

# STATEMENT OF COMPLIANCE

DATE OF REVISION: 2014

## **EMULSION VIRGIN PTFE**

CAS No: 9002-84-0

# PARTIAL TEST ON PLASTIC MATERIALS ACCORDING TO THE COMMISSION REGULATION (EU) NO 10/2011 OF 14 JANUARY 2011 AND ITS MODIFICATIONS

Plastic materials and articles intended to come into contact with foodstuffs. Certified by SGS Multilab France.

#### **TESTS COVERED**

Overall Migration to:

- · 3% acetic acid,
- 50% ethanol,
- · olive oil.

## FOOD & DRUGS ADMINISTRATION (FDA) DIRECTIVE 21 CFR 177.1550 AND 21 CFR 177.1380

Articles or components of articles intended to come into contact with foodstuffs. Certified by Intertek Polychemlab, USA.

#### 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 16th Dec 2013 is used in polymerisation or in any step of the HaloPolymer Granular Virgin PTFE production.

TESTED BY INTERTEK USA.

## 3-A SANITARY STANDARD PROCEDURE NO. 20-27 (LATEST REVISION)-USE PLASTIC MATERIALS

Certified by Element Material Technology, USA.

#### **TESTS COVERED**

- Cleanability Response;
- Product Treatment;
- Cleanability Comparison.

## ROHS DIRECTIVE 2011/65/EU

Restriction of Hazardous Substance in Electrical & Electronic Equipment. Certified by SGS Hong Kong Ltd.

#### **TESTS COVERED:**

- · Determination of Cadmium content;
- Determination of Lead content;
- · Determination of Mercury content;
- Determination of Hexavalent Chromium (Cr VI) content;
- Determination of sum of PBBs (Polybrominated biphenyls) and PBDEs (Polybrominated diphenylethers).

## UNITED STATES PHARMACOPOEIA (USP) CLASS VI

Certified by Pacific BioLabs, USA.

#### **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.

#### NO ANIMAL ORIGIN

HaloPolymer Granular Virgin PTFE does not contain, nor manufactured with, any animal products, animal fats, material of animal origin or grain alcohols.

## **PHIS-CHEM TESTS**

Certified by ELTEL Labs, USA.

Complies with all the requirements of following standard:

- IEC 60112 Comparative Tracking Index of Solid Insulating Materials Under Moist Conditions (CTI);
- UL 746-A Sec. 25: High-Voltage Arc-Tracking-Rate;
- UL 746-A Sec. 33 High-Current Arc Ignition;
- UL 746-A Sec. 32 Hot Wire Ignition;
- UL 94 Flammability of Plastic Materials Sec. 8 Vertical V0 V1 and V2.

MERL (Material Engineering Research Laboratory):

· Blister Testing of Polymeric Materials to API 17J.

EVALUATE THE BLISTER RESISTANCE OF PTFE.

US Office:

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