(b) Curdlan meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Analytical Methods for Specification Tests for Curdlan,'' by Takeda Chemical Industries, Ltd., 12–10 Nihonbashi, 2–Chome, Chuo-ku, Tokyo, 103, Japan, 1996, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(1) Positive for curdlan.

(2) Assay for curdlan (calculated as anhydrous glucose), not less than 80 percent.

(3) pH of 1 percent aqueous suspension, 6.0–7.5.

(4) Lead, not more than 0.5 mg/kg.

(5) Heavy metals (as Pb), not more than 0.002 percent.

(6) Total nitrogen, not more than 0.2 percent.

(7) Loss on drying, not more than 10 percent.

(8) Residue on ignition, not more than 6 percent.

(9) Gel strength of 2 percent aqueous suspension, not less than $600x10^3$ dyne per square centimeter.

(10) Aerobic plate count, not more than 10^3 per gram.

(11) Coliform bacteria, not more than 3 per gram.

(c) Curdlan is used or intended for use in accordance with good manufacturing practice as a formulation aid, processing aid, stabilizer and thickener, and texturizer in foods for which standards of identity established under section 401 of the act do not preclude such use.

Dated: November 27, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–31809 Filed 12–13–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 96F–0164]

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 sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: Effective December 16, 1996; written objections and requests for a hearing by January 15, 1997.

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 May 30, 1996 (61 FR 27085), FDA announced that a food additive petition (FAP 6B4504) had been filed by Asahi Denka Kogyo K.K., 2–13 Shirahata 5–Chome, Urawa City, Saitama 336, Japan. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the additional safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food.

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 food additive will achieve its intended technical effect, and that therefore, the regulations in § 178.3295 should be amended as set forth below.

FDA's review of this petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in the Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, ''* * * that data, reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

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.

Any person who will be adversely affected by this regulation may at any time on or before January 15, 1997 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.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Soffritti, M., C. Maltoni, F. Maffei, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, vol. 5, No. 5:699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of Conference concerning ''Formaldehyde;'' Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

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, 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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3295 is amended in the table in the entry for ''Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate'' by adding a new entry ''3.'' under the heading ''Limitations'' to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * *	* * * *
Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate (CAS Reg. No. 85209–91–2).	For use only: * * * * * 3. As a clarifying agent in olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts foods only of types I, II, IV–B, VI–A, VI–B, and VII–B as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV–A, V, VI–C, and VII–A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

Dated: November 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31808 Filed 12–13–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 93F–0318]

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 2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphepin-6-yl]oxy]-*N*, *N*-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethanamine as a process stabilizer in high density polyethylene and polypropylene polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective December 16, 1996; written objections and requests for a hearing by January 15, 1997.

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 October 4, 1993 (58 FR 51631), FDA announced that a food additive petition (FAP 3B4398) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]-*N*, *N*-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethanamine as a process stabilizer in high density polyethylene and polypropylene polymers complying with 21 CFR 177.1520 intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and that the regulations in § 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