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Regulatory Information Sheet

ECOZEN

SK Chemicals co-polyester resin designated as ECOZEN complies with the compositional requirements and specifications of **Food Contact Notification No. 1075** as administered by the U.S. Food and Drug Administration (FDA). Based on migration and toxicological studies performed on articles fabricated from ECOZEN, we conclude that this resin may be safely used as articles or component of articles in contact with food under the conditions of use noted under Food Contact Notification No. 1075 of this regulation.

These conditions of use are in contact with ***all types of food under Conditions of Use B (Boiling water sterilized) through H (Frozen or refrigerated storage)*** as described in 21 CFR176.170(c) (for definition of food type and detail of condition of use, refer to Tables 1 and 2 on the website <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm109358.htm>); not for use in infant formula packaging, nursing bottles, and training cups^{*1}.

Since the discovery of the Bisphenol-A (BPA) problem with polycarbonate, the FDA is now taking extra precautions with all new FCN materials that are intended to be used in contact with infant formula. In order to satisfy these new concerns, the FDA is now routinely requesting additional detailed toxicity study information before releasing a new material for use in this application.

The limitation on use in FCN 1075 was not based on any finding by the FDA that ECOZEN polymer was unsafe for use in food contact uses involving infants. SK Chemicals is currently in the process of developing a submission to the FDA that will expand the clearances for the product to include various food contact uses for infants. We anticipate that the lifting of this restriction will be achieved during the first quarter of 2013.

In cases where the conditions or methods of use are beyond our control, we do not assume any responsibility, and we expressly disclaim any liability, for any use of this material. Thus, customers take responsibility for any use of this material and shall not disclaim any liabilities. Customers take responsibility to ascertain whether the use of our product is safe and lawful in their intended applications. We shall not guarantee that the status of this product will remain unchanged if there exists a possibility of a change in law or regulations that are beyond our control.

For additional information, please contact your SK Chemicals sales representative or SK Chemicals marketing subsidiary.

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^{*1}: Training cups are used by infants for their sole source of food as they transition from nursing bottles. Also, any training cup might be used for a sole source of food, for example, for certain physically challenged children.