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Food Contact Review

March 11, 2013

Full Yarn Packaging Company Limited
Jinchuan Industrial Park, Xiegang
Dongguan, Guangdong 518000
China

RE: Your Food Contact Substance – PET Clamshell Container

Dear Sir or Madam:

We present our report and recommendations regarding the food contact substance you submitted for our review. After review of your food contact substance it does not appear that your product requires premarket notification to FDA so long as your substance complies with FDA regulations indicated in the following review.

Our recommendations for this particular food contact substance are detailed. Please feel free to contact us after you have reviewed this material to discuss our findings in detail.

We look forward to working with you to complete this project.

Very truly yours,

Megan Cahoon
Senior Regulatory Specialist

Dariel Hoppersberger
Regulatory Specialist

Section 1: Overview of Definitions and Requirements for a Food Contact Substance

1.1 Definition of Food Contact Surfaces – Food Contact Surfaces are any surface of equipment, utensils, containers, or wrappings that come in direct contact with food. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives (21 CFR 110.40(a)). Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms (21 CFR 110.40(b)).

1.2 Definition of Food Contact Substances (FCS) – Once known as indirect food additives, FDA now refers to these materials as food contact substances. FDA defines food contact substances as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food (21 USC.409(h)(6)). Regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. It is the responsibility of the manufacturer of an FCS to ensure that food contact materials comply with the specifications and limitations in all applicable authorizations. When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the *identity* of the substance, *specifications* including purity or physical properties and *limitations* on the conditions of use. Based on the FDA Food Contact Substances Compliance Guide May 2009 Edition, the individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material shall be covered by one of the following:

1.3.1 Title 21 Code of Federal Regulations (CFR) – The requirement for premarket approval in section 409 of the Food, Drug, and Cosmetic Act in 1958 resulted in the development of a petition process by which a person could request approval of a food additive for an intended use. The approval resulted in a regulation listed in Title 21 of the CFR. Components of a food packaging material used in compliance with a regulation in Title 21 of the CFR need no further FDA review.

1.3.2 Prior Sanction Letter – Prior Sanctioned substances are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.

1.3.3 GRAS Status – "GRAS" is an acronym for the phrase **Generally Recognized As Safe**. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, and is subject to premarket review and approval by FDA. A substance is **exempt** from this requirement if it is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

The use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

- Under 21 CFR 170.30(b), general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information.
- Under 21 CFR 170.30(c) and 170.3(f), general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers.

There must be evidence that the substance is safe under the conditions of its intended use. FDA has defined "safe" (21 CFR 170.3(i)) as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrates safety depends on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

1.3.4 Threshold of Regulation (TOR) Exemption – Threshold of Regulation Exemptions verify that a FCS is exempted from a petition or an Food Contact Notification (FCN) as a food additive because it becomes a component of food at levels that are below the threshold of regulation (21 CFR 170.39(a)). A substance used in a food contact article may be exempted by FDA from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb).

1.3.5 Effective Food Contact Notification (FCN) – FDA will accept FCNs for unapproved uses of food additives that meet the definition of an FCS. FDA believes that a substance that is GRAS or prior sanctioned for its intended use in contact with food also may be an FCS, and may be the subject of an FCN, even though authorization under the FCN process is not required for the FCS use (FDA Guidance for Industry: Preparation of Food Contact Notification May 2002). Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act states that an FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification and not effective for a similar or identical substance produced or prepared by a manufacturer other than a manufacturer identified in the prior notification. FCNs are proprietary to the manufacturer for which the notification is effective; therefore, the FCN must be obtained from that manufacturer.

1.4 Definition of Food Contact Material (FCM) – A food contact material is made with food contact substances and usually other substances. It is often, but not necessarily, a mixture, such as an antioxidant in a polymer. The composition may be variable (FDA Food Ingredients and Packaging Terms, <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm064228.htm#FCA>). Examples of FCMs may be plastic, glass, rubber, and other such materials that are used to make a final product that comes in contact with food.

1.5 Definition of Food Contact Article (FCA) – A food contact article is the finished product formed out of the FCM (FDA website "Food Ingredients and Packaging Terms," accessible at: <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm064228.htm#FCA>).

