

Substances

Limitations

Polyester resins (including alkyl type), as the basic polymer, formed as esters when one or more of the following acids are made to react with one or more of the following alcohols:

Acids:

5-sulfo-1,3-benzenedicarboxylic acid, monosodium salt (CAS Reg. No. 6362-79-4).

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-9112 Filed 4-19-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 175

[Docket No. 89F-0176]

Indirect Food Additives: Adhesives and Components of Coatings

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 disodium 4-isodecyl sulfosuccinate as a component of adhesives for articles intended to contact food. This action responds to a petition filed by the American Cyanamid Co.

DATES: Effective April 20, 1993; written objections and requests for a hearing by May 20, 1993.

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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of June 13, 1989 (54 FR 25174), FDA announced that a food additive petition (FAP 9B4122) had been filed by the American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470, proposing that § 175.105 *Adhesives* (21 CFR 175.105) and § 178.3400 *Emulsifiers and/or surface-active agents* (21 CFR 178.3400) of the food additive regulations be amended to provide for the safe use of disodium 4-isodecyl sulfosuccinate for use as a component of adhesives and as

an emulsifier in the production of food-contact polymers. The petitioner has requested that, at this time, the agency proceed only with the regulation of the additive for use as a component of adhesives in food-contact materials. The agency's decision regarding the petitioned use of the additive as an emulsifier in the production of food-contact polymers will be addressed in a future *Federal Register* document.

FDA has evaluated data in the petition and other relevant material. The agency concludes that these data establish the safe use of disodium 4-isodecyl sulfosuccinate as a component of adhesives for articles intended to contact food, and that § 175.105 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 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 May 20, 1993, 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 175

Adhesives, 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 of the Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry to the table to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
Disodium 4-Isodecyl sulfosuccinate (CAS Reg. No. 37294-49-8)	

Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-9113 Filed 4-19-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 177

[Docket No. 91F-0389]

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 an alternate method for determining the maximum *n*-hexane-extractable fraction of the polyolefins in *n*-hexane. This action is in response to a petition filed by Quantum Chemical Corp.

DATES: Effective April 20, 1993; written objections and requests for a hearing by May 20, 1993.

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: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of November 6, 1991 (56 FR 56656), FDA announced that a food additive petition (FAP 1B4291) had been filed by Quantum Chemical Corp., USI Division, 8805 North Tabler Rd., Morris, IL 60450, proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide an alternate method for determining the maximum extractable fraction of the polyolefins in *n*-hexane.

FDA has evaluated data in the petition and other relevant material. The agency finds that the proposed alternate method is suitable for determining the maximum *n*-hexane-extractable fraction of polyolefin and yields results equivalent to the existing method. Therefore, the agency concludes that the regulations in § 177.1520(d)(3)(ii) 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 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 determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before May 20, 1993, 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 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 177.1520 is amended by revising the introductory text of paragraph (d)(3)(ii) and by adding new paragraphs (d)(3)(ii)(e) through (d)(3)(ii)(j) to read as follows:

§ 177.1520 Olefin polymers.

* * * * *
(d) * * *
(3) * * *

(ii) *Olefin copolymers described in paragraph (a)(3)(i) of this section and polyethylene.* A preweighed sample is extracted at 50 °C for 2 hours and filtered. The filtrate is evaporated and the total residue weighed as a measure of the solvent extractable fraction. Alternatively, the sample is reweighed after the extraction period to give a measure of the solvent extractable fraction. The maximum *n*-hexane-extractable fraction may be determined by the methods set forth in paragraphs (d)(3)(ii)(a) through (d)(3)(ii)(i) of this section.

* * * * *
(e) *Extraction apparatus for alternate method.* Two-liter extraction vessel, such as a resin kettle or round bottom flask, fitted with an Allihn condenser (size C), a 45/50 male joint with a Teflon sleeve, and a Teflon coated stir bar. Water bath maintained at 49.5 °C ± 0.5 °C containing a submersible magnetic stirrer motor with power supply. Other suitable means of maintaining temperature control, such as electric heating mantles, may be used provided that the temperature range can be strictly maintained.

(f) *Sample basket (Optional).* A perforated stainless steel cylindrical basket that is approximately 1.5 inches in diameter, 1.6 inches high, and has perforations of 0.125 inches in diameter for 33 holes/in², or 40 percent open area. The basket should pass freely through the 45/50 female joint of the

extraction flask. A No. 6-32 stainless steel eye-bolt is attached to the lid for positioning the basket in the extraction vessel. The positioning rod, approximately 18 inches long and made from 1/16 inch outside diameter 316 stainless steel welding rod or equivalent and hooked at both ends, is used to position the basket in the extraction apparatus.

