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3M™ Dyneon™ TFM™ Modified PTFE Paste TFM 2001Z

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 BGVO[3]).

Restrictions exist for

TFE	SML = 0.05 mg/kg
PPVE	SML = 0.05 mg/kg

The above-mentioned restrictions and the global migration[4] have to be checked on the finished article by the manufacturer or seller.

[1] incl. amendment Regulations (EU) No 321/2011, 1282/2011, 1183/2012, 202/2014, 174/2015, 1416/2016, 752/2017, 79/2018, 213/2018 and 831/2018
[2] in its valid version
[3] in its valid version
[4] global migration limit: 10 mg/dm² or 60 mg/kg food

Dyneon has applied for and obtained positive food contact listing of its emulsifier system used in the manufacturing of the above mentioned product according regulation (EU) No 10/2011[5,6] about materials and articles made of plastics and intended to come into contact with foodstuff (in compliance with BGVO).

The corresponding required processing conditions encompass

- sintering of the product at temperatures higher than 280 °C for at least 10 minutes.
- processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles

In case your processing would not meet that requirement, we can on a case by case basis assess whether you reach equivalent safety.

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.

The above-mentioned product supplied by Dyneon™ complies also with FDA 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 applicable regulations (see FDA regulations for any limitations or conditions of use).

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.

[5] incl. amendment Regulations (EU) No 321/2011, 1282/2011, 1183/2012, 202/2014, 174/2015, 1416/2016, 752/2017, 79/2018, 213/2018 and 831/2018
[6] in its valid version
[7] in its valid version

Kind regards

i.V. Mühlbauer

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Product Stewardship – Compliance Management
Fluoroplastics