

# STATEMENT OF COMPLIANCE

Date of Revision: 25 January, 2021

## INOFLON® Fine Powder Modified PTFE

CAS No: 9002-84-0

### **Food & Drugs Administration (FDA) directive 21 CFR 177.1550**

Certified by TÜV India Private Limited.

Articles or components of articles intended to come into contact with foodstuff.

#### **Test covered:**

Determination of total extractives.

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

Certified by TÜV SÜD South Asia Private Limited.

INOFLON® Fine Powder Modified PTFE complies with the SVHC candidate list updated on 19 January, 2021.

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

Certified by TÜV SÜD South Asia Private Limited.

Restriction of Hazardous Substance in Electrical & Electronic Equipment.

#### **Tests covered:**

- Determination of Cadmium content
- Determination of Lead content
- Determination of Mercury content
- Determination of Hexavalent Chromium content
- Determination of PBBs (Polybrominated biphenyls) and PBDEs (Polybrominated diphenyl ethers)

### **United States Pharmacopoeia (USP) Class VI**

Certified by Bee Pharmo Labs Pvt. Limited, India.

#### **Tests Covered:**

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

### **Perfluorooctane Sulfonates (PFOS) and Perfluorooctanoic Acid (PFOA) content analysis**

Certified by TÜV India Private Limited.

Perfluorooctanoic acid (PFOA) itself and its salts (PFOS) are not used in polymerization or at any step of INOFLON® Fine Powder PTFE resin production.

## W270

Certified by Hygiene-Institut des Ruhrgebiets, Germany.

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

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

\*Applicable to MGN 7045 only.

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## EU 10/2011 and hence article 3 of European Regulation No.1935/2004, EC 1895/2005

Certified by TUV India Private Limited.

Plastic materials and articles intended to come into contact with foodstuff.

### Tests covered:

- a) Global Migration
  - b) Specific Migration of Heavy Metals
  - c) Specific Migration of Primary Aromatic Amines
  - d) Specific Migration of Phthalates
  - e) Specific Migration of PFOA
  - f) Specific Migration of Monomer
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## No Animal Origin

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

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## WRAS\*

Certified by Water Regulations Advisory Scheme Ltd.

The material is suitable for contact with wholesome for domestic purposes having met the requirements of BS6920-1:2000 and/or 2014.

\*Applicable to MGN 7045 only.

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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 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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