(g) *Vacuum oven.* Capable of maintaining 80 °C ± 5 °C and a minimum of 635 millimeters of mercury pressure.

(h) *Reagents.* *n*-Hexane, reagent or spectrograde, aromatic free (less than 1 milligram per liter), minimum 85 percent *n*-hexane. This reagent may be reused until it contains a maximum of 1.5 grams polyolefin extractables or has been used for 12 determinations.

(i) *Procedure.* Assemble the extraction vessel, condenser, and magnetic stir bar. Add *n*-hexane (1 liter) to the extraction vessel and clamp the assembly into a water bath set at 49.5 °C ± 0.5 °C. Start the water flowing through the jacket of the reflux condenser. Adjust the air flow through the stirring motor to give a smooth and uniform stir rate. Allow the *n*-hexane to preheat for 1 hour to bring the temperature to 49.5 °C ± 0.5 °C.

Temperature is a critical factor in this analysis and it must not vary more than 1 °C. If the temperature exceeds these limits, the test must be discontinued and restarted. Blown, compression molded, or extrusion cast films can be tested. Ideally, the film should be prepared by the same process as will be used with the production resin. Using gloves and metal tweezers to avoid sample contamination, cut about 2.7 grams of the prepared film (4 mils or less in thickness) into about 1-inch squares using clean sharp scissors. Proceed with Option 1 or 2.

Option 1. Using tweezers and noting the number of film pieces, transfer 2.5 grams (accurately weighed to 0.1 milligram) of polymer to the extraction vessel. Extract the film sample for 2 hours. Allow the vessel to cool and filter the contents through a fritted porcelain funnel. Wash the film pieces with fresh *n*-hexane, aspirate to dryness, and transfer, using tweezers, to a beaker. Recount the film pieces to verify that none were lost during the transfer. Place the beaker in the vacuum oven for 2 hours at 80 °C ± 5 °C. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the film pieces to the nearest 0.1 milligram. Calculate the percent hexane-extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in

paragraph (c) of this section. Repeat the above procedure for successive samples.

Option 2. Transfer 2.5 ± 0.05 grams of the prepared 1-inch film sections into a tared sample basket and accurately weigh to the nearest 0.1 milligram. Carefully raise the condenser until the hook on the positioning rod is above the neck of the 2-liter extraction vessel. The basket should be totally below the level of *n*-hexane solvent. Extract the sample resin film for 2 hours and then raise the basket above the solvent level to drain momentarily. Remove the basket and rinse the contents by immersing several times in fresh *n*-hexane. Allow the basket to dry between rinsings. Remove the excess solvent by briefly blowing the basket with a stream of nitrogen or dry air. Place the basket in the vacuum oven for 2 hours at 80 °C ± 5 °C. After 2 hours, remove and place in a desiccator to cool to room temperature (about 1 hour). After cooling, reweigh the basket to the nearest 0.1 milligram. Calculate the percent hexane extractables content from the weight loss of the original sample. Multiply the result by 0.935 and compare with extraction limits in paragraph (c) of this section. Repeat the above procedure for successive samples. The same solvent charge should remain clear and can be used for at least 12 determinations. Applications of solvent reuse should be confirmed for each resin type before use.

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Dated: April 2, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-9114 Filed 4-19-93; 8:45 am]

BILLING CODE 4160-01-F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 92-59; RM-7923, RM-8042]

Radio Broadcasting Services; Bradenton and High Point, FL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 278C for Channel 277C1 at Bradenton, Florida, and modifies the license for Station WDUV (FM) to specify operation on the higher powered channel, at the request of Sunshine State Broadcasting Company, Inc. See 57 FR 11458, April 3, 1992. Channel 278C can be allotted to Bradenton, Florida, in compliance with the

Commission's minimum distance separation requirements with a site restriction of 41.7 kilometers (25.9 miles) northeast, in order to avoid a short-spacing to a construction permit for Station WQOL(FM), Channel 279C2, Vero Beach, Florida and the licensed site of Station WRUF(FM), Channel 279C1, Gainesville, Florida. The coordinates for Channel 278C at Bradenton are North Latitude 27-49-20 and West Longitude 82-21-50. With this action, this proceeding is terminated.

EFFECTIVE DATE: May 28, 1993.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Walls, Mass Media Bureau, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, MM Docket No. 92-59, adopted March 23, 1993, and released April 14, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service Inc., (202) 857-3800, 1919 M Street NW., room 246, or 2100 M Street NW., suite 140, Washington, DC 20037. In Gettysburg, PA, the location is 1270 Fairfield Road, Gettysburg, PA 17325, (717) 337-1433.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Florida, is amended by removing Channel 277C1 and adding Channel 278C at Bradenton.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93-9125 Filed 4-19-93; 8:45 am]

BILLING CODE 6712-01-M