



# **Fine Power Modified PTFE**

CAS No: 9002-84-0

# STATEMENT OF COMPLIANCE

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

Plastic materials and articles intended to come into contact with foodstuff. Certified by TUV India Private Limited.

## **Tests covered:**

- a) Overall 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

# Food & Drug Administration (FDA) directive 21 CFR 177.1550

Articles or components of articles intended to come into contact with foodstuff. Certified by TUV India Private Limited.

#### **Tests covered:**

Determination of total extractives.

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

Certified by TUV SUD South Asia Private Limited.

INOFLON® Fine Powder modified 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 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 diphenyl ethers).

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

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

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

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.

#### 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.

\*Applicable to MGN 7045 only.

### **WRAS\***

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

Certified by Water Regulations Advisory Scheme Ltd.

\*Applicable to GN 7040 and MGN 7045 only.

# **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.

**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 prior permission of GFL may be sought.

#### SALES AND TECHNICAL SUPPORT

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