

Noviglio, 12/09/2023

Product code	Description
971	Tips, disposable for automatic micropipettes – PP – capacity 2 – 300 µL
9644	Rack for disposable tips - PP -
9752	Refill for disposable tips – PP -

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

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

Monomers and additives used to produce the products are listed in the Union List of Authorized Substances of Regulation 10/2011/EC
Dual use additives subject to restrictions in food as defined in Regulation 10/2011 EC are not intentionally used in the manufacture.

Food contact US

The base resin in these products meets FDA requirements contained in the Code of Federal Regulations 21 CFR 177.1520 (a)(1)(ii) e (c) 1.1b.

Phthalates

Phthalates are not used in the manufacture or the formulation of the raw material.

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

Tallow derived materials used in this production fulfill the requirements laid down in the Regulations 1069/2009/EC and 142/2011/EC and the "Note for Guidance EMEA/410/01 rev 3"

Heavy metals: RoHS

Raw materials comply with the requirements of the Directive 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polibrominated 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 1st of June 2008 and subsequent amendments, the plastic raw materials, as Polymers, are exempt of registration.

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 or the formulation of the raw materials and are not expected to be present. However tests have not been performed for these chemical materials.

**Polybrominated biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs),
Polybrominated Terphenyls (PBTs)**

Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl Ethers (PBDEs), Polybrominated Terphenyls (PBTs) are not used in the manufacture or the formulation of the raw materials and are not expected to be present. However tests have not been performed for these chemical materials.

Quality Assurance