Guidance for the Use of Polyurethanes in Food Contact Applications

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Purpose

Polyurethane manufacturers are often asked if their products have been approved for use in food contact applications by the United States Food and Drug Administration (FDA). Manufacturers supplying the polyurethane materials (hereinafter referred to as supplier) and manufacturers of the end-use article (hereinafter referred to as converter) have the independent responsibility to comply with applicable FDA regulations. This document is designed to address common questions related to the FDA's role in this area and to provide guidance as to where additional information may be obtained.

The FDA regulates the use of all resins whose intended use results, or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, unless the resin is generally recognized to be safe under the intended conditions of use.

Existing FDA regulations, effective Food Contact Substance Notifications (FCNs), and Threshold of Regulation exemption letters establish clearances for some food contact applications associated with polyurethane formulations. Your polyurethane supplier can provide you with a list of any clearances applicable to its products.

Guidance

1. What are typical food contact applications for polyurethane?

Polyurethanes are used in a variety of food contact applications including, but not limited to, conveyor systems, hoses and tubing, chutes and chute liners, hoppers, gaskets and seals, and adhesives for rigid and flexible food packaging.

2. Who regulates food contact applications?

The FDA established the Division of Food Contact Notification and Review within the Office of Food Additive Safety (OFAS), Center for Food Safety and Applied Nutrition (CFSAN), to help ensure components of food contact articles, including food packaging and processing equipment, are safe for their intended use.

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3. What types of FDA clearances apply to polyurethanes used in food contact applications?

Polyurethanes may be used in food contact applications if they adhere to all the general provisions applicable to indirect food contact additives (21 CFR 174.5). The components of the food contact article must be listed within 21 CFR 174 through 179 applicable to the type of substance and intended use, or be generally recognized as safe (GRAS), used in accordance with a prior sanction, be subject of an existing FCN, exempted by the Threshold of Regulation, or proven not to migrate. The food contact article, in its finished form, must meet test requirements or other specifications for use, as defined in the section for which clearance is required.

If it can be demonstrated through laboratory tests that no uncleared components migrate into food during the use of a specific formulation under its intended conditions of use, a "no migration" position can be taken in the form of legal opinion from a consulting law firm knowledgeable in FDA regulations.

A "no migration" position is based upon the fact that, if a substance is not reasonably expected to become a component of food, it is not a food additive and there is no need for explicit pre-market authorization from FDA to use the product.

4. Which FDA regulations may apply?

Regulations applicable to food, food additives, and food contact materials are described in Title 21 of the Code of Federal Regulations.

Many polyurethane resins are cleared for use as food contact materials through a number of regulations in 21 CFR, which include specific requirements for the composition of polyurethane resins as well as limitations on their conditions of use. Below is a list of other relevant sections of 21 CFR that may be applicable to both supplier and converters. Review the full text of the current regulation to determine the compliance status of any particular resin.

- Section 175.105 – *Adhesives* – identifies permitted substances for use as components of adhesives intended for use in packaging, transporting, or holding food
- Section 176.170 – *Components of Paper and Paperboard in Contact with Aqueous and Fatty Foods* – allows the use of a specific anionic polyurethane for use as a surface sizing agent in paper or paperboard
- Section 177.1210 – *Closures with Sealing Gaskets for Food Containers* – allows the use of certain polyurethane resins in closures with sealing gaskets for food containers
- Sections 177.1390 and 177.1395 – *Indirect Food Additives: Polymers* – permit the use of specific polyurethane resins as adhesives in laminate structures intended for use in food contact applications
- Section 177.1680 – *Polyurethane Resins* – specifies polyurethane resins which according to FDA may be safely used as the food contact surface of articles intended for use in contact with bulk quantities of dry food that do not have free surface fats or oils
- Section 177.2600 – *Rubber Articles Intended for Repeat Use* – specifies substances that may be used as components of rubber articles for repeated-use contact with food
- Section 178.2010 – *Antioxidants and/or Stabilizers for Polymers* – identifies antioxidants and/or stabilizers in polymers, that FDA concluded may be safely used in the manufacture of articles or components of articles
- Section 178.3740 – *Plasticizers in Polymeric Substances* – specifies plasticizers in polymeric substances, that according to FDA may be safely used in the manufacture of articles or components of articles

5. How do Threshold of Regulation exemptions and FCNs differ from food additive regulations?

Under FDA's "Threshold of Regulation" rule, FDA formally exempts food contact substances from the need for pre-market clearance as food additives.

Exemptions under the Threshold of Regulation are not listed in the food additive regulations. Instead, FDA publishes a list of materials it has exempted. This list is available on FDA's website at www.fda.gov, and may be relied upon by other suppliers and/or converters to market the identified substance.

Beginning in 2000, FCNs replaced food additive regulations as the primary means for obtaining FDA clearance for food contact materials. Although existing food additive regulations and Threshold of Regulation exemptions remain valid, FDA generally will no longer issue or amend food additive regulations.

Unlike food additive regulations, FCNs are proprietary to the company that manufacturers the FCN (the converter), and may only be relied on by the converter and its customers. Like Threshold of Regulation exemptions, effective FCNs are not listed in the food additive regulations. A listing of effective FCNs is available on FDA's website.

6. May a generic polyurethane product receive FDA clearance regardless of supplier?

Yes and no—it depends on the nature of the clearance.

All FDA regulations are generic. They do not pertain to polyurethane formulations of an individual converter, but rather list acceptable raw materials which may be used to formulate a polyurethane. Any polyurethane supplier that can provide a compound which meets the compositional requirements and specifications, if any, of an applicable regulation may certify such compliance. Extraction or other tests may have to be conducted on specific articles to meet the criteria of the applicable regulation.

Threshold of Regulation exemptions are also generic. They are issued to specific companies, but also may be relied on by other suppliers and/or converters.

FCNs are not generic. An FCN is proprietary to the supplier and/or converter, and may only be relied on by the manufacturer and its customers.

7. What is the responsibility of the material (resin) supplier as it relates to satisfying FDA requirements?

Material suppliers typically certify compliance by providing a letter to their converter describing the specific regulation in 21 CFR or any other regulatory basis for the food contact clearance of their products.

8. What does the certification letter tell the converter and/or end user?

A converter will seek a supplier's certification that the composition of the supplied material is listed in or complies with the specified regulation.

If a converter adds any additional components, it is their responsibility to ensure those components also comply with specified regulations for their intended use. It is also the converter's responsibility to ensure all the requirements of the article in its finished form are met which may include obligations related to extraction testing, ASTM testing, labeling, and barriers.

9. What if the applicable regulation, Threshold of Regulation exemption, or FCN sets limits on the clearance?

In addition to proof of compliance with respect to composition, certain applications may require extraction or other tests to meet specific end use applications. The type of extraction test required is dependent on the end use application and the requirements of the regulatory clearance. It is the responsibility of the converter/ the end-user who is introducing the food contact article into commerce to review the regulation and be aware of the test data required.

A clearance may also limit the applications in which the product may be used. Polyurethane suppliers will generally describe the uses for which their resins are cleared. It is the converter's responsibility to determine the permitted uses and comply with appropriate use limitations.

Legal Notice

For more information on material presented in this guidance document, please contact your supplier.