As described above, the overall regulatory status of a food contact material is dictated by the regulatory status of each individual substance that comprises the article. In addition, each individual substance that is reasonably expected to migrate to food because of its intended use in the food contact material shall be covered by one of the following:

- a regulation listed in Title 21 of the Code of Federal Regulations
- a prior sanction letter
- GRAS status of the substance (including but not limited to a GRAS regulation or GRAS notice)
- an effective Threshold of Regulation (TOR) Exemption
- or an effective Food Contact Notification (FCN)

A product in which each component is covered by one of the above conditions for its intended use does not require premarket notification to FDA prior to marketing the product. If a component of a formulation is not covered by one of the conditions described above for the intended use, then a Food Contact Notification should be submitted for the component. Registrar Corp does not assist with submitting Food Contact Notifications.

Section 2: Analysis of Your Food Contact Substance

- 2.1 Plastic Clamshell Container** – You stated that your Food Contact Article is a plastic clamshell to be used in packaging of fresh fruit such as berries, tomatoes, etc. The information provided for this review states that the product consists of 100% PET with the CAS number 25038-59-9. Based on the information you provided, it appears as though your Food Contact Substances would be classified in the category "polyethylene phthalate polymers."

FDA defines polyethylene phthalate polymer articles as consisting of a base polymer of ethylene terephthalate polymer or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in 21 CFR 177.1315(b)(3) (see Appendix A), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer (21 CFR 177.1630(b)). FDA states that polyethylene phthalate polymers may be safely used as, or as components of, plastics (films, articles, or fabric) intended for use in contact with food (21 CFR 177.1630). FDA states that the base sheet or base polymer could be an ethylene terephthalate polymer, prepared by the condensation of terephthalic acid and ethylene glycol or the condensation of dimethyl terephthalate and ethylene glycol (21 CFR 177.1630(e)(4)(ii)). Please see Appendix B for the full specifications for polyethylene phthalate polymers.

FDA permits optional substances to be added to the polyethylene phthalate polymer either as constituents of the base polymer or as constituents of coatings applied to the base polymer. The quantity of any optional substance employed in the production of polyethylene phthalate plastics should not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitations further provided (21 CFR 177.1630(d)). Any optional substances added to the polyethylene terephthalate polymer should be generally recognized as safe (GRAS) in food, prior sanctioned, or approved for use in polyethylene phthalate plastics, regulated as components of resinous or polymeric food-contact surfaces, or listed in 21 CFR 177.1630(e)(4) (21 CFR 177.1630(e)). If your FCS contains any optional substances please advise Registrar Corp so we can better assist you.

- 2.1.1 Intended Use** – It appears that your product is uncoated polyethylene phthalate plastic container. FDA requires that it be prepared as prescribed from substances identified in 21 CFR 177.1630(e)(4)(i) or (ii) (see above and in Appendix A). FDA provides the following requirements for your uncoated polyethylene phthalate plastic (21 CFR 177.1630(f)):

- The food contact surface, when exposed to distilled water at 250 deg. F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent; and
- The food contact surface, when exposed to *n*-heptane at 150 deg. F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.



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Plastics conforming to these specifications may be used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250 deg. F (21 CFR 177.1630(f)(2)).

Section 3: Summary

You have stated that your Food Contact Article is a plastic clamshell to be used in packaging of fresh fruit such as berries, tomatoes, etc. The information provided for this review states that the product consists of 100% PET with the CAS number 25038-59-9. It appears that FDA would classify your FCS as a "polyethylene terephthalate polymer" and permits its use for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250 deg. F (121°C). Provided that your substance conforms to the regulations of this report, it does not appear that this food contact substance requires notification to the FDA prior to introduction to the US market. If you feel that your product would not be classified as a polyethylene phthalate polymer, please inform Registrar Corp so we may better advise you.

Disclaimer

Certain components of labeling analysis are necessarily subjective. Our recommendations constitute our advice concerning prudent compliance with U.S. labeling regulations, and do not constitute a guaranty of acceptance by the U.S. Food and Drug Administration. Registrar Corp. does not offer legal advice and is not responsible for consequential damages resulting from any product rejection as a result of improper labeling or ingredients. For a legal opinion concerning construction or application of the regulations or statutes, we recommend retaining an attorney.

