Certificate

Food regulatory evaluation of ViskoTeepak's Fibrous® cellulose casing

Customer:	ViskoTeepak Belgium NV 3920 Lommel Belgium
Order No:	PA-1346-21
Samples:	clear sausage casings, cellulose based
Total pages of certificate:	5
Date of certificate:	21.05.2024

Scope

ViskoTeepak's Fibrous® casings are cellulose based casings. The casings shall be used at different processing and storage conditions including e.g. stuffing, reddening, drying smoking, cooking and ripening. The intended applications include the packaging of cheese, meat and sausage products (e.g. dry sausages).

Compliance of the cellulose casings with the regulatory safety requirements of Article 3 of the European Framework Regulation (EC) No 1935/2004, as well as the US American food contact regulations was investigated for representative or worst case samples (with respect to components of the additives and their use levels). For this purpose, ViskoTeepak disclosed the formulation of the Fibrous® casings to Fraunhofer IVV. Additional information on the used additives in the casings was provided by the suppliers of the additives.

Food regulatory status of the used components

Based on ViskoTeepak's information on the formulation of the Fibrous® casings the food regulatory status of the used components and raw materials was evaluated according to the following European and US American legislative requirements for food contact materials:

- Plastics Regulation (EU) No 10/2011 (last amendment by Regulation (EU) No 2020/1245) - Strictly speaking cellulose based casings are not covered by the Plastics Regulation (EU) No 10/2011. However, this regulation may also be used for the assessment of other materials than plastics that are not yet regulated on EU level.
- BfR Recommendations on Food Contact Materials, e.g. XXXVI. "Paper and Board for Food Contact" (as of 01.02.2023)
- 21 Code of Federal Regulations, e.g. 21 CFR § 176.170 "Components of paper and paperboard in contact with aqueous and fatty foods" (revised as of 01.04.2020) and evaluation of GRAS (Generally recognized as safe) status

Sample material

The following materials were covered by the evaluation (see Table 1).

Table 1: Materials of the investigated samples.

ViskoTeepak material name	Sample no. of the representative sample investigated
Hanko Fibrous Standard Regular SVC	1
Lommel Fibrous Standard Super protect Regular DVC	2
Hanko Fibrous Standard EP-E Max	3
Hanko Fibrous Standard MC-E	4
Hanko Fibrous Standard EP-R Max	5
Hanko Fibrous Standard EP-G Max	6
Lommel Fibrous Standard EP-H	7
Lommel Fibrous Standard EP-Z	8
Lommel Fibrous XL XHP-H	10
Lommel Fibrous Standard MC HP-H	11
Lommel Fibrous Standard Regular - Shirred ZIP-IT 30/RTU 70 - Vegetable oil	13
Hanko Fibrous Standard EP-L - Shirred ZIP-IT 70/RTU 30 - MO - Netted	14
Hanko Fibrous Standard MC-L - Shirred RTU - Vegetable Oil - Netted	15
Lommel Fibrous Standard MC HP-H - DLO Sewed	16
Hanko Fibrous Standard MC-L - SBA Sewed	17
Lommel Fibrous Standard MC HP-H - Sewed + Ribbon	18
Lommel Fibrous XL Regular	21
Lommel Fibrous Standard Regular - Shirred MO	24

Hanko Fibrous Standard EP-H - Smoke-E Black Forest shirred MO	26
Lommel Fibrous Standard EP-H - Smoke-E (ESMO S1) shirred MO	27
Hanko Fibrous Standard EP-H - Smoke-E (Medium) shirred MO	28
Hanko Fibrous HW EP-L	70
Lommel Fibrous Standard MC HP-L	72
Lommel Fibrous Flex MC HP-H	73
Fibrous shirred in Poznan with Mineral oil	74
Fibrous shirred in Poznan with Vegetable oil	75
Fibrous sewed in Poznan	77
Fibrous tied in Poznan	78
Hanko Fibrous EP-L	80

This includes the following brand names and types:

Brand names: Fibrous ST, Fibrous XL, Fibrous FLX, Fibrous Glide, Fibrous Super Protect, Fibrous MAX.

Types: REG Regular, EP Easy Peel, MC MeatCling, RTU Ready To Use, ZIPIT/RTU, Sewed SBA, Sewed DLO, Sewed Ribbon, Smoke,Vegetable Oil, Mineral Oil MO, Shirred casing, Net casing, Tied casing.

The sample materials to which this certificate relates to were investigated within Fraunhofer IVV order PA-1418-22, PA-1241-22, PA-1829-22, part 1 and PA-1457-22. In detail, the following parameters were evaluated:

- Determination of the specific migration of confidential components from representative or worst-case Fibrous® sausage casings (Fraunhofer IVV test report PA-1829-22 part 1, dated 22.05.2023 and PA-1418-22, dated 29.03.2023)
- Overall migration analyses
  The cellulose casings Fibrous® sample no 1 to 8, 10, 11, 13 to 17, 21, 24, 26 to 28, 63, 74, 75, 77 and 78 were investigated for the overall migration into 10 % ethanol and 3 % acetic acid by total immersion at the contact conditions 2 h by reflux followed 10 days at 40 °C according to the European Standard EN 1186-3. In addition, the overall migration was also determined into the food simulant isooctane (as alternative food simulants for olive oil) by total immersion at the contact conditions 24 h

at 60 °C followed 10 d at 40 °C according to the European Standard EN 1186-15, respectively EN 1186-14 (Fraunhofer IVV test report PA-1241-22, dated 05.10.2022).
The time and temperature conditions applied for the migration tests were determined based on the production process cycles as delivered by ViskoTeepak and are considered as extractive or worst case, respectively, due to the cellulose nature of the casings.

