

Granular Virgin 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 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 Per fluorooctanoic Acid (PFOA).

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

Certified by SGS India Pvt. Ltd.
INOFLON® Granular Virgin 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 TUV 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

BAM

Testing of material for uses sealing materials in valves and fittings or other components for oxygen service at operating temperatures up to 200°C and for liquid oxygen service.

Certified by BAM Federal Institute for Materials Research and Testing, Berlin.

* Applicable for INOFLON® 640 and INOFLON® 510 only.

W270

Enhancement of microbial growth on materials to come into contact with drinking water.

Certified by Hygiene-Institut des Ruhrgebiets, Germany.

Test carried out in accordance with recommendations contained in DVGW technical standard.

Underwriters Laboratories (UL)-File no. E321158

Certified by UL, Taiwan.

Complies with all the requirements of following standard:

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

Granular Virgin PTFE

No Animal Origin

INOFLON® Granular Virgin 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 polymers. 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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