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IVV

Certificate

Food regulatory evaluation of PTFE stuffing box packing TP619

Customer:	ProPack Dichtungen und Packungen AG 82054 Sauerlach
Date of certificate:	21.03.2017
Order:	PA/4832/16
Sample:	stuffing box packing TP619

The certificate is related to the investigation results of PA/4783/13 (sample 4) and PA/4832/16 (sample 2). Within the investigations of order PA/4783/13, among other analyses dichloro-methane extracts of the sample were investigated by screening test for potentially migrating volatile substances (Fraunhofer IVV test report PA/4783/13 part 3 dated 25.6. 2014). For the order PA/4832/16 the screening test was repeated (Fraunhofer IVV test report PA/4832/16 dated 21.11.2016; sample 2). In addition, the sample was again tested for perfluor-octanoic acid and perfluor-octane sulfonate (Fraunhofer IVV test report PA/4832/16 part 2 dated 21.03.2017; sample 2). The chromatograms obtained by screening test showed no significant differences so that the results from order PA/4783/13 can be transferred to the present sample.

The stuffing box packing TP619 is used in food processing machinery, pipes, etc. in particular for sealing rotating shafts, etc. in armatures, pumps and stirrer units. In such applications, the stuffing box is incorporated in a housing such that there is only contact via a narrow gap with the container or pipe containing the food. Only by incident, food can come into contact with the packing when it is pressed or sprayed into the packing housing through the gap. The width of this gap is approx. 1 mm. The systems, in particular in pumps, are generally designed such that any food on the shaft entering into the packing housing is transported away from the container and does not re-enter the container. Stuffing boxes are used in processing machineries with a throughput of more than 1000 l/h.

Stuffing box packings are manufactured from impregnated, braided and pressed yarns and can therefore not be considered as typical plastic materials according to Regulation (EU) No 10/2011. However those materials are neither regulated on national nor on European level specifically. All food contact materials must comply with the requirements of Article 3 of the EU Framework Regulation (EC) No. 1935/2004. According to Article 3 (1) of this Regulation materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health; bring about an unacceptable change in the composition of the food or a deterioration in the organoleptic characteristics thereof.

The overall migration and specific migration of detected components was evaluated based on article 17 (3) and (4) of Regulation (EU) No 10/2011 for caps,

gaskets, stoppers and similar sealing articles (last amendment by Regulation (EU) No 2016/1416).

In the USA, PTFE materials must comply with the requirements of 21 CFR § 177.1550 „Perfluorocarbon resins". However, our experiences have shown that the extraction tests as given for perfluorocarbon molded articles (21 CFR § 177.1550 (1)) and perfluorocarbon intended for use as coatings or components of coatings (21 CFR § 177.1550 (2)) are not applicable for stuffing box packings. Thus the evaluation of migratable compounds was assessed according to the "Threshold of Regulation" (TOR) (21 CFR § 170.39).

The overall migration test was performed according the European Standard EN 1186-3 and 13b with 3 % acetic acid (4 h / 100 °C) and modified polypropylene oxide (Tenax®) (2 h / 200 °C) (test report PA/4783/13, part 1 dated 31.1.2014).

For the evaluation of further potentially migratable components the dichloro-methane extracts and Tenax® migrates were investigated for semi volatile organic substances by gas chromatography with FID/MS detection. Furthermore the material was analysed for fluorinated compounds by purge and trap gas chromatography with fluorine selective detection. In addition, methanol extracts were investigated specifically for perfluoro carbonic acids (PFOA), perfluoro sufonamides (PFOA) and fluorotelomer alcohols (PFOH) using LC-MS and GC-MS (test report PA/4783/13 part 3 dated 25.6.2014 and test report PA/4832/16 part 2 dated 21.03.2017).

In the extracts of the sample as well as in the Tenax® migrates siloxane oligomers were found which can be assigned to the used silicon oil. According to the provided data sheet the silicon oil is in compliance with the specifications for polydimtehylsiloxane (MW > 6800 Da) (Ref. 76721) according to Regulation (EU) No 10/2011, the BfR recommendation XV "Silicones" and 21 CFR § 173.340 "Defoaming Agents" of FDA. Further migratable compounds, low volatile fluorinated components and PFOH were not detected at the respective detection limits.

In addition, traces of perfluoro octanoic acid (PFOA) were detected in the methanol extracts of the sample. The detected amounts do not indicate an intentional use as production aid. For this substance a TDI of 1.5 µg / kg body weight /day was set by EFSA. Taking into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm^2 surface area releasing the substance in the concentration of the migration limit this corresponds to a migration limit of 90 µg/kg food.

Based on these results the investigated stuffing box packing TP169 is in compliance with Article 3 of the Framework Regulation (EC) No 1935/2004 for the intended use as stuffing box packing (up to max. 200 °C) provided that the ratio between the contact area of the seal and the contact area of the sealed container is at least 1:55. In addition, the sample is in compliance with the safety requirements according to 21 CFR § 170.3 (i).

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Freising, 21.03.2017

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