



Napoli,

25.01.2024

To:: SedaD

Object: Certificate of Compliance for Food Contact Materials
SPE Virgin Fibers Cup -Hot cups

We confirm that for the production of our foodstuffs cup the following statements apply:

1 Packaging material description: (from the outer side to the food contact side)

Cup

- Flexographic / [virgin fiber paperboard + extruded PE layer]
- Process: the inks are applied onto the outer side by flexographic technology,
- PE layer of the [paperboard + PE] substrate is extruded on paperboard, no lamination thus no adhesive is applied.

2 Intended food contact

- Type of food: dry, wet (non-alcoholic), acid and fatty foodstuffs.
- Contact condition: any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where $70\text{ }^{\circ}\text{C} \leq T \leq 100\text{ }^{\circ}\text{C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.
- Side intended to go in contact with foodstuffs: PE (Polyethylene)

3 Legal compliance- on amendments to date

- Product complies with the Regulation 1935/2004/EC, article 3, 11(5), 15 and 17
- Product complies with EC Regulation 10/2011 and following amendments, with special reference to plastic layer extruded.
- Product complies with Italian DM 21.03.73 and following amendments.
- Product complies with EU Directive 94/62, art.11.
- Paperboard complies with German BfR recommendation XXXVI 2023 and following amendments.
- Paperboard complies with US Food, Drug and Cosmetic regulation of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under: 21 CFR, part. 176.170
- Printing inks comply with the EuPIA Exclusion List. The inks are also formulated and manufactured in accordance with the "Guidelines for printing EuPIA external food packaging"[2022].

SEDA ITALY S.p.A.

Soggetta all'attività di direzione e coordinamento di Seda International Packaging Group S.p.A.

Società con Socio Unico

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- Printing inks comply with Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21)
- Seda Italy products are manufactured in compliance with the European Regulation 2023/2006/EEC “on good manufacturing practice for materials and articles intended to come into contact with food”.

3.1 Statement on Genotoxic Substances, according to EU Reg. 1245/2020

Regulation (EU) 2020/1245 requires a communication within the supply chain of possible genotoxic substances, if it cannot be ruled out that a migration of more than 0.00015 mg/kg food or food simulant is expected from the final material.

Based on the information received from our raw material suppliers and the knowledge of our production process, we confirm that no potential genotoxic substance, not authorized in any positive list of European or National legislation, is intentionally used to manufacture the final article.

4 Packaging Substances List

Substances used in the barrier do not contain substances with specific migration limit (SML) according to Commission Regulation (EU) 10/2011.

The list of dual use substances that could be present in the packaging are following listed:

Dual Use (as per EC Reg. 1129/2011, 1333/2008, 1334/2008)

PM/Ref. N° - E N°	Substance name
FL 02.082	Ethylhexanol
E 321	2,6-Di-tert.-butyl-p-cresol
E 422	Glycerol
E 1520	Propylene Glycol
E 914	Polyethylene waxes oxidized
E900	dimethylpolysiloxane
E570	stearic acid
E1520	Propylene glycol
E1521	Polyethyleneglycole
E251	Sodium nitrate
E514	Sodium sulphate
E565	Sodium lignosulfonate

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E330	Citric acid
E355	Adipic acid
E493	Sorbitan laurate
E514	Sodium sulphate
E517	Ammonium sulphate
E520	Aluminum sulphate
E524	Sodium hydroxide
E236	Formic acid
E513	Sulphuric acid
E1404	Starch
E511	Magnesium chloride
E551	Silicon Dioxide

The list of other monomers/additives which may be present in the other packaging materials cannot be disclosed since is covered by confidentiality agreement between Seda and its suppliers. These information are provided to the best of our knowledge, based on our suppliers' declaration and the knowledge of our manufacturing processes.

5 Food Safety Testing

All the food safety analysis have been performed on similar items representative of the product supplied (made of same raw materials and manufactured using same process).

The testing protocol was designed on the basis of declaration of our raw material suppliers', our manufacturing process and final food application.

Since the PE is not a total functional barrier to prevent the migration of all kinds of substances, food safety analysis have been performed in order to demonstrate that the migration level of substances comes from the whole packaging, including the inks and varnish applied on external side, is always below the applicable legal limits.

