

Product Identifier: Polyester Monofilaments of Series
9** H-, P-, Q-, R-, S-, T-, U-, W- and Y-Type

Generated: 29 December 2022

Manufacturer: PERLON NEXTRUSION MONOFIL GmbH
Max-Fischer Str. 11
D-86399 Bobingen
Hahl Filaments GmbH
Rottenackerstraße 2-18
D - 89597 Munderkingen
www.perlon.com

Issuing department: Product safety – Dipl.-Ing. Andreas Fischer
☎: +49 (0) 8234 99-1377
✉: andreas.fischer@perlon.com

Food Contact Declaration

Note

This declaration is valid only for the products above. Since Perlon Nextrusion Monofil GmbH has no influence on further processing and conditions of use of our product, this declaration cannot be considered as an enclosed declaration of compliance for food contact articles. In fact, this document shall enable the customer to compile such a declaration of compliance, considering all relevant regulations and the responsibility delegated by this document.

Within Germany and the EU:

Materials and articles intended to come into contact with food are regulated by several European regulations. Regulation (EC) No 1935/2004 sets the frame. During the manufacturing process of our filaments we adhere to the relevant rules according to **Regulation (EC) No 2023/2006 „Good Manufacturing Practice“**.

Regulation (EC) No 10/2011 and their amendmend EU 2020/1245

Monomers, base materials and additives contained in our filaments fulfil the criteria of the regulation mentioned above, most recently amended by Regulation (EU) No 2020/1245. We would like to point out that the manufacturer of the final product who introduces the article into circulation is responsible to ensure that the global migration limit and all specific migration limits are observed as well as the demands stated in annex II of this regulation.

The following substances are subject to restrictions:
(name, FCM-No., SML) refer to: Annex I, table 1

➤ Antimony trioxide	398	0.04 mg/kg (expressed as antimony)
➤ Diethyleneglycol	263	30 mg/kg
➤ Ethyleneglycol	227	30 mg/kg
➤ Dimethyl-terephthalic acid	288	
➤ Terephthalic acid	785	7.5 mg/kg
➤ Titanium dioxide	610	
➤ Butylenterephthalate	885	

Product Identifier: Polyester Monofilaments of Series
9** H-, P-, Q-, R-, S-, T-, U-, W- and Y-Type

Generated: 29 December 2022

Coloured monofilaments of the above mentioned types may contain additionally:
(name, FCM-No., SML)

➤ Silicates	84	natural (with the exception of asbestos)
➤ Stearic acid, salt of cobalt	106	
➤ 1,1,1-trimethylolpropane	141	SML = 6,0 mg/kg
➤ Tetrahydrofuran	246	SML = 0,6 mg/kg
➤ 1,4-butanediol	254	SML = 5,0 mg/kg
➤ Isophthalic acid	291	SML = 5,0 mg/kg
➤ Terephthalic acid	785	SML = 7.5 mg/kg
➤ Polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols	799	

All colourants used comply with the requirements of the European Resolution AP (89) 1 with respect to maximum concentration of heavy metals, primary aromatic amines, sulfonated aromatic amines and polychlorinated biphenyles.

The restrictions of regulation 10/2011 and its amendments have to be followed. In the case of coloured monofilaments the migration of substances usually will go below the limits due to the low addition of the colour masterbatch (< 1%)

Restrictions according to Annex II of the regulation (EC) No 10/2011 amended by EU 2020/1245:

➤ Aluminium:	SML = 1 mg/kg
➤ Antimony:	SML = 0.04 mg/kg
➤ Arsenic:	SML = ND (Not Detectable)
➤ Barium:	SML = 1 mg/kg
➤ Cadmium:	SML = ND (Not Detectable)
➤ Chromium:	SML = ND (Not Detectable)
➤ Cobalt:	SML = 0.05 mg/kg
➤ Copper:	SML = 5 mg/kg
➤ Europium:	SML = 0.05 mg/kg
➤ Gadolinium:	SML = 0.05 mg/kg
➤ Iron:	SML = 48 mg/kg
➤ Lanthanum:	SML = 0.05 mg/kg
➤ Lead:	SML = ND (Not Detectable)
➤ Lithium:	SML = 0.6 mg/kg
➤ Manganese:	SML = 0.6 mg/kg SML
➤ Mercury:	SML = ND (Not Detectable)
➤ Nickel:	SML = 0.02 mg/kg
➤ Terbium:	SML = 0.05 mg/kg
➤ Zinc:	SML = 5 mg/kg
➤ Primary Aromatic Amines	SML < 0.01 mg /kg

Dual Use Additives (name, FCM-No., EU-ingredient list – No.)

