

STATEMENT OF COMPLIANCE

Date of Revision: 25 January, 2021

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

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 19 January, 2021 is used in polymerisation or in any step of the INOFLON® Granular Virgin PTFE production.

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

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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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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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, INOFLON® 230, 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

No Animal Origin

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

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
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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 INOFロン® PTFE resins.

Note Warning: Do not use any of the INOFロン® 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.



Gujarat Fluorochemicals Limited

Corporate & Marketing office: INOX Towers, 17, Sector 16-A, Noida–201301, INDIA.
Phone: +91 120 6149 600, Fax: +91 120 6149 610, Email: inoflon@gfl.co.in
Factory & Works: 12/A, GIDC Dahej Industrial Area, Tehsil: Vagra, District: Bharuch,
392130, Gujarat, India. Website: www.inoflon.com