



DECLARATION OF COMPLIANCE

(in compliance with EC 1935/2004 Art 16 and
EU 10/2011 Art 15, Annex IV)

To whom it may concern.

We declare that

Crown corks 29mm for bottles with PVCfree (general use) liner

produced by Pelliconi & C SpA via Emilia 314, 40064 Ozzano Emilia (BO) - Italy

are compliant

with regulations pertaining to this type of packaging device for application on beverages, with special reference to the following Regulation:

- *Regulation EC 10-2011 "PIM" (included Reg: EC 321/2011, EC 1282/2011, EC 1183 /2012, EC 202/2014, EC 174/2015, EC 1416/2016, EC 752/2017, EC 79/2018, EC 2018/213, EC 831/2018, EC 2019/37, EC 2019/1338 and EC 2020/1245).*
- *Regulation EC 2023/2006 "GMP" and CAST Project - "Guidelines for the application of the Regulation EC 2023/2006 to the supply chain of materials and articles intended to come into contact with food" (Rapporti ISTISAN 11/37), § B7.1.3.5*
- *Regulation EC 1935/2004 "Framework" also considering amendments provided by the Reg EC 1416/2016 (Art. 3, 4, 5 and 6)*
- *Regulation EC 1895/2005 "Epoxy derivatives"*
- *Regulation EC 1907/2006 "REACH"*
- *FDA 21CFR § 177.1210 "Closures with sealing gaskets for food containers"*
- *OEHHA (Office of Environmental Health Hazard Assessment) Proposition 65, California State "Safe Drinking Water and Toxic Enforcement Act" 1986*
- *Swiss Utilities Ordinance 817.023.21 on materials and objects for food contact*
- *Italian D.M. 21/03/1973 and following updates*

The plastic lining material (the only component in contact with the beverage):

- does not contain neither PVC nor plasticizers (included phthalates), whose are therefore not expected to be present with the exception of ubiquitous traces;
- contains ingredients subject to restriction in use (% in formulation and/or SML) provided by the above Regulation;

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- when properly used respects admitted % in formulation, total and specific migration limits with reference to approved application conditions, as proved by the lining compound manufacturer and verified by independent accredited laboratories;
- as stated by the manufacturer contains “Double use” ingredients subject to restriction in use provided by the above Regulations to be verified by the end user to respect the limits after application; the identity of the “dual use” additives is specific for every batch of product, and it’s reported on the pertaining delivery documents (“Packing list”);
- does not contain plastic materials from recycling according to Reg EC 282/2008, Art.2,(2) b); the formula could contain plastic materials from internal reuse, according with Art.1(2) b);
- does not contain ingredients that could impart features and performances of active material/packaging as provided by Reg EC 450/2009;
- does not contain ingredients acknowledged as potential allergens by the Reg EC 1169/2001, Annex II, updated by Reg EU 1155/2013 and EU 78/2014, whose are therefore not expected to be present with the exception of ubiquitous traces;
- being mostly made by petrochemistry raw materials, there is no potential for the presence of GMO (Genetically Modified Organisms) and BSE/TSE risk materials; however, some additives along the supply chain could be of plant or animal origin; typical examples are fatty acids derivatives used for the production of lubricants and stabilisers: considering the process conditions this is not within the scope of Regulations EU 1829/2003 and EU 1830/2003 about GMO, nor Regulations EU 1069/2009 and EU 142/20 about TSE/BSE risk materials;
- does not contain components with the intended purpose of imparting properties which are attributed to nano scale particles (engineered nano materials, ENM); some raw materials may contain a fraction of particles, which would fall under the nano scale definition (< 100 nm), but which are not Engineered Nano Materials according to Recommendation 2011/696/EU;
- does not contain epoxy resins, BisPhenol-A (CAS 80-05-7) and/or other bisphenols, whose are therefore not expected to be present with the exception of ubiquitous traces;
- does not fulfil the criteria classifying microplastics according to ECHA guidelines, therefore Pelliconi products do not intentionally contain nor release microplastics: if properly collected and wasted at the end of life according to the applicable regulation, Pelliconi products are not expected to release and/or degrade into microplastics;
- SVHC according to Reg EC 1907/2006/CE “REACH” are not intentionally used in the manufacture, therefore not expected to be present with the exception of ubiquitous traces;

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- is suitable for use in the beverage industry, with special reference to the bottling of beverages to be filled in compliance with current market standard requirements, included standard pasteurization treatments (e.g. approx. 20min at approx. 70°C), and distributed at ambient temperature or refrigerated;
- does not withstand to sterilization (“retort”) treatment, and is not intentionally designed for hot filling process, requiring a dedicated preliminary approval;
- plastic lining compounds are suitable for contact with food, the compliance of which has to be assessed using simulants A, B, C or D1, therefore aqueous beverages with low alcohol content and/or low level of pH (acidic), like for example (indication only) still and sparkling mineral water, soft drinks, fruit juices, wines and other alcoholic beverages, dairy products (milk and yoghurt), for use on bottles with an internal volume of 20cl or higher;
- is not intentionally designed for contact with spirits (high alcohol content beverages), baby food, and fat/oily foods, requiring a dedicated preliminary approval;
- does not contain heavy metals (<100ppm), as provided by Directives 94/62/EC (art.11) and 2004/12/EC, and in compliance with Toxics in Packaging Legislation (CONEG).

This Declaration of Compliance is valid with all indicated limits, restrictions and application, from the issue date and remains valid until:

- significant changes will be introduced in the production/manufacture of the material/article, causing a significant change in the material/article features, or performance pertaining to the suitability for intended use, or
- above Legislative references will be updated and require a new assessment of material/article compliance for intended use.

To complete and support this declaration, the lining material manufacturer's contact may be provided at the request of the user asking for confidential information requiring a specific non-disclosure agreement.

The end user of the product/material intended to be used in contact with foodstuffs is responsible for:

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- inform the manufacturer about any restriction applicable to the specific foodstuff to package, due to the specific composition (additives and ingredients) and/or to restrictions provided by specific regulations applicable to the business, and
- verify and approve the technical suitability for use of the product/material when applied in real application conditions, especially where thermal treatments are applied (pasteurization and/or hot filling).

Date: 2022, Jan 28th


Signature

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Disclaimer.

The content of this document is based on information shared along the supply chain, on the best of our current knowledge and experience and on legislation in effect on the date of issue.

This compliance statement does not warrant against any modifications of this product, nor against any inadequate use and/or storage of this product or the materials and articles containing it.

It is the user's responsibility to inspect and verify that Pelliconi products are adequate and suitable for the intended use and purposes of the customer, who is responsible for the appropriate, safe and legal use as well as the treatment and management of the products described in this document in real industrial operations.

The information in this document refers exclusively to Pelliconi products: no liability could be accepted for the use of Pelliconi products in combination with other products or materials.

The present statement also does not warrant compliance with legislation changed after the date above.

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