Noviglio, 01/01/2016

Item codes	Description
317	N/M BOTTLE PE, 50 ml
319	N/M BOTTLE PE, 125 ml
323	N/M BOTTLE PE, 250 ml
324	N/M BOTTLE PE, 500 ml
325	N/M BOTTLE PE, 1000 ml
326	N/M BOTTLE PE, 2000 ml

Kartell SpA Labware Division declares under its own responsibility that the above mentioned products, to which this declaration refers, conform to the Company specifications, the inspection plan and the deposited samples

The raw materials used to produce the above mentioned items comply with the relevant requirements of:

#### Food-contact EU

- Regulation 1935/2004/EC
- Regulation 2023/2006/EC (GMP)
- Regulation 10/2011/EC (PIM)

The monomers and additives used in production process are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments

Dual additives subject to restrictions in food as defined in regulation 10/2011/EC are not intentionally used in the manufacturing or formulation of the raw material.

The raw material contains one or more Dual Use Additive sas defined in Regulation 10/2011/EC :

E 551 Silicon Dioxide

**Quality Assurance** 

Massimiliano Capitanio

### Food contact US

The base resin meets the FDA requirements contained in the Code of Federal Regualtions in 21 cfr. § 177.1520 (a)(2)(i) and (c) 2.2

The raw material meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170 (c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170 (c), Table 1.

#### Phthalates

The raw material complies with Directive CE 2005/84 related to ABSENCE of PHATALATES.

# Bovine Spongiform Encephalopathy (BSE) Transmissible Spongiform Encephalopathy (TSE)

Components derived from animal sources are not used in the manufacture or formulation of the raw material.

Tallow derived components are not used in the manufacture or formulation of the raw material

#### Heavy metals: RoHS

The raw materials comply with the requirements of the Directives 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE)

## **REACH/SVHC**

With reference to Regulations REACH (n. 1907/2006) concerning the Recording, the Evaluation and the Authorization of the chemical substances applied starting from the 1<sup>st</sup> of June 2008 and subsequent amendments, the plastic raw materials, as Polymers, are exempt of registration.

**Quality Assurance** 

Massimiliano Capitanio

Kartell SpA **LABWARE** Division

The raw materials Supplier is committed to fully respect REACH Legislation and will only use fully REACH compliant raw materials.

### LATEX

No materials containing latex or natural rubber are used in the manufacturing , handling and packaging process.

### BISPHENOL-A (BPA) AND BISPHENOL-F (BPF)

Bisphenol-A (BPA) and Bisphenol-F (BPF) are not used in the manufacture process of the plastic raw materials and are not expected to be present. However tests have not been performed for these chemical materials.

**Quality Assurance** 

Massimiliano Capitanio