Substances	Limitations
* * *	* * *
Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, compd. with 1,1′,1″-nitrilotris [2-propanol] (1:1) (CAS Reg. No. 221281–21–6)	For use only at levels not to exceed 0.45 percent by weight of the pigment. The pigmented articles may contact all food under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * *

Dated: December 17, 1999.

L. Robert Lake,

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

[FR Doc. 99–33398 Filed 12–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–1421]

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 tetradecanoic acid, lithium salt as a stabilizer for polypropylene and certain polypropylene copolymers intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: This regulation is effective December 27, 1999. Submit written objections and requests for a hearing by January 26, 2000.

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 24, 1999 (64 FR 28000), FDA announced that a food additive petition (FAP 9B4665) had been filed by Asahi Denka Kogyo K.K., 5–2–13, Shirahata, Urawa City, Saitama 336–0022, Japan. The petition proposed to amend the food additive regulations to provide for the safe use of tetradecanoic acid, lithium salt as a stabilizer in polypropylene and certain olefin copolymers intended for use in contact with food.

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 21 CFR 178.2010 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4665. 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 any time on or before January 26, 2000, 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 are to be submitted and are to 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 office above 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 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * * * *	
Tetradecanoic acid, lithium salt (CAS Reg. No. 20336–96–3)	For use only at levels not to exceed 0.15 percent by weight of polypropylene and polypropylene copolymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b. The finished polymers may only be used in contact with food of Types I, II, IV–B, VII–B, and VIII as described in table 1 of § 176.170(c) of this chapter under conditions of use B through H as described in table 2 of § 176.170(c) of this chapter, and with food of Types III, IV–A, V, VI–A, VI–B, VI–C, VII–A, and IX described in table 1 of § 176.170(c) of this chapter under conditions of use C through G as described in table 2 of § 176.170(c) of this chapter.
* * * * * * *	

Dated: December 17, 1999.

L. Robert Lake,

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

[FR Doc. 99–33397 Filed 12–23–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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-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. This action responds to a petition filed by BASF Corp.

DATES: This regulation is effective December 27, 1999. Submit written objections and requests for a hearing by January 26, 2000.

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. 65212–77–3).

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 § 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 (address above) 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 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 January 26, 2000 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