



Declaration of Compliance for materials and objects intended to come into contact with food products n° 25-0001

This statement concerns the following article:

Code	Product name	Materials
FM/42	CALICE EVENT 47 cl	Copoliestere
FM/41	CALICE EVENT 33 cl	Copoliestere

We declare that the products described above are in accordance with the following regulations:

- **European regulations and legislation**

Regulation (EC) No 1935/2004 (and amendments) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Regulation (EC) No 2023/2006 (and amendments) on good manufacturing practice (GMP) for materials and articles intended to come into contact with food;

Regulation (EU) No 10/2011 (and amendments);

- **Italian Legislation**

Italian DPR 777/82 Art. 2 comma 1 - Execution of Council Directive (EEC) No. 76/893 relating to plastic materials and articles intended to come into contact with foodstuffs (and amendments, as D. Lgs. N.108/92 that applies to Dir. n. 89/109/CEE relating to materials and articles intended to come into contact with foodstuffs);

Italian Ministerial Decree 21/03/1973 (and amended) - Discipline health of packaging, containers and utensils intended to come into contact with foodstuffs or with substances for personnel;

- **Other Legislation**

USA – FDA CFR Title 21 Section 210.2

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Investigations and results

The conformity was determined by:

- Migration tests according to Art.18 of Regulation (EU) N. 10/2011 and/or DM 21/03/73
- Supplier confirmations
- Theoretical calculations
- Risk analysis

Migration results are based on the EU-convention which is valid for a surface to mass ratio of 6 dm² material in contact with 1 kg of food.

The maximum ratio between the surface in contact with the foodstuff and the volume for which compliance has been verified in accordance with Articles 17 and 18 of Regulation (EU) 10/2011 is 0.6 cm²/cm³. This value represents the most stringent condition found in actual use of the article.

The material was tested using the simulants (defined in Annex III, Table 1, Reg. (EU) No 10/2011) and test conditions (defined in Annex V, Table 3, Reg. (EU) No 10/2011) presented below:

FOOD SIMULANT	TEST CONDITIONS
Simulante B – Acido Acetico al 3%	3X2h a 70°C
Simulante C – Etanolo al 20%	3X2h a 70°C

The material complies and is therefore suitable for contact

- with all types of aqueous foodstuffs, including acids and alcoholic foodstuffs with an alcohol content of up to 20 %, according to Annex III, Table 3, Reg. (EU) No 10/2011
- under any contact conditions including hot filling and/or heating up to a temperature T, where $70\text{ °C} \leq T \leq 100\text{ °C}$ for $t = 120/2^{[(T-70)/10]}$ minutes maximum, which is not followed by prolonged storage at room temperature or refrigerated temperature, according to Annex V, Table 3, Reg. (EU) No 10/2011.

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The material contains substances submitted to restriction in the mentioned legislations:

SUBSTANCE	Ref. No	CAS No	SML [mg/kg]	SML(T) [mg/kg] (Restrizione di Gruppo No)
2,2,4,4-tetrametilciclobutan-1,3- diolo	25187	3010-96-6	5	

The article does not contain any "Dual Use" additives that are subject to restriction in food as stated in Article 11.3 of Regulation 10/2011 (and authorised as food additives by Regulation (EC) No. 1333/2008 or as flavourings by Regulation (EC) No. 1334/2008).

The article does not contain MOSH, MOAH and BPA as they are not present in the raw material, as declared by the supplier, and are not intentionally added during the manufacturing process.

Any Non-Intentionally Added Substances derived from reaction intermediates and/or decomposition products (NIAS) were considered, under the conditions of use described, in a risk assessment according to Art. 19 of EU Regulation 10/2011 and were found to comply with the limits prescribed in the framework regulation.

The industrial or commercial use of above-mentioned material depends on verification of its compliance with current regulation, including their restrictions, and on technological suitability for the purpose of its use. This declaration is not valid in case of an improper use of the above-mentioned product (for instance, by addition of any other substance not in conformity with the above legislation or by any processing technique or condition which could deteriorate the composition of the above-mentioned product).

The article is not suitable for use in microwave ovens
It is recommended to wash the article thoroughly before use.

This Declaration is valid from the below-mentioned date and will be replaced when any substantial changes in our production, capable of altering essential requisite of conformity, will intervene.

Luogo e data:

Creazzo

16/05/2025

Autorizzato da:

Brevetti Waf S.r.l.

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