

CAS No: 24937-79-9

### STATEMENT OF COMPLIANCE

#### EC 10/2011 and hence article 3 of European regulation no. 1935/2004 (Amendment to EU regulation no. 2002/72/EC)

Plastic material and article intended to come into contact with foodstuffs.

Certified by TUV India Private Limited.

##### Test Covered:

- Overall Migration
- Specific Migration of Heavy Metals
- Specific Migration of Primary Aromatic Amines
- Specific Migration of Phthalates
- Specific Migration of Monomer

INOFLAR™ PVDF complies with the specific restrictions contained in Annex XVII of REACH Regulations & specific migration limits mentioned in Annex I of EU 10/2011 Regulation.

#### Food & Drug Administration (FDA) directive 21 CFR 177.1520

Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces.

Certified by TUV India Private Limited.

##### Tests covered:

- Determination of maximum amount of Extractives in n-Hexane
- Determination of maximum Soluble Fraction in Xylene

#### Food & Drug Administration (FDA) directive 21 CFR 177.2510

Substances for Use Only as Components of Articles Intended for Repeated Use Food Contact Surfaces.

Certified by TUV India Private Limited.

##### Tests covered:

- Determination of maximum Extractable Fraction in Distilled Water
- Determination of maximum Extractable Fraction in n-Heptane
- Determination of maximum Extractable Fraction in 50% Ethanol

#### ROHS Directive 2011/65/EU

Restriction of Hazardous Substances in Electrical and Electronic Equipment.

Certified by TUV India Private Limited.

##### Test 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 diphenylethers)

# PVDF

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

Certified by TUV India Private Limited.

INOFLAR™ PVDF complies with the SVHC candidate list updated on January 17, 2023.

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

Perfluorooctanoic Acid (PFOA), its salts and Perfluorooctanesulfonate (PFOS) are not used in polymerization or at any step in the production of INOFLAR™ PVDF.

## United States Pharmacopeia (USP) Class VI

Certified by Labcorp, USA.

### Test Covered:

- Systemic Injection test
- Intracutaneous Injection test
- Intracutaneous Implantation test

Applicable to INOFLAR™ 1005, 1011, 1020 and 1125.

## NSF/ANSI/CAN 61

Plastic material and article intended to come into contact with drinking water application.

Certified by NSF, USA.

### Test Covered:

Chemical Extraction Qualification.

Applicable to INOFLAR™ 1005, 1011, 1020.

## 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.

Applicable to INOFLAR™ 1005, 1011, 1020.

## No Animal Origin

INOFLAR™ PVDF does not contain nor manufactured with any animal products, animal fats and material of animal origin or grain alcohols.

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**Note Warning:** Do not use any of INOFLAR™ PVDF 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.

## SALES AND TECHNICAL SUPPORT

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