- Investigation of the colored Fibrous® sausage casings for volatile, semivolatile and non-volatile components by non-target screening analysis (Fraunhofer IVV test report PA-1457-22, rev. version, dated 15.05.2024).
- Further substances have been evaluated prior to the analytical work by worst-case calculation, assuming a total transfer of the substances added.

Regulatory background and assessment

To date, there are no specific regulations established for cellulose or fibrous materials used in direct contact to food at the European level. In order to evaluate compliance with the inertness requirements of Article 3 of the Framework Regulation (EC) No 1935/2004, the overall migration from the Fibrous® cellulose casings into food simulants was determined following the rules for migration and compliance testing set out by Annex III and V of the European Plastics Regulation (EU) No 10/2011.

These overall migration values were evaluated based on the overall migration limit set out for plastic material used in contact with food according to the European Plastics Regulation (EU) No 10/2011.

The overall migration limit is 10 mg/dm² contact surface according to Art. 12 of the European Plastics Regulation (EU) No 10/2011 (last amendment by Regulation (EU) No 2020/1245).

The Plastics Regulation defines correction factors for different types of fatty food (Annex III, Table 2 of Regulation (EU) No 10/2011).

The investigated Fibrous® casings are in compliance with the overall migration limit for fatty foods for which a correction factor of at least 3 is set (e.g. meat, meat products, cheese, and fish) at all cooking applications up to 121 °C followed by long term storage at room temperature or below.

The overall migration into aqueous food simulants was exceeding the overall migration limit at the applied test conditions for some samples.

However, it should be noted that for papers, pulp or fibrous materials, overall migration limit used as reference value is often exceeded due to readily water-soluble natural ingredients. For the investigated cellulose casings, the customer provided additional information on the formulation of the cellulose-based casings to Fraunhofer IVV. As a common practice, this type of casings is treated by additives (plasticizers and/or humectants, such as glycerol, propylene glycols and vegetable and synthetic oils), which may significantly contribute to the overall migration values.

Taking into account the nature of the cellulose-based sample materials as well as the performed migration test for overall migration, the investigated Fibrous®

cellulose casings can be considered to be in compliance with the inertness requirements for food contact materials according to Article 3 of the European Framework Regulation (EC) No 1935/2004 for the intended application contact with meat products, sausage and cheese at the all cooking conditions up to 121 °C with subsequent long-term storage at room temperature and below.

Specific migration analysis were performed for confidential additives used in the casings (Fraunhofer IVV test report PA-1829-22 part 1, dated 22.05.2023 and PA-1418-22, dated 29.03.2023) that were disclosed to Fraunhofer IVV.

Based on the performed non-target screening analyses by Headspace GC-FID/MS on the casing itself and by GC-FID/MS and LC-MS on the dichloromethane and 95% ethanol extracts of the casing no indication for the presence of undesired or critical substances was given.

It should also be noted that not all of detected substances could be identified or that only a tentative identification proposal is available due to the low concentrations of these substances present in the extracts, which is a typical limitation of such non-target screening approaches (Fraunhofer IVV test report PA-1457-22, rev. version, dated 15.05.2024). For the screening analyses representative samples (with respect to the composition of the casings and their additives) were selected.

In summary, based on the disclosed formulations, on the manufacturer's and pre-suppliers' regulatory statements of compliance and on the worst-case calculations using customer dosage information, as well as on the performed screening and migration analyses, it can be concluded that the migration of components originating from the investigated, clear Fibrous® casings, as listed above, complies with the requirements of Article 3 of the EU Framework Regulation (EC) No 1935/2004 and of Article 49 of the Swiss Regulation 817.023.21 "Lebensmittel- und Gebrauchsgegenständeverordnung" (LVG; dated 01.12.2020) for the intended use as packaging of processed meat products (e.g. ham, salami, bacon, sausages) and natural cheeses.

Based on the information on the formulation of the above listed Fibrous® casings provided by ViskoTeepak all used raw materials are authorized for the use in food contact materials either as indirect food additives according to 21 CFR § 176.170 "Components of paper and paperboard in contact with aqueous and fatty foods" or as adjuvants and production aids according to 21 CFR § 178.3400 "Emulsifiers and/or surface-active agents" or are approved as 'generally recognized as safe' (GRAS status).

Fraunhofer Institute
Process Engineering
and Packaging

Freising, 21.05.2024

Diana Kemmer
Digital unterschrieben von Diana Kemmer
Datum: 2024.05.22 08:34:07 +02'00'

Dr. Diana Kemmer
(Head of Department Product Safety and Analytics)

Lisa Hetzel
Digital unterschrieben von Lisa Hetzel
Datum: 2024.05.21 09:30:36 +02'00'

Lisa Hetzel
(Scientist)