Appendix A
Specifications for Ethylene-1, 4-Cyclohexylene Dimethylene Terephthalate Copolymers

TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS

Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec. 177.1315 Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.

Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymer may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and of part 174 of this chapter.

(a) *Identity.* For the purposes of this section, ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers (1,4-benzene dicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25640-14-6) or (1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25038-91-9) are basic copolymers meeting the specifications prescribed in paragraph (b) of this section, to which may have been added certain optional substances required in their production or added to impart desired physical or technical properties.

(b) *Specifications:*

| Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers | Inherent viscosity | Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface) | Test for orientability | Conditions of use |
|--|--|---|------------------------|--|
| 1. <i>Non-oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 66 mole percent of ethylene glycol and 1 to 34 mole | Inherent viscosity of a 0.50 percent solution of the copolymer in phenol-tetrachloroethane (60:40 ratio wt/wt) solvent is not less than 0.669 as determined by using a | (1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with water added at 82.2 deg. C (180 deg. F) and allowed to cool to | No test required | In contact with foods, including foods containing not more than 25 percent (by volume) aqueous alcohol, excluding carbonated beverages and |

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|--|---|---|----------------|---|
| <p>percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer)</p> | <p>Wagner viscometer (or equivalent) and calculated from the following equation: Inherent viscosity = (Natural logarithm of $(N_r)/(c)$ where: N_r = Ratio of flow time of the polymer solution to that of the solvent, and c = concentration of the test solution expressed in grams per 100 milliliters</p> | <p>48.9 deg. C (120 deg. F) in contact with the food-contact article</p> | | <p>beer. Conditions of hot fill not to exceed 82.2 deg. C (180 deg. F), storage at temperatures not in excess of 48.9 deg. C (120 deg. F). No thermal treatment in the container.</p> |
| | <p>.....do</p> | <p>(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with 3 percent (by volume) aqueous acetic acid added at 82.2 deg. C (180 deg. F) and allowed to cool to 48.9 deg. C (120 deg. F) in contact with the food-contact article</p> | <p>.....do</p> | <p>Do.</p> |
| | <p>.....do</p> | <p>(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface when extracted for 2 hours with <i>n</i>-heptane at 48.9 deg. C (120 deg. F). The heptane extractable results are to be divided by a factor of 5</p> | <p>.....do</p> | <p>Do.</p> |
| | <p>.....do</p> | <p>(4) 0.16 microgram per square centimeter (1.0 microgram per</p> | <p>.....do</p> | <p>Do.</p> |

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| | | square inch) of food-contact surface when extracted for 24 hours with 25 percent (by volume) aqueous ethanol at 48.9 deg. C (120 deg. F) | | |
| 2. <i>Oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 85 mole percent ethylene glycol and 1 to 15 mole percent of 1,4-cyclohexanedi-methanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer) |do | (1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of the oriented copolymer when extracted with water added at 87.8 deg. C (190 deg. F) and allowed to cool to 48.9 deg. C (120 deg. F) in contact with the food-contact article | When extracted with heptane at 65.6 deg. C (150 deg. F) for 2 hours: terephthaloyl moieties do not exceed 0.09 microgram per square centimeter (0.60 microgram per square inch) of food-contact surface | In contact with nonalcoholic foods including carbonated beverages. Conditions of hot fill not exceeding 87.8 deg. C (190 deg. F), storage at temperatures not in excess of 48.9 deg. C (120 deg. F). No thermal treatment in the container. |
| |do | (2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 3 percent (by volume) aqueous acetic acid added at 87.8 deg. C (190 deg. F) and allowed to cool to 48.9 deg. C (120 deg. F) in contact with the food-contact article |do | Do. |
| |do | (3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food- |do | Do. |

