



Granular Modified PTFE

CAS No: 9002-84-0

STATEMENT OF COMPLIANCE

EC 10/2011 and hence article 3 of European regulation no. 1935/2004 (Amendment to EU regulation no. 2002/72/EC)

Plastic materials and articles intended to come into contact with foodstuffs. Certified by TUV India Pvt. Ltd.

Tests covered:

- a) Overall Migration
- b) Specific Migration of Heavy Metals
- c) Specific Migration of Primary Aromatic Amine
- d) Specific Migration of Phthalates

Food & Drug Administration (FDA) directive 21 CFR 177.1550

Articles or components of articles intended to come into contact with foodstuffs. Certified by SGS India Pvt. Ltd.

Tests covered:

a) Determination of amount of Extractives

German Food, Articles of daily use and Feed code of September 1, 2005 (LFGB), Section 30. BFR recommendation

Tests covered:

Non-stick coating-Specific migration of Perfluorooctanoic Acid (PFOA).

REACH-Substances of Very High Concern (EC) No. 1907/2006

Certified by TUV India Private Limited.

INOFLON® Granular modified PTFE complies with the SVHC candidate list updated on January 17, 2023.

RoHS Directive 2011/65/EU

Restriction of Hazardous Substance in Electrical & Electronic Equipment. Certified by SGS India Pvt. Ltd

Tests covered:

- a) Determination of Cadmium content
- b) Determination of Lead content
- c) Determination of Mercury content
- d) Determination of Hexavalent Chromium content
- e) Determination of PBBS (Polybrominated biphenyls) and PBDES (Polybrominated diphenylethers)

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United States Pharmacopoeia (USP) Class VI

Certified by Toxikon, USA. Tests Condition: 121°C.

Tests Covered:

- a) Systemic test to evaluate the impairment or activation of a system-rather than the impairment of individual cells or organs
- b) Intracutaneous test to evaluate the potential of test materials-or their extracts-to cause irritation on the exposed part of the body
- c) Implant tests to evaluate the pathological effects on living tissue, at both the gross and microscopic level

3-A Sanitary Standard for Multiple-Use Plastic Materials

Certified by Argen Polymer LLC, USA.

Tests Covered:

- a) Cleanability Response
- b) Product Treatment
- c) Cleanability Comparison

End of Life Vehicles

Directive 2000/53/EC, 2002/525/EC, 2005/673/EC, 2005/63/EC, 2005/437/EC, 2005/438/EC. Certified by TUV SUD South Asia, India.

Tests Covered:

- a) Determination of Cadmium content
- b) Determination of Lead content
- c) Determination of Hexavalent Chromium
- d) Determination of Mercury

Underwriters Laboratories (UL)-File no. E321158

Certified by UL, Taiwan.

Complies with all the requirements of following standard:

The Standard for Test for Flammability of Plastic Material for parts in Devices and Applications, UL 94.

No Animal Origin

INOFLON® Granular Modified PTFE does not contain, nor manufactured with, any animal products, animal fats, material of animal origin or grain alcohols.

Disclaimer: The above information is furnished as per tests carried out on representative samples made from GFL base polymer. GFL shall bear no liability as a result of any loss or damage caused due to use of any information provided in this document. If requested, customers are liable to provide the compliance certificates for the components manufactured from INOFLON® PTFE resins.

Note Warning: Do not use any of the INOFLON® PTFE resins in medical devices that are designed for permanent implantation in the human body. For other medical uses, prior permission of GFL may be sought.

SALES AND TECHNICAL SUPPORT

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