Issued in Renton, Washington on May 11, 1999.

Donald E. Gonder,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 95F–0191]

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 polyestercarbonate resins produced by the condensation of 4,4′-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride. The finished resins are composed of 45 to 85 mole percent ester, of which up to 55 mole percent is the terephthaloyl isomer, as articles or components of articles in contact with food. This action responds to a petition filed by the General Electric Co.

DATES: This regulation is effective May 19, 1999; written objections and requests for a hearing by June 18, 1999.

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: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 31, 1995 (60 FR 39000), FDA announced that a food additive petition (FAP 5B4470) had been filed by the General Electric Co., 1 Lexan Lane, Mt. Vernon, IN 47620–9364. The petition proposed to amend the food additive regulations in § 177.1585 *Polyestercarbonate resins* (21 CFR 177.1585) to provide for the safe use of polyestercarbonate resins produced by the condensation of 4,4′-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride. The finished resins are composed of 45 to 85 percent ester, of which up to 55 percent is the terephthaloyl isomer, as articles or components of articles in contact with food. (The agency will subsequently use mole-percent to describe these resins because this term better describes the resin composition.)

In its evaluation of the safety of this food additive, FDA has reviewed the safety of the additive itself, the starting materials used, 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 residual amounts of methylene chloride, which has been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as methylene chloride, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the general safety standard of section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), 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 food additives anticancer, or Delaney, clause of the act (409(c)(3)(A)) 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 standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended 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, polyestercarbonate resins, as food packaging, will not significantly increase the overall exposure to polyestercarbonate oligomers, monomers, *p*-cumylphenol, and methylene chloride above the exposure from the currently regulated uses of these polyestercarbonate resins (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive use of which 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 on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by methylene chloride, the carcinogenic chemical that may be present as an impurity in the additive. This risk evaluation of methylene chloride has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Methylene Chloride

FDA has estimated the exposure to methylene chloride from the petitioned and regulated uses of polyestercarbonate resins as articles intended to contact food to be no more than 4.9 parts per billion in the daily diet (3 kilogram), or 15 micrograms per person per day (Ref. 1). The agency used data in the National Toxicology Program Report No. 306 (January 1986), on inhalation studies in F344/N rats and $B6C3F_1$ mice to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned and regulated uses of the additive (Ref. 3). The authors reported that the test material caused an increased incidence of liver cell neoplasms and lung neoplasms in both male and female $B6C3F_1$ mice.

Based on the agency's estimate that exposure to methylene chloride will not exceed 15 micrograms/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the regulated and petitioned uses of the polyestercarbonate resins is 1×10^{-7} or 1 in 10 million (Ref. 4). Because of numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to methylene chloride is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the

agency concludes that there is reasonable certainty that no harm from exposure to methylene chloride would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of methylene chloride present as an impurity in the additive. The agency finds that the specification currently in § 177.1585 is adequate to insure that the risk from methylene chloride resulting from the petitioned use of the polyestercarbonate resins in contact with food is insignificant and that use of the resins is safe.

III. Conclusion on Safety

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed uses for the food additive in food-contact articles are safe, that the food additive will achieve its intended technical effect, and that the regulations in § 177.1585 should be amended as set forth in the codified of this document.

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 previously. As provided in § 171.1(h)(2), 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. Paperwork Reduction Act of 1995

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.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 18, 1999, file with the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections and the grounds for the objection. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision 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.

VII. 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 April 25, 1996, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216) entitled ''FAP 5B4470 (MATSt 825, M2.0 and 2.1—General Electric Company (GE) Polyestercarbonate (PEC) resins. Submission dated 6-1-95.''

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

3. ''Toxicology and Carcinogenesis Studies of Dichloromethane (Methylene Chloride) (CAS Reg. No. 75–09–2) in F344/N Rats and B6C3F$_1$ Mice (Inhalation Studies),'' National Toxicology Program Technical Report Series, No. 306 (January 1986).

4. Memorandum, dated June 4, 1996, from the Indirect Additives Branch, (HFS–216), to Executive Secretary, Quantitative Risk Assessment Committee (QRAC), (HFS–308), entitled ''Estimation of Upper-bound Lifetime Human Risk from Methylene Chloride in Polyestercarbonate Resins, the Subject of FAP 5B4470 (General Electric Co.).''

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

2. Section 177.1585 is amended by revising paragraphs (a) and (c)(1) to read as follows:

§ 177.1585 Polyestercarbonate resins.

* * * * *

(a) Polyestercarbonate resins (CAS Reg. No. 71519–80–7) are produced by the condensation of 4,4′-isopropylidenediphenol, carbonyl chloride, terephthaloyl chloride, and isophthaloyl chloride such that the finished resins are composed of 45 to 85 molepercent ester, of which up to 55 mole-percent is the terephthaloyl isomer. The resins are manufactured using a phthaloyl chloride/carbonyl chloride mole ratio of 0.81 to 5.7/1 and isophthaloyl chloride/terephthaloyl chloride mole ratio of 0.81/1 or greater. The resins are also properly identified by CAS Reg. No. 114096–64–9 when produced with the use of greater than 2 but not greater than 5 weight percent *p*-cumylphenol (CAS Reg. No. 599–64–4), as an optional adjuvant substance in accordance with paragraph (b)(2) of this section.

