DATES: Effective October 24, 1995; written objections and requests for a hearing by November 24, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 15, 1991 (56 FR 51719), FDA announced that a food additive petition (FAP 1B4287) had been filed by Keller and Heckman, 1001 G St. NW., suite 500 West (formerly, 1150 17th St. NW.), Washington, DC 20001. The petition proposed that the food additive regulations be amended in § 177.2910 *Ultra-filtration membranes* (21 CFR 177.2910) to provide for the safe use of ultra-filtration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer for processing foods.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that § 177.2910 should be amended as set forth below.

Information in the petition indicates that one of the components of the surface modifier for the ultra-filtration membrane, tetraethylene glycol diacrylate (TEGDA), may be a weak rodent carcinogen when applied to the skin (Ref. 1). FDA evaluated this study and has concluded that the evidence that TEGDA may be a weak dermal carcinogen in rodents does not preclude a conclusion that the petitioned use of the food additive is safe.

First, in the dermal rodent study, there was evidence of systemic exposure to the test compound and an assessment of TEGDA's ability to induce tumors at sites distant from the dermal application. The study reported that an examination of several sentinel tissues, including heart, lung, spleen, kidney, bladder, thyroid, adrenal, testes, prostate, and stomach provided no evidence that TEGDA causes tumors systemically. Second, dermal carcinogenicity is not highly predictive of carcinogenicity by other routes of exposure (Ref. 2). These observations support the agency's view that there is no evidence that suggests that TEGDA is likely to be a carcinogen when orally ingested, which is the route of exposure most directly relevant to the safety assessment of food additives.

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 November 24, 1995, 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. Barkley, W., and L. Klaus Stemman, ''Chronic Mouse Dermal Toxicity Study,'' revised May 1986, submitted to Keith A. Bearson by Department of Environmental Health, University of Cincinnati Medical Center, Cincinnati, OH, (unpublished), submitted in Food Additive Petition No. 1B4287, p. 430, 1991.

2. Tobin, Paul S. et al., ''An Evaluation of Skin Painting Studies as Determinants of Tumorigenesis Potential Following Skin Contact With Carcinogens,'' *Regulatory Toxicology and Pharmacology*, vol. 2, 22–37, 1982.

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

2. Section 177.2910 is amended by revising the introductory text, by adding new paragraph (a)(4), by redesignating paragraphs (e) and (f) as paragraphs (f) and (g), and by adding a new paragraph (e) to read as follows:

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section may be safely used in the processing of food, under the following prescribed conditions;

(a) * * *

(4) Ultrafiltration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer.

* * * * *

(e) Ultrafiltration membranes identified in paragraph (a)(4) may be used to filter aqueous or acidic foods containing up to 13 percent of alcohol at temperatures not to exceed 21°C (70°F).

* * * * *

Dated: October 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26268 Filed 10–23–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 92F–0189]

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′-methylenebis(4,6-di-*tert*-butylphenyl)2-ethylhexyl phosphite as an antioxidant and/or stabilizer in polypropylene articles intended for contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K. K.

DATES: Effective October 24, 1995; written objections and requests for a hearing by November 24, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 20, 1992 (57 FR 21415), FDA announced that a food additive petition (FAP 2B4320) had been filed by Asahi Denka Kogyo K. K., c/o 775 S. 23d St., Arlington, VA 22202 (formerly 1002 Pennsylvania Ave. SE., Washington, DC 20003). 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′-methylenebis(4,6-di-*tert*-butylphenyl)2-ethylhexyl phosphite as an antioxidant and/or stabilizer in polypropylene articles intended for contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe and that the regulations in § 178.2010 should be amended as set forth below.

FDA's review of the subject 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 a 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, ''* * * that data concerning the Soffritti study 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 histopathologic 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 November 24, 1995, 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., 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 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings

''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b) * * *

* * * * *

Substances	Limitations
* * *	* * *
2,2′-Methylenebis(4,6-di-*tert*-butylphenyl)2-ethylhexyl phosphite (CAS Reg. No. 126050–54–2).	For use only at levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter. The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV–B, VI–B, VII–B, and VIII under conditions of use B through H described in Table 2, § 176.170(c) of this chapter, and with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV–A, V, VI–A, VI–C, VII–A, and IX under conditions of use C through G described in Table 2, § 176.170(c) of this chapter.
* * *	* * *

Dated: October 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26221 Filed 10–23–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 91F–0423]

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 *N,N*-bis(2-hydroxyethyl)alkyl((C_{13}–C_{15})amine as an antistatic agent in the manufacture of olefin polymer articles intended to contact food. This action is in response to a petition filed by ICI Americas, Inc.

DATES: Effective October 24, 1995; written objections and requests for a hearing by November 24, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., 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 November 29, 1991 (56 FR 61022), FDA announced that a food additive petition (FAP 2B4297) had been filed by ICI Americas, Inc., Concord Pike and Murphy Rd., Wilmington, DE 19897. The petition proposed that the food additive regulations be amended in § 178.3130 *Antistatic and/or antifogging agents in food-packaging materials* (21 CFR 178.3130) to provide for the safe use of *N,N*-bis(2-hydroxyethyl)alkyl(C_{13}–C_{15})amine as an antistatic agent in the manufacture of olefin polymer articles intended to contact food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A), the so-called ''general safety clause'' of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The anticancer or Delaney clause (section 409(c)(3)(A) (the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive (*Scott* v. *FDA*, 728 F. 2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, *N,N*-bis(2-hydroxyethyl)alkyl(C_{13}–C_{15})amine, will result in exposure to the additive of no greater than 0.26 part per million (ppm) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from subchronic rat and dog toxicity studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive, 1,4-dioxane and ethylene oxide. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of