

## **FDA approval for sealing food packaging in the United States**

► CASE ► Sealants

**Foam gaskets for food packaging, even if they are in contact with food only for a short time, must comply with the strict criteria of the FDA (U.S. Food and Drug Administration) for approval of food and medication in the U.S.**

Recently, the Sonderhoff USA Corporation from Elgin, Illinois was granted the coveted approval for a two-component flexible foam gasket of the product line Fermapor K31, specifically developed for food packaging, by a renowned and independent US certification and testing institute.

The certificate was issued in accordance with title 21 of the US Code of Federal Regulation, 21 CFR – 174.5 "General Provisions Applicable to Indirect Food Additives". According to the approval, the polyurethane foam gasket product Fermapor K31 with the type description "A-LA-384-12-I-2" in connection with the hardener Fermapor K31-B-23 may be used for sealing food packaging.

"We are very proud to have been certified within a relatively short period of one year, thus demonstrating that our new flexible foam gasket Fermapor K31 A-LA-384-12-I-2 meets the strict FDA standards for food packaging", says Holger Hulsken, President and CEO of Sonderhoff USA Corp. "Using the Sonderhoff mixing and dosing technology as a full or semi-automated system solution, this foam gasket makes it possible to acquire new customers from the food packaging sector."

To date, the American packaging industry has been using EPDM or die-cut gaskets, mainly inserted manually, for sealing food packaging. According to Hulsken, the cost disadvantage of this labor-intensive work and the resulting loss of material due to potential post-treatment and rejects were eliminated by the automation of the gasket application by means of the Sonderhoff mixing and dosing systems.

The FDA-certified polyurethane foam gasket Fermapor K31 is applied to the food packaging directly on site and hardens at room temperature. An additional advantage compared to the inserted EPDM gaskets is that the polyurethane foam gasket for food packaging provides a seamless seal – in contrast to gasket inserts, the coupling point is not visible and maintains its sealing function even at this position.

The automated process for sealing food packaging with polyurethane foam gaskets is considered an innovation in the USA which has previously not existed in the market. The FIPFG (formed in-place foam gasket) technology is still new in the American industry and requires time-consuming information campaigns in the production plants.

"The mixing and dosing systems by Sonderhoff Engineering give us a technological advantage which we are using to establish the FIP procedure for potting products and the FIPFG procedure for housing gaskets as the industry standard in the market", says Holger Hulsken. The customers' decision to invest in an automated system solution was often a long process in many cases, according to Hulsken. In the medium or long term, however, the customers realized that the use of mixing and dosing machines is significantly more economic and efficient.

Referring to information provided by Sonderhoff USA, more than 70 mixing and dosing systems have been commissioned in the USA, Mexico and Canada to date. "The certification of Fermapor K31 foam seals for food packaging opens up a promising market for Sonderhoff USA in the NAFTA countries – USA, Canada and Mexico," says Holger Hulsken. "However, FDA approval alone does not generate new business.

Other factors such as quality, a good price–performance ratio and comprehensive customer service also play a role that is at least as important." According to him, these are the strong points of Sonderhoff USA. The company celebrates its 10–year anniversary this year.

## Gallery

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**FERMAPOR K31 - The reaction process**

The reaction of FERMAPOR K31 sealing foams is initiated by mixing the A and B components. This results in a chemical reaction which proceeds steadily at room temperature. The applied mass foams equally in all dimensions to form the gasket.