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3M™ Dyneon™ TFM™ Modified PTFE Granules TFM 1600
3M™ Dyneon™ PTFE Granules TF 1620

USP Class VI –121°C / 70 °C - Compliance Status

Dear valued customer,

1. Representative samples manufactured with the following product have been certified in accordance with USP protocol (USP Class VI - 121°C) by North American Science Associates (NAMSA) – Ohio / USA:

- 3M™ Dyneon™ TFM™ Modified PTFE Granules TFM 1600 (28.05.2010)

Three USP Biological Reactivity Test, *In Vivo* have been carried out to satisfy USP Plastic Class VI – 121 °C requirements with the corresponding ISO standards indicated in brackets:

- USP Systemic Toxicity Study in the Mouse
- USP Intracutaneous Toxicity Study in the Rabbit
- USP Muscle Implantation Study in the Rabbit

The test articles met the requirements of USP Plastic Class VI for use up to 121°C.

2. Representative samples manufactured with the following product have been certified in accordance with USP protocol (USP Class VI – 70 °C) by Toxikon Corporation:

- 3M™ Dyneon™ PTFE Granules TF 1620 (27.10.2004)

Three USP Biological Reactivity Test, *In Vivo* have been carried out to satisfy USP Plastic Class VI – 70 °C requirements with the corresponding ISO standards indicated in brackets:

- USP Systemic Injection Test in the Mouse
- USP Intracutaneous Test in the Rabbit
- USP Implantation Test in the Rabbit

The test articles met the requirements of USP Plastic Class VI for use up to 70°C. Based on our experiences with other fluoropolymers we expect same results also at the extractions temperature of 121 °C.

All testing in accordance with USP protocol has to be carried out on finished products as „article tests“ and is the responsibility of the manufacturer or seller.

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.

Please feel free to contact us for any further question.

Kind regards



Dr. Hans-Peter Mühlbauer
Dyneon GmbH

Product Stewardship – Compliance Management
Fluoroplastics