

STATEMENT OF COMPLIANCE

Date of Revision: 5 April, 2015

INOFLON® Fine Powder Modified PTFE

CAS No: 9002-84-0

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 Pvt. Ltd.

Test covered

Determination of amount of Extractives

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

No substance included in candidate list updated on Dec'17, 2014 are present in INOFLON® Fine Powder Modified PTFE.

RoHS Directive 2011/65/EU

Restriction of Hazardous Substance in Electrical & Electronic Equipment

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) Class VI

Certified by Bee Pharmo Labs Pvt. Ltd, India

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

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

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EC 10 2011 (Amendment to EU regulation no. 2002/72/EC)*

Plastic materials and articles intended to come into contact with foodstuffs

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 Monomer

* Applicable for MGN7045 and MGN7055 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 uses, prior permission of GFL may be sought.



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