| | | | | |
|--|------------------|---|------------------|---|
| | | contact surface of oriented copolymer when extracted for 2 hours with <i>n</i> -heptane at 48.9 deg. C (120 deg. F). The heptane extractable results are to be divided by a factor of 5 | | |
| |do | (4) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 20 percent (by volume) aqueous ethanol heated to 65.6 deg. C (150 deg. F) for 20 minutes and allowed to cool to 48.9 deg. C (120 deg. F) in contact with the food-contact article |do | In contact with foods and beverages containing up to 20 percent (by volume) alcohol. Conditions of thermal treatment in the container not exceeding 65.6 deg. C (150 deg. F) for 20 minutes. Storage at temperatures not in excess of 48.9 deg. C (120 deg. F). |
| |do | (5) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 50 percent (by volume) aqueous ethanol at 48.9 deg. C (120 deg. F) for 24 hours |do | In contact with foods and beverages containing up to 50 percent (by volume) alcohol. Conditions of fill and storage not exceeding 48.9 deg. C (120 deg. F). No thermal treatment in the container. |
| 3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or | No test required | For each corresponding condition of use, must meet specifications | No test required | For each corresponding specification, may be used as a base sheet and base |

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| terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer) | | described in 177.1630(f), (g), (h), or (j) | polymer in accordance with conditions of use described in 177.1630(f), (g), (h), or (j). |
|--|--|--|--|

(c) *Analytical method for determination of extractability.* The total extracted terephthaloyl moieties can be determined in the extracts, without evaporation of the solvent, by measuring the ultraviolet (UV) absorbance at 240 nanometers. The spectrophotometer (Varian 635-D, or equivalent) is zeroed with a sample of the solvent taken from the same lot used in the extraction tests. The concentration of the total terephthaloyl moieties in water, 3 percent acetic acid, and in 8 percent aqueous alcohol is calculated as bis(2-hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cyclic trimer (C₆H₄CO₂C₂H₄CO₂)₃, by reference to standards prepared in 95:5 percent (v/v) heptane: tetrahydrofuran.

[45 FR 39252, June 10, 1980, as amended at 47 FR 24288, June 4, 1982; 49 FR 25629, June 22, 1984; 51 FR 22929, June 24, 1986; 60 FR 57926, Nov. 24, 1995]

Appendix B
21 CFR 177.1630

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS

Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec. 177.1630 Polyethylene phthalate polymers.

Polyethylene phthalate polymers identified in this section may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food in accordance with the following prescribed conditions:

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in 177.1315(b) (3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in 177.1315(b) (3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

(c) (1) Polyethylene phthalate spunbonded nonwoven fabric consist of continuous filaments of ethylene terephthalate polymer and ethylene terephthalate-isophthalate copolymer to which may have been added optional adjuvant substances required in their preparation and finishing.

(2) The ethylene terephthalate-isophthalate copolymer component of the fabric shall not exceed 25 percent by weight. The filaments may be blended with other fibers regulated for the specific use and the spunbonded fabric may be further bonded by application of heat and/or pressure.

(3) The fabric shall be used only in accordance with paragraph (i) of this section.

(d) The quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonably required to accomplish the intended physical or technical effect or any limitations further provided. Any substance employed in the production of polyethylene phthalate plastics that is the subject of a regulation in parts 174, 175, 176, 177, 178 and 179 of this chapter conforms with any specification in such regulation.

(e) Substances employed in the production of polyethylene phthalate plastics include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in polyethylene phthalate plastics and used in accordance with such sanction or approval.

(3) Substances which by regulation in parts 174, 175, 176, 177, 178 and 179.45 of this chapter may be safely used as components of resinous or polymeric food-contact surfaces subject to the provisions of such regulation.

(4) Substances identified in this paragraph (e)(4) subject to the limitations prescribed:

List of Substances and Limitations

(i) Base sheet:

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid.

Ethylene terephthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid with ethylene glycol, modified with one or more of the following: Azelaic acid, dimethyl azelate, dimethyl sebacate, sebacic acid, pyromellitic dianhydride. The level of pyromellitic dianhydride shall not exceed 0.5 percent by weight of the finished copolymer which may be used under conditions of use E through H as described in table 2 of 176.170(c) of this chapter.

Ethylene terephthalate-isophthalate copolymers: Prepared by the condensation of dimethyl terephthalate or terephthalic acid and dimethyl isophthalate or isophthalic acid with ethylene glycol. The finished copolymers contain either:

(a) 77 to 83 weight percent or

(b) At least 97 weight percent of polymer units derived from ethylene terephthalate.

(ii) Base sheet and base polymer:

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in 177.1315(b) (3).

Ethylene terephthalate polymer: Prepared by the condensation of dimethyl terephthalate and ethylene glycol.

