



March 29, 2024

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RE: Prenotification Consultation (PNC) 003070

Dear Dr. Fiorotto:

This letter is in response to your submission, received on March 1, 2024, on behalf of Versalis S.p.A. (Versalis), requesting a no objection letter (NOL) confirming the capability of Versalis' secondary recycling process to produce recycled polystyrene (rPS) that is suitable for food contact applications. The rPS material is intended to be used at levels up to 100% recycled content for the production of packaging materials in contact with all food types under Conditions of Use (COU) C through G, as described in Tables 1 and 2 (*see Enclosure 1*). Your submission was logged as Prenotification Consultation (PNC) No. 003070.

We have reviewed the proposed recycling process and the provided supporting information, and we have determined that Versalis' control of the feedstock and recycling process as described in PNC 003070 are expected to produce rPS of a suitable purity for the intended use specified above, provided that the feedstock comes from food contact articles and complies with 21 CFR § 177.1640 *Polystyrene polymers*, and all other applicable authorizations.

The rPS material should comply with all applicable authorizations, including 21 CFR § 174.5 *General provisions applicable to indirect food additives*. For example, in accordance with section 402(a)(3) of the Federal Food, Drug and Cosmetic Act, use of the recycled material should not impart odor or taste to food rendering it unfit for human consumption.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Laura A. Dye  
Consumer Safety Officer  
Division of Food Contact Substances  
Office of Food Additive Safety  
Center for Food Safety  
and Applied Nutrition

Enclosure (1)

Enclosure 1

**Definitions of Food Types and Conditions of Use for Food Contact Substances**

*These tables were created for easy reference for notifications relating to a food contact substance.*

**Table 1--Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, to include oil-in-water emulsions of low- or high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, to include water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

**Table 2--Condition of use**

- A. High temperature heat-sterilized (*e.g.*, over 212 deg. F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150 deg. F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  1. Aqueous or oil-in-water emulsion of high- or low-fat.
  2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg. F.