# **STATEMENT OF COMPLIANCE**

Date of Revision: 20 August, 2020

# INOF-LON° FEP

CAS No: 25067-11-2

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# 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 Private Limited.

#### **Tests covered**

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

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- d) Specific Migration of Phthalates
- e) Specific Migration of monomer

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

#### **Test covered**

Overall Migration 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 TUV India Private Limited.

#### **Test covered**

a) Determination of amount of Extractives

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

Certified by TUV India Private Limited. INOFLON<sup>®</sup> FEP complies with the SVHC candidate list updated on January 16, 2020.

## **RoHS Directive 2011/65/EU**

Restriction of Hazardous Substance in Electrical & Electronic Equipment Certified by TUV India Private Limited.

#### 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)

# 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

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c) Implant tests to evaluate the pathological effects on living tissue, at both the gross and microscopic level

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## Perfluorooctane Sulfonates (PFOS) and Perfluorooctanoic Acid (PFOA) compliance

Perfluorooctanoic acid (PFOA) itself and its salts (PFOS) are not used in polymerization or at any step of INOFLON<sup>®</sup> FEP production.

## No Animal Origin

INOFLON<sup>®</sup> FEP does not contain, nor manufactured with, any animal products, animal fats and material of animal origin or grain alcohols.

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## Underwriters Laboratories (UL)-File no. E321158

Certified by UL India Pvt. Ltd., India INOFLON<sup>®</sup> FEP complies with UL 94. Certified grades: FEP 4007, FEP 4021

**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® FEP resins.

**Note Warning:** Do not use any of the INOFLON<sup>®</sup> FEP 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

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