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Certificate

Food regulatory evaluation of stuffing box P63/TP63

Customer:	ProPack Dichtungen und Packungen AG 82054 Sauerlach
Order No:	PA/4301/19
Date of certificate:	03.04.2019
Total pages of certificate:	3
Sample:	stuffing box packing P63/TP63

According to the customer, the material P63/TP63 is a mixture of meta-aramide yarn impregnated with PTFE and a PTFE yarn. According to an informal document of the pre-supplier, the used PTFE yarn consists of PTFE, talcum and the silicone oil "Silfar 1000". According to the customer, the packings P63 and TP63 only differ in their thickness. In addition, the packings are additionally impregnated with the silicone oil "Silfar 100".

The certificate is related to the investigation results of PA/4384/18 (sample 5, variant without silicone oil "Silfar 100" and sample 6, variant with silicone oil "Silfar100"). The stuffing box packings are used in food processing machines and only get into incidental food contact.

Stuffing box packings manufactured from impregnated, braided and pressed yarns cannot be considered as typical plastic materials according to Regulation (EU) No 10/2011 and are not regulated on national or EU level by specific measures. Such 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 2019/37).

Tetrafluoroethylene, the monomer for the production of PTFE, is approved according to Regulation (EU) No 10/2011 with a specific migration limit of 0.05 mg/kg of food (simulant). Due to its high volatility, the limit in food cannot be exceeded.

The determination of the migration of 1,3-phenylenediamine (monomer of meta-aramid) and the screening tests were carried out on the sample material without further impregnation with silicone oil. The results can be transferred to the sample with additional silicone oil impregnation. The evaluation of the migration of the silicone oil is performed based on the overall migration value.

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 / 175 °C) (test report PA/4384/18 part 1 dated 26.06.2018).

According to the European Plastics Regulation (EU) No 10/20111, 3-phenylenediamine is approved for the use as a monomer or starting substance for plastic materials in food contact. Migration into the food must not be detectable at a detection limit of 0.01 mg/kg (10 µg/kg). The migration of 1,3-phenylenediamine was determined in 3% acetic acid (2 h / 70 ° C) (test report PA/4384/18 part 4 dated 31.01.2019). Due to the instability of the analyte, the migration test could not be performed at higher temperatures.

According to the submitted data sheets from Wacker Chemie AG, the used silicone oils "Silfar 100" and "Silfar 1000" are in compliance with the specifications for polydimethylsiloxane (MW > 6800 Da) (Ref. 76721) according to Regulation (EU) No 10/2011 and the BfR Recommendation XV "Silicones". Polydimethylsiloxane (MW> 6800 Da) is authorized without a specific migration limit according to Regulation (EU) No 10/2011.

For the evaluation of further potentially migratable components, dichloromethane 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/4384/18 part 2 dated 03.04.2019).

In the extracts of the sample as well as in the Tenax® migrates, open-chained siloxanes were identified, which most probably originate from the used silicon oil "Silfar 1000".

Fluorotelomer alcohols were not detected in the material at the corresponding detection limit. By means of purge & trap gas chromatography, volatile fluorine-containing substances were detected in traces. 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 perfluoro octanoic acid a tolerably weekly intake value of 6 ng/kg body weight/ week was established by EFSA[1]. Under the conventional assumption of an average body weight of an adult person of 60 kg and a daily consumption of 1 kg of the contaminated food, this corresponds to a migration limit of 51 ng/kg food.

Based on these investigation results and the provided information on the composition, the investigated stuffing box packing P63/TP63 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 sealing and the total contact area of the sealed container is 1 dm² to at least 72.7 dm² or 1 dm² to at least 20 kg of food for the intended use in food processing machines.

[1] European Food Safety Authority; Scientific opinion; Risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food; EFSA Journal 2018; 16(12):5194

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