Ethylene terephthalate polymer: Prepared by the condensation of terephthalic acid and ethylene glycol.

(iii) Coatings:

Acrylic copolymers (CAS Reg. No. 30394-86-6): Prepared by reaction of ethyl acrylate (CAS Reg. No. 140-88-5), methyl methacrylate (CAS Reg. No. 80-62-6), and methacrylamide (CAS

Reg. No. 79-39-0) blended with melamine-formaldehyde resin (CAS Reg. No. 68002-20-0). For use in coatings for polyethylene phthalate films complying with paragraph (a) of this section.--

Ethylene azelate-terephthalate copolymer: The copolymer, dissolved in 1,1,2-trichloroethane and/or methylene chloride, may be used as a heat-activated sealant on polyethylene terephthalate film intended for sealing polyethylene terephthalate pouches that are used as containers of either nonalcoholic beverages or alcoholic beverages containing not more than 15 percent ethyl alcohol. The copolymer has a terephthalate/azelate molecular ratio of 1.25/1.00 and a relative viscosity of not less than 1.5 as determined by a method title "General Procedure of Determining the Relative Viscosity of Resin Polymers," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection, at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Total residual copolymer solvent (1,1,2-trichloroethane and/or methylene chloride) shall not exceed 0.13 milligram per square inch of film, and food contact of the film shall be limited to not more than 1 square inch per 250 grams of beverage.

2-Ethylhexyl acrylate copolymerized with one or more of the following:

Acrylonitrile.

Methacrylonitrile.

Methyl acrylate.

Methyl methacrylate.

Itaconic acid.

Vinylidene chloride copolymerized with one or more of the following:

Methacrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.

Acrylic acid and its methyl, ethyl, propyl, butyl, or octyl esters.

Acrylonitrile.

Methacrylonitrile.

Vinyl chloride.

Itaconic acid.

Styrene-maleic anhydride resin, partial 2-butoxyethyl ester, ammonium salt (CAS Reg. No. 68890-80-2). For use only as a coating for polyethylene phthalate films complying with paragraph (a) of this section, at levels not to exceed 0.025 gram per square meter (0.016 milligram per square inch) of the film, in contact with food of types VIII and IX in table 1 of 176.170(c) of this chapter, under use conditions E, F, and G in table 2 of 176.170(c)

of this chapter.

(iv) Emulsifiers:

Sodium dodecylbenzenesulfonate: As an adjuvant in the application of coatings to the base sheet or base polymer.

Sodium lauryl sulfate: As an adjuvant in the application of coatings to the base sheet or base polymer.

2-Sulfoethyl methacrylate, sodium salt (CAS Reg. No. 1804-87-1). For use only in copolymer coatings on polyethylene phthalate film under conditions of use E, F, and G described in table 2 of 175.300(d) of this chapter, and limited to use at a level not to exceed 2.0 percent by weight of the dry copolymer coating.

(v) Modifier:

1,4-Benzenedicarboxylic acid, dimethyl ester, polymer with 1,4-butanediol and [alpha]-hydro-*omega* -hydroxypoly(oxy-1,4-butanediyl) CAS Reg. No. 9078-71-1) meeting the following specifications:

Melting point: 200deg. to 215 deg. C as determined by ASTM method D2117-82, "Standard Test Method for Melting Point of Semicrystalline Polymers by the Hot Stage Microscopy Method," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Density: 1.15 to 1.20 as determined by ASTM method D1505-68 (Reapproved 1979), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

The modifier is used at a level not to exceed 5 percent by weight of polyethylene terephthalate film. The average thickness of the finished film shall not exceed 0.016 millimeter (0.0006 inch).

Hexanedioic acid polymer with 1,3-benzenedimethanamine (CAS Reg. No. 25718-70-1) meeting the specifications in 177.1500(b), item 10, when tested by the methods given in 177.1500(c). The modifier is used in polyethylene terephthalate at a level not to exceed 30 percent by weight of the polyethylene terephthalate.

Chloroform-soluble extractives shall not exceed 0.08 milligram/centimeter² (0.5 milligram/inch²) of food-contact surface of the modified polyethylene terephthalate article when exposed to the following solvents at temperatures and times indicated:

(a) Distilled water at 49 deg. C (120 deg. F) for 24 hours;

(b)n -Heptane at 49 deg. C (120 deg. F) for 24 hours;

(c) 8 percent ethyl alcohol at 49 deg. C (120 deg. F) for 24 hours.

