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3M™ Dyneon™ PTFE Compound TF 4103

Food Contact Regulation: EU Directive, BGVO (BfR, LFGB) and FDA Status

The monomers used for the production of the above-mentioned product supplied by Dyneon™ are listed in the regulation (EU) No 10/2011^{1/2} about materials and articles made of plastics and intended to come into contact with foodstuffs (in compliance with BGVO³).

Restrictions exist for

TFE SML = 0.05 mg/kg

The above mentioned restrictions and the global migration⁴ have to be checked on the finished article by the manufacturer or seller.

The basic monomers of the above-mentioned product comply in respect of species, quantity and purity with the German Recommendations LI

¹ incl. amendment Regulations (EU) No 321/2011, 1282/2011, 1183/2012, 202/2014 and 174/2015

² in its valid version

³ in its valid version

⁴ global migration limit: 10 mg/dm² or 60 mg/kg food

„Temperaturbeständige Beschichtungssysteme..." and LII „Füllstoffe für Bedarfsgegenstände aus Kunststoffen“ as issued by the „Bundesinstitut für Risikobewertung“ (BfR).

Furthermore the basic monomers of the above-mentioned product comply with 21 CFR 177.1550 and may be used as articles or components of articles intended to contact food.

It is the customer's responsibility to test finished articles to ensure compliance with the extractives limitations of the applicable regulations (see FDA regulations for any limitations or conditions of use).

The glass fibre filler used for the production of the above-mentioned compound supplied by Dyneon is listed in regulation (EU) No 10/2011^{5/6} about materials and articles made of plastics and intended to come into contact with foodstuffs or toys.

The glass fibre filler of the above-mentioned product comply with the German Recommendation LII "Füllstoffe für Bedarfsgegenstände aus Kunststoffen" as issued by the „Bundesinstitut für Risikobewertung“ (BfR).

Above-mentioned glass fibre compound comply with FDA 21 CFR 177.1550. The glass fibre filler is Generally Recognized as Safe (GRAS) and may be compounded with perfluorocarbon resins per FDA 21 CFR 177.1550 (b).

There are no objections against the use of the above mentioned material for articles intended to come into contact with foodstuffs or toys as referred to in the German "Lebensmittel- und Futtermittelgesetzbuch (LFGB)⁷ § 2 Section (6), Nr. 1 (in compliance with EU 1935/2004) and Nr. 5" provided the finished article is fabricated by good manufacturing practice and is generally suitable for the intended use.

⁵ incl. amendment Regulations (EU) No 321/2011, 1282/2011, 1183/2012 202/2014 and 174/2015

⁶ in its valid version

⁷ in its valid version

It is the responsibility of the customer to determine whether its specific formulation and intended use comply with applicable laws and is suitable for its intended applications.

Kind regards



Dr. Hans-Peter Mühlbauer
Dyneon GmbH

Product Stewardship – Compliance Management
Fluoroplastics