➤ Titanium dioxide	610	E171
➤ montanic acids and/or their esters	67	E 912

Product Identifier: Polyester Monofilaments of Series
9** H-, P-, Q-, R-, S-, T-, U-, W- and Y-Type

Generated: 29 December 2022

IAS (Intentionally Added Substances):

➤ none

NIAS (Non-Intentionally Added Substances):

The monomers and additives used to produce this product are listed in the Union List of Authorised Substances of Regulation 10/2011/EC and all amendments up to and including Commission Regulation (EU) 2020/1245 of 2 September 2020. Specific Migration Limits (SMLs) for certain substances of this material are imposed by the European Union and have been proven to meet the requirements under the specified conditions of use via testing. The Commission Regulation (EU) No 10/2011 includes a limit of 10 mg/dm² on the overall migration from finished plastic articles into food. Overall migration testing was performed, and the products listed meet the required limit under specified conditions of use. Compliance testing was completed based on the conditions set out in Regulation (EU) No 10/2011 and the conventional EU food contact ratio of 1kg of food in contact with 6 dm² of surface area.

	Food simulant	Contact conditions	Migration criteria
Overall migration	10% Ethano/1000ml	10 days at 40°C	conform
Overall migration	3% Essigsäure/1000ml	10 days at 40°C	conform
Overall migration	Olivenöl (D2)	10 days at 40°C	conform
Specific migration	95% Ethanol	10 days at 40°C	conform
Specific migration	3% Essigsäure	10 days at 40°C	conform

OML and SML compliance of the final application is the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food. The user should verify applicable requirements and compliance for their own application.

Within the USA: FDA (Food and Drug Administration):

The polyester monofilamentes of the 9**-series cited above contain polyethylene terephthalate as the basic polymer, listed in title 21 Code of Federal Regulations §177.1630 (polyethylene phthalate polymers). These monofilaments may be used in direct contact with food. Restrictions and indications have to be observed.

In the case of coloured polyester monofilaments of the 9**-series only those with the labelling „FIT“ are admitted for direct food contact. These color-masterbatches comprise only substances

- with colorants listed in title 21 CFR §178.3297 (Colorants for Polymers),
- with constituents exempt from 21 CFR §170.39,
- that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact

Product Identifier: Polyester Monofilaments of Series
9** H-, P-, Q-, R-, S-, T-, U-, W- and Y-Type

Generated: 29 December 2022

applications in full compliance with the Food, Drug and Cosmetic Act and all applicable food additive regulations,

- that are GRAS (Generally Recognized as Safe) for use in contact with food,
- that are „Prior Sanctioned“ for use in this application,
- that are the subject of applicable Food Contact Substance Notifications.

The composition of the used polymer carrier complies with the requirements of „Federal Food, Drug and Cosmetic Act“ and all applicable „Food Additive Regulations“ including 21 CFR §177.1660 (poly tetramethylene terephthalate). Restrictions and indications have to be observed.

Scope of application: Synthetic Filaments for repeated use in contact with food

It is the responsibility of the manufacturer of the final product to ensure migration fastness under the conditions of use.

Spinfinish on the Monofilaments:

A spinfinish is applied as a processing aid to the surface of the monofilaments, influencing the friction behaviour and the antistatic. The spinfinish has to be washed off before the monofilaments get into contact with food.

Sincerely,
ppa. Dipl.-Ing. Andreas Fischer
CTO PERLON®-group

This information was compiled electronically and is therefore valid without signature

Note

This information and our technical advice – whether verbal, in writing or by way of trials – are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved. Our advice does not release you from the obligation to check its validity and to test our products as to their suitability for the intended processes and use. The application use and processing of our products and the products manufactured by you based on our technical advice are beyond our control and, therefore, entirely your own responsibility. Our products are sold in accordance with our General Conditions of Sale