

STATEMENT OF COMPLIANCE

Date of Revision: 16 January, 2020

INOFLON® Granular Modified PTFE

CAS No: 9002-84-0

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 SGS 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

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

Test covered

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

Food & Drugs Administration (FDA) directive 21 CFR 177.1550

Articles or components of articles intended to come into contact with foodstuffs
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Test covered

- a) Determination of amount of Extractives

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

No substance included in candidate list updated on Jan' 16, 2020 is used in polymerisation or in any step of the INOFLON® Granular Modified PTFE production.

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)

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
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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
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United States Pharmacopoeia (USP) ClassVI

Certified by Bee Pharmo Labs Pvt. Ltd, India

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
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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, UL94

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 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.



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