layers. This amendment is reflected in this final rule.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive as a nonfood-contact layer of: (1) Multilayer films and (2) rigid plastic containers composed of polypropylene food-contact and exterior layers is safe, that the additive will have the intended technical effect, and therefore, that the regulations in §§ 177.1390 and 177.1500 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 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

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

2. Section 177.1390 is amended by redesignating paragraph (c)(1)(i)(e) as paragraph (c)(1)(i)(f) and adding a new paragraph (c)(1)(i)(e) to read as follows:

§ 177.1390 **Laminate structures for use at temperatures of 250 °F and above.**

* * * * *

(c) * * *

(1) * * *

(i) * * *

(e) Nylon MXD-6 resins that comply with item 10.3 of the table in § 177.1500(b) of this chapter when extracted with water and heptane under the conditions of time and temperature specified for condition of use A, as set forth in Table 2 of § 176.170(c) of this chapter.

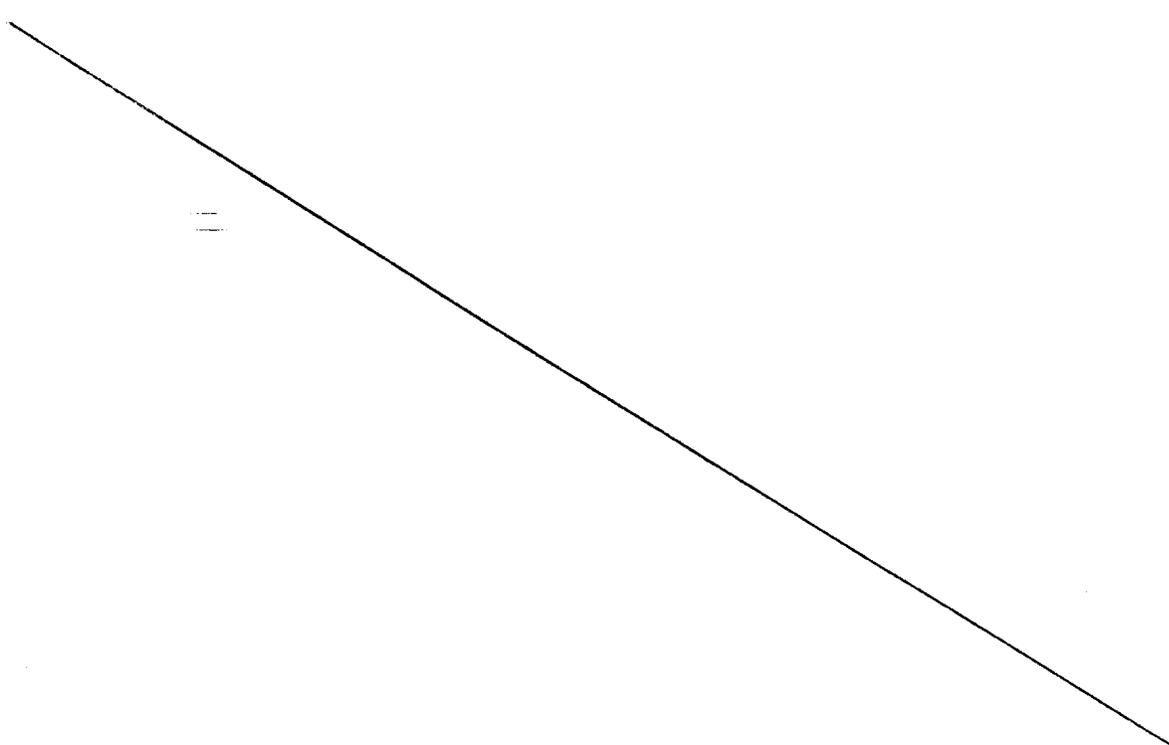
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3. Section 177.1500 is amended in the table in paragraph (b) by adding item “10.3” to read as follows:

§ 177.1500 **Nylon resins.**

* * * * *

(b) * * *



tilayer films and (2) rigid plastic containers composed of polypropylene food-contact and exterior layers, as defined in § 177.1520(c), item 1.1(a) and 1.1(b), of this chapter. The finished food-contact laminate, in the form in which it contacts food, when extracted with the food simulating solvent or solvents characterizing the conditions of the intended use as determined from Table 2 of § 176.170(c) of this chapter, shall yield not more than 0.5 micrograms of *m*-xylylenediamine-adipic acid cyclic monomer per square inch of food-contact surface, when the food simulating solvent is analyzed by any appropriate, properly validated method.

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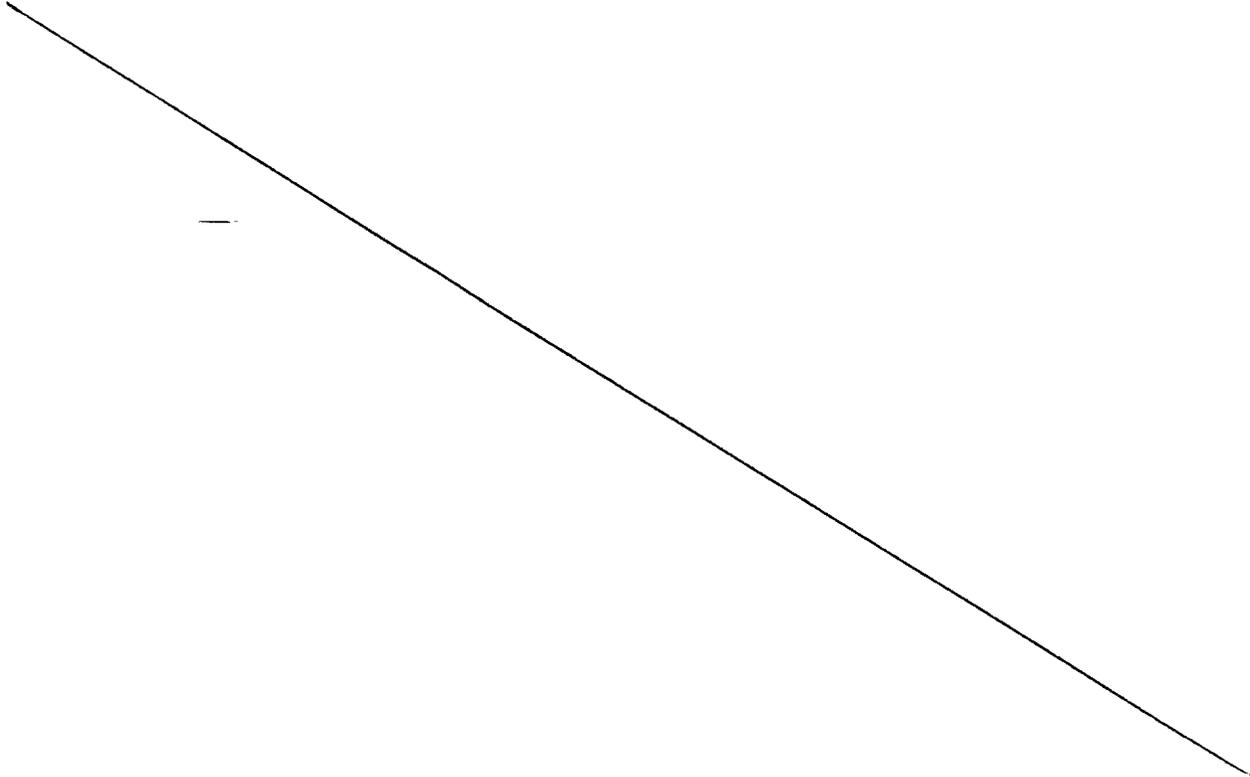
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Dated: 1/20/99
January 20, 1999

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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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be 'C. G. ...'.