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

§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b) * * *

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Substances	Limitations
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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

the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. 1,4–Dioxane

FDA has estimated the hypothetical worst-case exposure to 1,4-dioxane from the petitioned use of the additive in the manufacture of olefin polymer food-contact articles to be 3 parts per billion (ppb) of the daily diet or 9 micrograms per person per day (ug/person/day) (Ref. 1). The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted by the National Cancer Institute (Ref. 3) to estimate the upper-bound lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 3). The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the estimated worst-case exposure of 9 ug/ person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the use of the subject additive is 3.15×10^{-7}, or 3.15 in 10 million (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to 1,4-dioxane would result from the proposed use of the additive.

B. Ethylene Oxide

FDA estimated that the hypothetical worst-case exposure to ethylene oxide from the petitioned use of the additive in the manufacture of olefin polymer food-contact articles is 0.03 ppb of the daily diet or 90 nanograms (ng)/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted for the Institute of Hygiene, University of Mainz, Germany, to estimate the upper-bound level of lifetime human risk from exposure to ethylene oxide stemming from the proposed use of the additive (Ref. 5). The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach.

Based on a potential exposure of 90 ng/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to ethylene oxide from the use of the subject additive is 1.68×10^{-7}, or 1.68 in 10 millon (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is reasonable certainty that no harm from the exposure to ethylene oxide would result from the proposed use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to these impurities, even under worst-case assumptions, are very low, less than 3.15 in 10 million for 1,4-dioxane and less than 1.68 in 10 million for ethylene oxide, respectively.

III. Conclusion

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the additive in olefin polymer food-contact articles is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 178.3130 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.

IV. Environmental Impact

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.

V. 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. Memorandum dated August 30, 1993, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216) concerning FAP 2B4297, ICI Americas, Inc., exposure to the food additive and its components (1,4-dioxane and ethylene oxide).

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in Chemical Safety Regulation and Compliance, edited by F. Homburger and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Bioassay of 1,4–Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

4. Memorandum, ''Report of the Quantitative Risk Assessment Committee,'' October 7, 1993.

5. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2–Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46: 924, 1982.

VI. Objections

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.

List of Subjects in 21 CFR Part 178

Food additive, 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 178.3130 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
N,N–Bis(2-hydroxyethyl)alkyl(C_{13}–C_{15})amine (CAS Reg. No. 70955–14–5)..	For use only as an antistatic agent at levels not to exceed 0.2 percent by weight in molded or extruded high-density polyethylene (having a density ≥ 0.95 g/cm^3) and polypropylene containers that contact food only of the types identified in § 176.170(c) of this chapter, Table 1, under types I, VI-B, VII-B, and VIII, under the conditions of use E through G described in Table 2 of § 176.170(c) of this chapter, provided such foods have a pH above 5.0.
* * *	* * * *

Dated: October 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–26359 Filed 10–23–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–94–057]

Drawbridge Operation Regulations; Plum Island River, MA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating rules governing the Plum Island Bridge at mile 3.3, over the Plum Island River between Newburyport and Plum Island, Massachusetts, by requiring advance notice for openings at all times. This action is being taken because there have been increasingly fewer requests for bridge openings in recent years. This will relieve the bridge owner of the unnecessary burden of having personnel at the bridge at all times.

EFFECTIVE DATE: November 24, 1995.

ADDRESSES: Documents referred to in this preamble are available for copying and inspection at the First Coast Guard District, Bridge Branch office located in the Captain John Foster Williams Federal Building, 408 Atlantic Ave., Boston, Massachusetts 02110–3350, room 628, between 6:30 a.m. and 3 p.m., Monday through Friday, except federal holidays. The telephone number is (617) 223–8364.

FOR FURTHER INFORMATION CONTACT: John W. McDonald, Project Manager, Bridge Branch, (617) 223–8364.

SUPPLEMENTARY INFORMATION:

Drafting Information: The principal persons involved in drafting this final rule are Mr. John W. McDonald, Project Officer, Bridge Branch, and Lieutenant Commander Samuel R. Watkins, Project Counsel, District Legal Office.

Regulatory History

On December 12, 1994, the Coast Guard published a notice of proposed rulemaking entitled ''Drawbridge Operation Regulations; Plum Island River, Massachusetts'' in the Federal Register (59 FR 63943). The Coast Guard received no letters commenting on the notice of proposed rulemaking. No public hearing was requested, and none was held.

Background and Purpose

The Plum Island Bridge over the Plum Island River between Newburyport and Plum Island, Massachusetts has a vertical clearance of 13′ above mean high water (MHW) and 21′ above mean low water (MLW). This final rule will permit the bridge to open on signal April 1 to November 30, 5 a.m. to 9 p.m., if at least one hour advance notice is given. At all other times the draw will open on signal if at least three hours advance notice is given.

There has been a decrease in requests for bridge openings during the last several years at the Plum Island Bridge. As a result of this decreasing demand for bridge openings, the Massachusetts Highway Department asked the Coast Guard to change the operating rules to allow the bridge to operate on advance notice at all times.

Discussion of Comments and Changes

The Coast Guard received no comments on the notice of proposed rulemaking. Therefore, no changes to the proposed rule were made.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This conclusion is based on the fact that the regulation will not prevent mariners