SOLVAY

May 8, 2015

Re: FDA Status - Radel® R 5000 NT Polyphenylsulfone

The U.S. Food and Drug Administration has cleared Radel® R polyphenylsulfone resin for use in food contact applications. Radel® R polyphenylsulfone is the subject of Food Contact Notification (FCN) 000083, which became effective on September 23, 2000. Details concerning this clearance and specifications/limitations associated with it can be found in FDA's letter, which is attached. FCN 000083 has been added to the list of effective notifications for food contact substances available at FDA's Internet site at http://www.cfsan.fda.gov/~dms/opa-fcn.html.

Clearance of FCN 000083 permits the base resin Radel R polyphenylsulfone to be used in repeat use food contact applications with all food types, under FDA conditions of use B through H as described in Tables 1 and 2 of 21 CFR 176.170(c). However, the FDA status of individual Radel® R grades containing additives or pigments must be evaluated separately.

You have specifically requested information on the regulatory status of Radel® R-5000 NT. Radel® R-5000 NT, as manufactured, is compliant with FDA regulations based on clearances granted by FCN 000083. It is, however, the responsibility of the customer to determine that all conditions and specifications outlined in FCN 000083 are met, and that the products fabricated from these materials are acceptable to the FDA for use in their intended food-contact applications.

Any clearances granted by an FCN are proprietary to the submitter of the FCN, which is Solvay Specialty Polymers USA, L.L.C. in this case. These clearances may be extended to customers who use the FCN substance provided that documents linking the customer's product to the cleared FCN are maintained, and that the intended use is in accordance with the notification.

If you should require clarification or additional information, please contact your Account Manager directly.

Sincerely,

Migdalia Alvarado
Product Stewardship Coordinator

SOLVAY SPECIALTY POLYMERS USA, LLC
4500 McGinnis Ferry Road, Alpharetta, GA 30005-3914, USA - T: +770 772 8200 - F: +770 772 8213
www.solvay.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

September 22, 2000

Ralph A. Simmons
Keller and Heckman LLP
1001 G Street N.W.
Suite 500 West
Washington, DC 20001

Re: Food Contact Substance Notification FCN 000083

Dear Mr. Simmons:

This is in reference to your notification, submitted on behalf of BP Amoco Chemicals, Inc., for the food contact substance and use described as follows:

Food Contact Substance
Poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene) (CAS Reg. No. 25839-81-0.

Notifier
BP Amoco Chemicals, Inc.

Manufacturer/Supplier
BP Amoco Chemicals, Inc.

Intended Use
For repeated use in contact with food

Limitations/Specifications
1. The basic resins are produced by reacting 4,4'-biphenol and 4,4'-dichlorodiphenylsulfone according to the process described in your notification, so that the finished resin has a weight average molecular weight of at least 43,000.

2. The basic resins are to be used in contact with all food types under conditions of use B through H as described in Tables 1 and 2 of 21 CFR 176.170(c).

This is to inform you that as of September 23, 2000, FCN 000083 will become effective. It will be added to the list of effective notifications for food contact substances available on the agency's internet site at http://www.cfsan.fda.gov.

The agency has determined that allowing this notification to become effective will not have a significant impact on the quality of the human environment and therefore 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, will be publicly available after the effective date of the notification.

This effective notification is applicable only to Poly(oxy[1,1'-biphenyl]-4,4'-diyloxy-1,4-phenylenesulfonyl-1,4-phenylene (CAS Reg. No. 25839-81-0. manufactured by BP Amoco Chemicals, Inc. and is limited to the use of the food contact substance identified above. You should inform the agency of any modification in the FCS limitations/specifications given in the notification or of any alteration in the manufacturing process that would result in a change in the impurities in the FCS. Such changes may require submission of a new notification.

The existence of an effective notification for a food contact substance does not relieve use of the subject substance from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act or with 21 CFR §174.5 General provisions applicable to indirect food additives. For example, in accordance with section 402(a)(3) of the Act, use of the food contact substance should not impart odor or taste to food rendering it unfit for human consumption.

If new data or information become available to FDA demonstrating that the intended use of the food contact substance is no longer safe, the agency will inform you of its determination that the intended use of the food contact substance is no longer safe. In addition, if you become aware of data that raise questions about the safety of the intended use of the food contact substance, you should notify the agency immediately and be prepared to supply data necessary to resolve the questions.

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

Sincerely,

Hortense S. Macon

Hortense S. Macon
Division of Product Policy, HFS-205
Center for Food Safety
and Applied Nutrition

SOLVAY SPECIALTY POLYMERS USA, LLC
4500 McGinnis Ferry Road, Alpharetta, GA 30005-3914, USA | Tel: +1.770.772.8200 | Fax: +1.770.772.8213 | www.SolvaySpecialtyPolymers.com