

# Certificate

## Evaluation of the compliance of PTFE joint-sealant-tape "TEADIT 24 B" with food legislation

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

Order: PA/PA/4756/11

Sample: joint-sealant-tape: TEADIT 24 B with and without assembling aid  
(adhesive strip)

The PTFE material is used as a joint-sealant-tape in food processing machineries and pipes. The material is partially added with an adhesive strip on the non food contact side (amount of adhesive: 50 g/m<sup>2</sup>).

In such applications, the joint-sealant-tape is only in contact with food in a gap of maximum 1 mm. For an axis or pipe with a diameter of 50 mm the maximum possible food contact area is 0,02 dm<sup>2</sup>. The sealing material is exclusively used in food processing machineries, pipes, armatures, etc. in contact with huge amounts of food (in throughput or in charge of at least 1000 l/h). In Europe for sealings and stoppers migration deals with the total amount of food which comes into contact.

The adhesive is not in direct food contact. The composition of the adhesive was disclosed to Fraunhofer IVV on the basis of confidentiality. Thus the used resin and petroleum compounds are in compliance with the specifications as laid down in Regulation (EU) No. 10/2011.

For Europe, the food regulatory compliance of the material for the use in food processing machineries was evaluated according to Regulation (EU) No. 10/2011 and to Art. 3 of Framework (EC) No. 1935/2004. For USA the PTFE material and adhesive compounds are assessed according to 21 CFR §177.1550 „Perfluorocarbon resins“ resp. § 175.105 „Adhesive“ and to § 170.39 „Threshold of Regulation“.

The food regulatory compliance was evaluated via quantitative determination and estimation of possible migration of compounds from the joint-sealant-tape into foods.

The overall migration was determined into 95 % ethanol (6 h/60 °C), isooctane (6 h/60 °C), 3 % acetic acid (4 h/100 °C) and onto modified polyphenylene oxide (Tenax®) (2 h / 200 °C) according to the European Standard EN 1186. The total extractives and fluoride extractives were determined into dest. water, 50 % ethanol, *n*-heptane and ethyl acetate (2 h at reflux temperature) according to 21 CFR § 177.1550 (e)(1) (test report PA/4960/10 part 1 dated 2.5.2011).

For evaluation of further possibly present migratable compounds, dichloromethane extracts as well as the 95 % ethanol, isooctane and Tenax® migrates were investigated for semi volatile substances via gas chromatography with FID-

/MS-detection. In addition methanol extracts were investigated for fluorinated compounds via high resolution mass spectrometer and the material was screened for fluorinated compounds using purge & trap gas chromatography with EPED-detection (test report PA/4960/10 part 2 dated 14.10.2011)

Migration of fluorinated compounds as well as of other possibly migrating substances was below the US Threshold of Regulation (21 CFR 170.39). 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 is in compliance the migration of non-approved substances through functional barriers according to Regulation (EU) No. 10/2011. Non-detectability at a detection limit of 10 ppb corresponds also with the lowest specific migration limit for carcinogenic monomers.

The resin and petroleum compounds used in the adhesive are in compliance with specifications laid down in Regulation (EU) Nr. 10/2011 and are approved in plastic materials without specific restrictions according to the suppliers information. According to 21 CFR § 172.878 the petroleum compound is permitted for direct addition to food. The used resin compound is approved in adhesives according to § 175.105 without restrictions.

The used additive in the adhesive is not approved in Regulation (EU) No. 10/2011. In the USA this substance can be used as antioxidants / stabilizers for polymers up to 0,1 % according to 21 CFR § 178.2010. Assuming a theoretical total transfer (worst case) and assuming a maximum contact area of 0,02 dm<sup>2</sup> migration of this substance is far below the Threshold of Regulation (21 CFR § 170.39). In real applications, the adhesive is separated from the food by a PTFE joint-sealant-tape which acts as a functional barrier according to Art. 13 of Regulation (EU) No. 10/2011.

The sample is in compliance with the overall migration limit in contact with all types of food including short term heating up to 200 °C (for 2 h) according to Regulation (EU) No. 10/2011 as well as with the extraction limits according to 21 CFR § 177.1550.

There is no concern to use the investigated PTFE joint-sealant-tape in food processing machineries. The above mentioned joint-sealant-tape complies with food safety requirements as defined in US 21 CFR 170.3 (i) and in Art.3 of Framework Regulation (EC) No. 1935/2004.

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Freising, 2.11.2011



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