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Certificate

Evaluation of the food regulatory compliance of the gasket „TF 1570"

Customer:	TEADIT Deutschland GmbH Schanzenstraße 35 51063 Köln
Order No:	PA/4411/14
Sample:	Gasket „TF 1570"

The gasket "TF 1570" consisting of polytetrafluoroethylene (PTFE) filled with glass shall be used as sealing material for food processing machines.

For Europe, the evaluation was performed according to the requirements of Regulation (EU) No 10/2011 and the EU-Framework Regulation No 1935/2004.

The overall migration test was performed according the European Standard EN 1186 with 3 % acetic acid, 95 % ethanol and isooctane (4 h / 100 °C resp. reflux temperature) and modified polypropylene oxide (Tenax®) (2 h / 200 °C) (test report PA/4411/14, part 1 dated 18.07.2014).

In the USA, PTFE materials must comply with the requirements of 21 CFR § 177.1550 „Perfluorocarbon resins". The extraction tests specified in 21 CFR §177.1550 (e) were carried out (test report PA/4290/14, dated 03.06.2014)

Tetrafluoro ethylene, the monomer for the production of PTFE, is authorized with a specific migration limit of 0.05 mg/kg food (simulant) according to Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 202/2014). Due to its high volatility the limit cannot be exceeded in food. By-products or other "non-intentionally added substances" (NIAS) are tested according of the general requirements on food contact materials according to Article 3 of the EU Framework Regulation (EC) No 1935/2004.

For the evaluation of potentially migrating components the dichloromethane extracts were investigated by screening analysis. Evaluation was done according to the general requirements on food contact materials according to Article 3 of the Framework Regulation (EC) No 1935/2004 and 21 CFR §170.39 "Threshold of Regulation".

Potential migration from the sealing material is given in mg/dm² using the total contact area between sealing material and sealed container according to Article 17 (3) of Regulation 10/2011. The evaluation was done according to the functional barrier principle of Article 13 of Regulation (EU) No 10/2011. According to this, migration must not exceed a limit of 10 µg/kg food resp. 1.67 dm² contact area (EU cube). Applying a surface/volume ratio of 6 dm²/kg (EU cube) this corresponds to an area related limit of 1.67 µg/dm².

In addition, methanol extracts were investigated specifically for perfluoro carboxylic acids (PFOA), perfluoro sulphonamides (PFOS) and fluoroterlomer

alcohols (FTOH) using LC-MS/GC-MS. Furthermore a screening analysis for high volatile fluorine containing substances was performed using purge and trap gas chromatography with EPED-detection (test report PA/4411/14 part 2, dated 18.07.2014).

Based on the screening results the investigated sample is in compliance with the safety requirements of Article 3 of Regulation (EC) No1935/2004 and 21 CFR §170.39 "Threshold of Regulation" in the intended application as a sealing material at temperatures up to 200 °C, provided that the ratio of sealing area and sealed container is at least 1:37.

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