* * * * *

(c) * * *

(1) *Specifications*. Polyestercarbonate resins identified in paragraph (a) of this section can be identified by their characteristic infrared spectrum. The resins shall comply with either or both of the following specifications:

(i) The solution intrinsic viscosity of the polyestercarbonate resins shall be a minimum of 0.44 deciliter per gram, as determined by a method entitled ''Intrinsic Viscosity (IV) of Lexan® Polyestercarbonate Resin by a Single Point Method Using Dichloromethane as the Solvent,'' developed by the General Electric Co., September 20, 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–215), 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; or

(ii) A minimum weight-average molecular weight of 27,000, as determined by gel permeation chromatography using polystyrene standards.

* * * * *

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12531 Filed 5–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–99–034]

Drawbridge Operating Regulation; Gulf Intracoastal Waterway, TX

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District has issued a temporary deviation from the regulation in 33 CFR 117.977 governing the operation of the Pelican Island Causeway bascule drawbridge across the Gulf Intracoastal Waterway, mile 356.1 at Galveston, Galveston County, Texas. This deviation allows the Galveston County Navigation District to maintain the bridge in the closed-to-navigation position from 7 a.m. until 7 p.m. from Monday, May 17, 1999, until Friday, June 4, 1999. Additionally, the bridge may remain in the closed-to-navigation position continuously from 7 a.m. on Thursday, May 20, 1999, until 7 p.m. on Sunday, May 23, 1999. At all other times, the bridge will operate normally for the passage of vessels. This temporary deviation is issued to allow for the replacement of the bridge fendering system.

DATES: This deviation is effective from 7 a.m. on Monday, May 17, 1999, until 7 p.m. on Friday, June 4, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. David Frank, Bridge Administration Branch, Commander (ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana 70130–3396, telephone number 504–589–2965.

SUPPLEMENTARY INFORMATION: Navigation on the waterway consists of tugs with tows, fishing vessels, sailing vessels, and other recreational craft. The Galveston County Navigation District requested a temporary deviation from the normal operation of the bridge in order to accommodate the replacement of the fender system of the bridge. The fender system will be replaced in-kind.

This deviation allows the draw of the Pelican Island Causeway bascule span drawbridge across the Gulf Intracoastal Waterway, mile 356.1 at Galveston, Galveston County, Texas, to remain in the closed-to-navigation position from 7 a.m. until 7 p.m. from Monday, May 17, 1999, until Friday, June 4, 1999. Additionally, the bridge may remain in the closed-to-navigation position continuously from 7 a.m. on Thursday, May 20, 1999, until 7 p.m. on Sunday, May 23, 1999. At all other times, the bridge will operate normally for the passage of vessels. Presently, the draw opens on signal for the passage of vessels; except that, from 7 a.m. to 8:30 a.m., 12 noon to 1 p.m., and 4:15 p.m. to 5:15 p.m. Monday through Friday, except Federal holidays, the draw need not open for the passage of vessels. Public vessels of the United States and vessels in distress shall be passed at any time.

Dated: May 12, 1999.

A. L. Gerfin, Jr.,

Captain, U.S. Coast Guard Commander, 8th Coast Guard Dist., Acting.

[FR Doc. 99–12610 Filed 5–18–99; 8:45 am]

BILLING CODE 4310–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WY–001–0002a and WY–001–0003a; FRL–6344–2]

Approval and Promulgation of State Implementation Plans; Wyoming

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA approves two revisions to the Wyoming State Implementation Plan (SIP) regarding particulate matter. The SIP revisions include clarification and revisions to the particulate matter control requirements in section 25 of the Wyoming Air Quality Standards and Regulations (WAQSR) for the FMC Corporation Trona plant in the Trona Industrial Area of Wyoming, and the addition of guidelines for best available control technology (BACT) in the minor source construction permitting requirements of section 21 of the WAQSR for large mining operations. The State submitted these SIP revisions to EPA for approval on September 15, 1982 and on May 16, 1985, respectively. We approve these SIP revisions because they are consistent with Federal requirements.

We also revise 40 CFR 52.2620 to list subsections 21(a)(iv), 24(a)(xix), 24(b)(iv), and 24(b)(xii)(H) of the WAQSR in the ''Incorporation by reference'' section. We approved these subsections in previous SIP approvals (on November 29, 1994 and on November 3, 1995, respectively) but we inadvertently neglected to identify those subsections as incorporated into the SIP in the CFR.

DATES: This rule is effective on July 19, 1999 without further notice, unless we receive adverse comment by June 18, 1999. If we receive adverse comments, we will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: You should mail your written comments to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, Environmental Protection Agency (EPA), Region VIII, 999 18th Street, Suite 500, Denver, Colorado, 80202. Copies of the documents relative to this action are available for inspection during normal business hours at the Air and Radiation Program, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2466. Copies of the Incorporation by Reference material are available at the Air and Radiation Docket and Information Center, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460. Copies of the State documents relevant to this action are available for public inspection at the Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming 82002.

FOR FURTHER INFORMATION CONTACT: Vicki Stamper, EPA Region VIII, (303) 312–6445.

SUPPLEMENTARY INFORMATION:

I. What Action Is EPA Taking Today?

We approve two revisions to the Wyoming SIP pertaining to particulate matter. Specifically, we approve the following: (A) clarification and revisions to the particulate matter control requirements for the FMC Corporation in the Trona Industrial Area of Sweetwater County, Wyoming; and (B)