

Drawn up in accordance with Article 16 (Declaration of Compliance) and Article 17 (Traceability) of REGULATION (EC) No. 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of October 27, 2004 on materials and articles intended to come into contact with foodstuffs

Report n° 22.59599 dated 27/01/2023

Kartell S.P.A Labware Division

DECLARES

The results of migration found the following articles produced in Polyethylene PE:

Product codes	Descriptions	Raw material
179	WASH BOTTLES, 50 ml	PE Polyethylene
180	WASH BOTTLES, 100 ml	PE Polyethylene
182	WASH BOTTLES, 250 ml	PE Polyethylene
183	WASH BOTTLES, 500 ml	PE Polyethylene
185	WASH BOTTLES, 1000 ml	PE Polyethylene

Compliant with

- REGULATION (EC) NO. 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with foodstuffs and repealing directives 80/590/EEC and 89/109/EEC
- COMMISSION REGULATION (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with foodstuffs, as amended.
- COMMISSION REGULATION (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with foodstuffs
- Decree of the Minister of Health March 21, 1973 and subsequent amendments.

- Specifications for the use of the item:

i) types of food with which it is intended to come in contact:

All kinds of food

ii) time and temperature of treatment and storage in contact with the food product:

Repeated contact for any contact condition that includes heating up to 70°C for up to 2 hours or up to 100°C for up to 15 minutes not followed by prolonged storage at room temperature or below

iii) maximum ratio between the surface in contact with the food stuff and the volume for which compliance has been verified

30 dm²/Kg

In accordance with "Annex V - Compliance testing, Chapter 3, point 3.4.2 Food simulant substitutes" of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with foodstuffs, the overall migration testing for fatty food assessment was conducted using the appropriate alternative simulants (95% ethanol and isooctane) and considering the highest migration value.

For point 2.2.4 of the aforementioned Regulation, specific migrations were carried out in the appropriate alternative simulant.

Tests performed according to EU Regulation 10/2001 and subsequent amendments

Simulants

- Global Migration and Dyes in Acetic Acid 3% (w/v) in aqueous solution [10 days at 40°C]- Compliant
- Global Migration and Dyes in 50% (v/v) ethanol in aqueous solution [10 days at 40°C] Compliant
- 95% (v/v) ethanol in aqueous solution [10 days at 40°C] Compliant
- Global Migration and Dyes in Vegetable Oil [10 days at 40°C] - Compliant
- Specific migration of certain substances (Al, Ba, Co, Cu, Fe, Li, Mn, Zn, Sb, As, Cd, Cr, Eu, Gd, La, Pb, Hg, Tb,)- Compliant
- Release of Primary Aromatic Amines - Compliant

Quality Dep. Labware Division