Polyurethane manufacturers are often asked if their products are United States Food and Drug Administration (FDA) “approved.” This brochure is designed to address this and other questions or issues relating to the FDA and to provide direction as to where further detail 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 Notifications (FCNs), and Threshold of Regulation exemption letters establish clearances for polyurethane formulations for some food-contact applications. Your polyurethane supplier can provide you with a list of any clearances applicable to its products.

1. What are typical food-contact applications for polyurethane?

Polyurethanes are often used in adhesives used in food packaging.

Polyurethanes may also be used as the surface layer in conveyor belts and in hose and tubing for conveying certain liquids.

2. Who regulates food-contact applications?

The Center for Food Safety and Applied Nutrition (CFSAN) is the regulating arm of the FDA, with respect to food-contact applications.

3. What types of FDA clearances are applicable to polyurethanes used in food-contact applications?

Polyurethanes may be used in food-contact applications if they are the subject of an applicable food additive regulation, Threshold of Regulation exemption, or effective Food Contact Notification (FCN).

If it can be demonstrated through laboratory tests (a specific protocol is required for each formulation in each application) that no uncleared components extract during the use of a specific formulation under its intended conditions of use, a “no migration” position can be taken.

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. This position requires a legal conclusion as to the status of the substance under the Federal Food, Drug, and Cosmetic Act, and requires reliable data to establish that there is no reasonable expectation of migration from the food-contact surface into food under the intended conditions of use.

4. Which FDA regulations apply?

Title 21 of the Code of Federal Regulations, Section 177.2600, specifies substances that may be used for repeated use rubber articles for all food types. Compliance with 21 CFR 177.2600 does not give a product clearance for single use applications, such as packaging materials used for meat, poultry, and dry foods, where the polyurethane is in continuous and direct contact with the food product until it is consumed. The standards for single service use are more restrictive than those for repeated use.
Section 177.1680 specifies polyurethane resins which 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 175.105 identifies permitted substances for use as components of adhesives intended for use in packaging, transporting, or holding food.

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 are not listed in the food additive regulations. Instead, FDA publishes a list of materials exempted by the Agency. This list is available on FDA’s website at www.fda.gov, and may be relied upon by other manufacturers to market the identified substance.

Beginning in 2000, Food Contact Notifications (FCNs) replaced food additive petitions and Threshold of Regulation requests 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 or Threshold of Regulation exemptions. Unlike food additive regulations, FCNs are proprietary to the company that files the FCN (the notifier), and may only be relied on by the notifier and its customers. Like Threshold 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 individual manufacturers, 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 demands 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 manufacturers.

FCNs are not generic. An FCN is proprietary to the notifier (the filing company), and may only be relied on by the notifier and its customers.

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

Resins intended for food contact must be the subject of an applicable food additive regulation, a Threshold of Regulation exemption, or an FCN. Material suppliers typically certify compliance by providing a letter to their converter.

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

A converter can rely on a supplier’s certification that a compound is the subject of an applicable FDA clearance (listed above). If a converter adds any additional components, it is the converter’s responsibility to assure that the additional components also comply with FDA requirements as to both chemical composition and specifications.

9. What if the applicable regulation, Threshold 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 applicable regulation, Threshold exemption, or FCN. It is the responsibility of the converter to 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.

10. What is the role of the United States Department of Agriculture?

The United States Department of Agriculture (USDA) inspects meat and poultry establishments. Operators of inspected establishments must maintain on file certifications from packaging material suppliers that such materials are in compliance with FDA regulations.

Processing equipment used in USDA-inspected facilities no longer requires specific approval by USDA. In the absence of this approval process, meat and poultry product manufacturers may request a letter of assurance from their polyurethane suppliers to ensure that only safe and suitable compounds are used.
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