



## ***Regulatory Information Sheet***

### ***DRYSTAR 0827 Copolyester***

*DRYSTAR 0827 Copolyester* may lawfully be used as articles or components of articles intended for use in contact with food subject to provisions of U. S. Food and Drug Administration regulations 21 CFR 177.1315, 21 CFR 175.300 and 21 CFR 174.5.

*DRYSTAR 0827 Copolyester* complies with the compositional and inherent viscosity requirements of the FDA regulations at 21 CFR 177.1315 (b)(1). The specifications of 21 CFR 177.1315(b)(1) clear the following conditions of use for non-oriented copolymers: hot-fill temperatures not to exceed 180°F (82.2°C) for contact with foods including foods containing up to 25% aqueous alcohol by volume, excluding carbonated beverages and beer; storage temperatures not to exceed 120°F (48.9°C); and, no thermal treatment in container. Compliance tests performed by Eastman on non-oriented film made by Eastman from polymer samples representative of *DRYSTAR 0827 Copolyester* met the requirements of 21 CFR 177.1315(b)(1) for foods, including up to 15% ethanol by volume. From these results, we expect that other non-oriented articles made from our product, under good manufacturing practices and according to our recommendations, will meet the compliance requirements of the regulation including up to 15% ethanol.

*DRYSTAR 0827 Copolyester*, as supplied by Eastman Chemical Company, is permitted for use as a polyester resin pursuant to 21 CFR 175.300 (b) (3) (vii), as administered by the FDA. Such polyester resins may be used to formulate coatings on articles intended to contact food under the conditions described in 21 CFR 175.300. According to this regulation, the final coating in the form in which it is to contact food is subject to extraction testing characterizing the type of food and conditions of use. In addition, the general provisions for indirect food additives in 21 CFR 174.5 are applicable. Polyesters regulated at 21 CFR 175.300(b)(3)(vii) are also permitted for use in certain applications that are referenced in other food additive regulations. For example, such polymers are permitted by cross-reference for use as components of the food-contact surface of paper and paperboard (21 CFR 176.170(b)(1)), for use in closures with sealing gaskets in both closure-sealing gaskets and overall discs (21 CFR 177.1210(b)), and for use in adhesives (21 CFR 175.105), subject to the limitations of the respective regulations.

*DRYSTAR 0827 Copolyester* complies with the compositional requirements of the European Union Directive 90/128/EEC, and its subsequent amendments including 1999/91/EEC, for plastics used in food-contact applications. Compliance with the compositional requirements of the EU Directive cited above means compliance with national legislation for monomers used to make plastics. The monomers are all in Section A, List of Authorized Monomers and Other Starting Substances, of Directive 90/128/EEC. The final product must meet the global migration limit of 60 mg/kg of food or 10 mg/square decimeter of the plastic. There are also specific migration limits for terephthalic acid (7.5 mg/kg of food) and EG plus diethylene glycol (30 mg/kg of food). Migration testing conducted by our laboratories showed that amorphous films of *DRYSTAR 0827 Copolyester*, prepared by Eastman, met both global and specific migration requirements.

It is the responsibility of our customers to determine that their use of our product(s) is safe, lawful, and technically suitable in their intended applications. Because of possible changes in the law and in regulations, as well as possible changes in our products, we cannot guarantee that the status of this product will remain unchanged. We, therefore, recommend that customers continuing to use this product verify its status no less frequently than two years from the date of this publication. For additional information about this product, please contact your Eastman sales representative or the appropriate Eastman marketing subsidiary.

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