For use in contact with all types of foods except (a) those containing more than 8 percent alcohol, or (b) those at temperatures over 49 deg. C (120 deg. F).

(f) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (f)(1) of this section are used as provided in paragraph (f)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 deg. F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to n -heptane at 150 deg. F for 2 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding food, excluding alcoholic beverages, at temperatures not to exceed 250 deg. F.

(g) Polyethylene phthalate plastics conforming with the specifications prescribed in paragraph (g)(1) of this section are used as provided in paragraph (g)(2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f)(1) of this section; and

(ii) The food contact surface when exposed to 50 percent ethyl alcohol at 120 deg. F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic beverages that do not exceed 50 percent alcohol by volume.

(h) Uncoated polyethylene phthalate plastics consisting of a base sheet or base polymer prepared as prescribed from substances identified in paragraphs (e)(4)(i) and (ii) of this section and conforming with the specifications prescribed in paragraph (h)(1) of this section are used as provided in paragraph (h)(2) of this section:

(1) *Specifications.* (i) The food contact surface, when exposed to distilled water at 250 deg. F for 2 hours yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent; and

(ii) The food contact surface, when exposed to n - heptane at 150 deg. F for 2 hours, yields chloroform-soluble extractives not to exceed 0.02 milligram/inch² of food contact surface exposed to the solvent.

(2) *Conditions of use.* The plastics are used to contain foods during oven baking or oven cooking at temperatures above 250 deg. F.

(i) Polyethylene phthalate fabric, identified in paragraph (c) of this section and conforming with the specifications prescribed in paragraph (i)(1) of this section, is used

only as provided in paragraph (i) (2) of this section.

(1) *Specifications.* Chloroform-soluble extractives shall not exceed 0.2 milligram/inch² of food-contact surface when exposed to the following solvents at temperatures and times indicated:

- (i) Distilled water at 212 deg. F for 2 hours.
- (ii) *n*- Heptane at 150 deg. F for 2 hours.
- (iii) 50 percent ethyl alcohol at 120 deg. F for 24 hours.

(2) *Conditions of use.* The plastics are intended for:

- (i) Dry food contact.
- (ii) Bulk food (excluding alcoholic beverages) repeated use applications, including filtration, at temperatures not exceeding 212 deg. F.
- (iii) Filtration of bulk alcoholic beverages, not exceeding 50 percent alcohol by volume, at temperatures not exceeding 120 deg. F.
- (j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in 177.1315(b) (3), conforming with the specifications prescribed in paragraph (j) (1) of this section, are used as provided in paragraph (j) (2) of this section.

(1) *Specifications.* (i) The food contact surface meets the specifications in paragraph (f) (1) of this section and

(ii) (a) *Containers with greater than 500 mL capacity.* The food-contact surface when exposed to 95 percent ethanol at 120 deg. F for 24 hours should not yield chloroform-soluble extractives in excess of 0.005 mg/in².

(b) *Containers with less than or equal to 500 mL capacity.* The food contact surface when exposed to 95 percent ethanol at 120 deg. F for 24 hours should not yield chloroform-soluble extractives in excess of 0.05 mg/in².

(2) *Conditions of use.* The plastics are used for packaging, transporting, or holding alcoholic foods that do not exceed 95 percent alcohol by volume.

[42 FR 14572, Mar. 15, 1977, as amended at 42 FR 18611, Apr. 8, 1977; 44 FR 40886, July 13, 1979; 45 FR 6541, Jan. 29, 1980; 47 FR 11844, Mar. 19, 1982; 47 FR 53346, Nov. 26, 1982; 48 FR 30361, July 1, 1983; 49 FR 10110, Mar. 19, 1984; 50 FR 31047, July 24, 1985; 51 FR 3772, Jan. 30, 1986; 52 FR 32917, Sept. 1, 1987; 54 FR 15750, Apr. 19, 1989; 54 FR 24898, June 12, 1989; 60 FR 57927, Nov. 24, 1995; 60 FR 61654, Dec. 1, 1995; 61 FR 46718, Sept. 5, 1996]