Based on the results provided by overall migration (sect. 5.1) and NIAS screening (5.2), we confirm that the migration level such substances is always below the applicable legal limits.

5.1 - Overall migration and specific migration:

The overall and specific migration analysis have been performed according to EN 1186-5 and Italian D.M. 21/3/73 and following amendments, on representative samples on the finished product, in simulant A, (ethanol 10%), B (acetic acid 3%) and D2 (vegetal oil or ethanol 95% + isooctane)*.

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The analysis have shown that the specific migration of the searched substances is below the law limit, according to limit set in the EU Reg. 10/2011. The compliance computations have been arranged assuming that 1kg of food comes in contact with 6 dm² of packaging material
The overall migration limit (10 mg/dm² or 60 mg/kg) stipulated in the Commission Regulation (EU) 10/2011** is not exceeded.

Test conditions: the migration test was carried out by putting the food contact side in direct contact with the simulant under the following conditions: contact time = 10 days /Temperature=40°C – OM2

The overall migration result is below the law limit, according to EC Regulation 10/2011.

Surface/volume ratio test: 0,98 dm²/0,9 dL,1

** The migration in isooctane at 20°C for 2 days and the migration in ethanol at 95% at 40°C for 10 days are the substitute tests for migration in rectified olive oil at 40°C for 10 days according to the conventional conditions reported in Table 4 of Decree n° 338 of 22/07/1998 (updating to the Ministerial Decree 21/03/73).*

***According to Article 14 of the Commission Regulation (EU) 10/2011: In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation. Overall migration limits and specific migration limits of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles. In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.*

5.2 NIAS screening

Identification of volatile and semi-volatile compounds come from packaging materials have been evaluated by GC-MS submitted the sample to static headspace in vials and put the sample in contact with organic solvent.

The analysis allows to investigate the toxicological risk due to the volatile and semi-volatile substances on surface intended for contact with food. The quantification is performed using a mixture of substances represented by the various chemical classes of volatile and semi-volatile molecules.

The identification of the substances is performed by comparing the mass spectrum with database, finding level of correspondence with the reference mass spectrum. It's considered a good correspondence when the match is higher than 90% and a not significant correspondence when it is lower than 80%.

The number of organic substances that can be detected in this research is relevant, considering also the presence of more isomers, therefore only a small part of them can be found in mass

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spectrum libraries. For this reason, it is often impossible to associate each spectrum to a similar or very likely library attribution.

From the performed analysis, no significant identified peaks have been detected.

Considering the amounts detected and applying the conversion factors recognized in the case of total migration from 6 dm² in 1 kg of food, by application of worst-case scenario that include theoretical calculation and evaluation by hazard class of the compounds and toxicological exposure, the product complies with requirements of EU Reg. 1935/2004 set in the article 3.

5.3 - Heavy metals

According to limit set in the EU Directive 94/62 [art.11], the sum of the concentration levels of Cadmium (Cd), Mercury (Hg), Lead (Pb), and Hexavalent Chromium (Cr+6) is <100mg/kg.

5.4 - Olfactory Organoleptic test according to UNI EN 10192:2000

The average scores obtained from the test are below 2.5 value*.

**the sample is recognized to have a potential impact on the product if the average score is higher than 2.5.*

6 General

By observing the above regulations, we have fulfilled our duty of care regarding the compliance of the product we supply.

The product is intended for non-alcoholic foodstuffs use, it is the responsibility of the user to verify its suitability for his own intended food application.

This letter is intended for your company only and replaces any previous Certificates of Compliance. It is valid only when signed by us. After a break in delivery lasting more than 12 months, this letter ceases to be valid for new deliveries of the relevant product.

This statement applies only to above identified products and is based on available data, which may include but is not limited to, supplier compliance statements, product composition, product analysis of similar items and our use of good manufacturing practices.

The Customer is responsible for the product safety, lawfulness (except as provided specifically in this Declaration) and technical suitability for its intended application use. Any non-conforming use of this product is outside the scope of this Declaration. The guarantees of use are expressly indicated in this document


Lucio Vignes
Q.A. Director

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