

Certificate

Food regulatory evaluation of PTFE tape

Customer: Chesterton International
Am Lenzenfleck 23
85737 Ismaning

Order: PA/4195/14

Sample: 800 GoldEnd Tape consisting of 100% PTFE

The investigated PTFE tape is used for the sealing of pipes in food processing machines. In this application food contact is only accidental and over a very small gap.

For Europe, the applicability for food processing machines is evaluated according to Regulation (EU) No 10/2011 and Art. 3 of the EU-Framework Regulation No 1935/2004 based on the potential migration of components from the material into the food and the maximum concentrations resulting therein.

The evaluation of NIAS was done according to the functional barrier principle according to Article 13 of the Regulation (EU) No 10/2011. According to this the migration limit of 10 µg/kg food must not be exceeded. Applying a surface-volume ratio of 6 dm²/kg (EU-cube) this correlates to an area related limit of 1.67 µg/dm².

The overall migration test was performed according the European Standard EN 1186 with 3 % acetic acid (4 h / 100 °C), modified polypropylene oxide (Tenax®) (2 h / 175 °C), 95 % ethanol (4 h / reflux temperature) and isooctane (4 h / reflux temperature) (test report PA/4195/14, part 1 dated 6.6.2014).

The overall migration limit is set at 10 mg/dm² food contact area according to Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 202/2014).

For the evaluation of potentially migrating components the dichloromethane extracts and 95 % ethanol migrates were investigated for semi volatile substances by gas chromatography with FID-/MS detection. In addition, fluorinated compounds were investigated specifically in methanol extracts using a high resolution mass spectrometer. Furthermore the material was analysed for fluorinated compounds by purge and trap gas chromatography with EPED-detection (test report PA/4195/14 part 2 dated 12.6.2014).

With an assumed sealing area of 1 dm² the limit of 10 µg/kg for non-evaluated substances is met at a total contact area between sealing material and sealed container of at least 6 dm².

Deduced from this, the ratio between the contact area of the seal and the contact area of the sealed contained must be at least 1:6.

In the methanol extracts of the sample perfluoro octanoic acid (PFOA) was detected. For this substance EFSA has defined a TDI of 1.5 µg/kg body weight/day. Under the conventional assumption of an average body weight of 60 kg and

a daily consumption of 1 kg food containing the mentioned substance in this concentration this correlates to a limit of 90 µg/kg food. With an assumed sealing area of 1 dm² this limit is met at any total contact area between sealing material and sealed container

The investigated sample is in compliance with the overall migration limit in contact with all types of foodstuff at long term storage at room temperature as well as heating up to 175 °C.

Therefore there are no objections to the use of the investigated PTFE tape in food processing machines. The tape mentioned above is in compliance with the food regulatory requirements of Article 3 of the Framework Regulation (EC) No 1935/2004.

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