Fraunhofer Institut
Verfahrenstechnik
und Verpackung

Certificate

Food regulatory evaluation of PTFE gaskets

Customer: Teadit International Prod. GmbH.
Rosenheimer Straße 10
6330 Kufstein, Austria

Order: PA/PA/4631/10 A

Sample: PTFE gasket sheet: Typ „TEADIT 24 SH"

The investigated PTFE material is used as gasket sheets in food processing machineries e.g. in pipes and containers. The inside of the gasket (maximum approx. 4 mm) are in direct food contact.

For Europe, the food regulatory compliance for the use in food processing machineries was evaluated according to the EU Plastics Directive 2002/72/EC (lastly amended by Regulation (EC) No. 975/2009), for USA according to 21 CFR §177.1550 „Perfluorocarbon resins". Furthermore possibly migrating compounds were assessed according to Art. 3 of the EU Framework (EC) No. 1935/2004 and § 170.39 „Threshold of Regulation".

Overall migration was performed according the European Standard EN 1186-13b and -14 using 95 % ethanol (6 h / 60 °C), isooctane (6 h / 60 °C) and modified polypropylene oxide (Tenax®) (2 h / 175 °C). The „Total extractives" and „Fluorine extractives" were determined in dest. water, 50 % ethanol, *n*-heptane and ethyl acetate (2 h / reflux) according to 21 CFR §177.1550 (e) (1) (test report PA/4632/10 part 1 dated 1.10.2010).

A screening on possibly migrating compounds in the dichloromethane and ethyl acetate extracts as well as in the 95% ethanol, isooctane and Tenax® migrates was carried out using gas chromatography with FID and MS detection. Furthermore typical fluorine-containing compounds were investigated in the ethyl acetate extracts and Tenax® migrates using high-resolution mass spectrometry. In addition the material was investigated for fluorine-containing compounds using purge and trap gas chromatography and ECED detection (test report PA/4631/10 part 2 dated 1.10.2010).

Migration of fluorinated compounds as well as other possibly migrating substances is below the US Threshold of Regulation (21 CFR 170.39) at a surface-to-volume ratio of maximum 0,3 dm²/kg food. The Threshold of Regulation (TOR) was set by FDA as a specific limit value for exposure via food which is considerably less than values which typically induce toxic effects. The TOR was defined after assessing the carcinogenic and non-carcinogenic effects of large number of representative substances. Compliance with the TOR hence means

that safety concerns are negligibly small. The TOR is 0,5 µg/kg in the daily diet. For evaluation migration results, the statistical fraction of the food that is expected to contact the substances is additionally considered (consumption factor CF). When no statistical data are available, a consumption factor of 0,05 is used. This corresponds to a maximum migration of 10 µg/kg (ppb). This restriction corresponds to the migration limit for non-approved substances through functional barriers according to Article 7a of the EU Plastics Directive 2002/72/EC (Directive 2007/29/EC). Non-detectability at a detection limit of 10 ppb is furthermore in agreement with the lowest specific migration limit for carcinogenic monomers.

The sample is in compliance with the overall migration limit in contact with all types of food up to 175 °C according to the EU Plastics Directive 2002/72/EC (lastly amended by Regulation (EC) No. 975/2009) as well as with the extraction limits according to 21 CFR § 177.1550.

The use of the above mentioned PTFE gasket sheets in food processing machineries up to 175 °C complies with the food safety requirements as defined in US 21 CFR 170.3 (i) and in Art. 3 of the EU Framework Regulation (EC) No. 1935/2004.

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Freising, 26.10.2010

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