

This document is a Declaration of Compliance within the meaning of Article 16(1) of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

1. General Product Information

Date:	21.06.2019	Rev. Nr.	00
Producer:	Constantia Alucap srl Via Paludi 29 I-38051 Borgo Valsugana (Trento) - Italy		
Customer:	PACKINOV Parc d'activité les 2 B 58 chemin du Dérontet 01360 Béligneux - FRANCE		
Customer Spec.:	Die-cut lids Ø82,5mm PET white 50my unprinted (art. 01966988)		

Material description (from the outer to the inner layer):

Layer:	based on
PET white film	Polyethylenterephthalat
Sealing primer	Acrylate-olefin/polyester
Heat Sealing lacquer to PP/PS/PET	Acrylate-olefin/polyester

Food contact layer: heat sealing lacquer

Type of package/application: peelable lid intended for dairy products.

2. Compliance with Food Contact Legislation

2.1 General

The product named on this declaration complies with the applicable requirements of

- EU "Framework" Regulation (EC) No. 1935/2004
- Commission Regulation (EU) No 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs
- Regulation (EC) No. 2023/2006 on good manufacturing practice
- Directive 94/62/EC and the Model Toxics in Packaging Legislation (as drafted by the Toxics in Packaging Clearinghouse/ Source Reduction Council of CONEG) regarding the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium < 100 ppm.

Italy:

- D.Min. 21/03/1973 and subsequent updates and appendices.

2.2 Conditions of Use

The product is suitable for direct contact with food.

Nature of food: dairy products, yoghurts.

Time/temperature conditions: continuous cold storage.

A surface to volume ratio of 6 dm²/kg food has been used to determine compliance.

2.3 Compliance with Overall Migration Limit (OML) of the Food Contact Layers

EU Regulation No. 10/2011 sets out the test conditions for **plastic** materials and articles. Other test conditions for the determination of the overall migration may be considered for products which do not fall under the scope of 10/2011/EC or for which specific measures exist on national level.

The product is in compliance with the OML of 10 mg/dm² following evaluation of relevant samples under following test conditions:

Food simulant	Testing conditions (time/temperature)	Global Migration in [mg/dm ²]
3 % acetic acid	10 d 20°C	<10
50 % ethanol	10 d 20°C	<10

The compliance refers only to migration compliance and not to technical fit-for-use.

2.4 Compliance of Non Food Contact Side

2.4.1 Print primer

The lacquer fulfils the requirements of Article 3 of the EU-Framework Regulation 1935/2004/EC if applied on the non-food contact surface of food packaging.

2.5 Plastic

The composition of the PET film is according to Regulation (EU) No 10/2011 and amendments.

2.6 Compliance of the Food Contact Layers

Layer	Country	Legal Provisions (recommendations, code of practice, decrees) for plastics, paper, adhesives, coatings and other components
PET film	EU	All starting monomers and additives are listed in the union list of EU Regulation No. 10/2011 as amended
	USA	21 CFR § 177.1630 for all types of food
heat seal layer	EU	All starting monomers and additives are listed in the union list of EU Regulation No. 10/2011 as amended
	USA	21 CFR § 177.300

2.7 Compliance with Specific Restrictions

The used raw materials contain substances that have a restriction according to EU Regulation No. 10/2011 as amended.

The restricted substances listed in the following table may be present in the finished product:

Chemical name	CAS nr.	PM/Ref	Restriction*		
Acetic acid, ethyl ester	141-78-6	30140	60	mg/kg	SML
Terephthalic acid	100-21-0	24910	7,5	mg/kg	SML
Isophthalic acid	121-91-5	19150	5	mg/kg	SML
Ethylene glycol	107-21-1	16990	30	mg/kg	SML
Alpha-methylstyrene	98-93-9		0.05	mg/kg	SML
Xylene isomers	1330-20-7		1,2	mg/kg	SML
Ethyl Benzene	100-41-4		0,6	mg/kg	SML
Butadiene	106-99-0	10630	1	mg/kg	QM
Maleic anhydride	108-31-6		30	mg/kg	SML (T)
2,6-Di-tert-butyl-p-cresol (BHT)	128-37-0	46640	3	mg/kg	SML
Silicon dioxide	7631-86-9		60	mg/kg	SML
Talc	14807-96-9		60	mg/kg	SML
Methylproxitol	107-98-2		60	mg/kg	SML
2-ethyl-1-hexanol	104-76-7	17050	30	mg/kg	SML

* restrictions can be a specific migration limit (SML), a maximum concentration (QM), a maximum quantity per surface area (QMA), or a 'no detectable migration' (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers.

The restrictions have been checked by an accredited 3rd party laboratory. For migration tests suitable food simulants have been used. The restrictions were proved not to be exceeded either by analytical testing or by worst case calculation when used under the conditions specified in section 2.2. For the evaluation an area / volume ratio of 6 dm² / 1 kg food was taken into account.

2.8 Dual Use Additives

As required by EU Regulation No. 10/2011 the following table identifies substances used as additives in plastics and subject to a restriction in food through an authorization as food additive or flavouring (as listed in the Union *Guideline* on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, point 3.6.3 table 1 and 2.)

Chemical name	Food Additive	Restriction in plastics
2,6-Di-tert-butyl-p-cresol (BHT)	E321	SML 3 mg/kg
Talc	E553b	SML 60 mg/kg
Silicon dioxide	E551	SML 60 mg/kg

The above list of dual use additives is complete to the extent that accurate information was received from our raw material suppliers.

3. Supporting Documents

Appropriate documentation including supplier DoCs, test results, calculations and other evidence on the safety or reasoning demonstrating compliance are retained on the production site and can be shown to the competent authority on their request.

4. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It describes the status of the products specified under General Product Information. The user of the product (or downstream user, if applicable) is responsible for ensuring that the finished food package complies with applicable migration limits in the food itself under actual conditions of use. Furthermore, the food packer is responsible for verifying possible interactions of the products or its components with the foodstuffs (e.g. modification of odour, taste, consistency, migration etc.) which are to be checked prior to use and in function of the end-uses and to ensure the general appropriateness of the packaging material for the intended use.

This declaration replaces all previous declarations for the same specification. It remains valid until a relevant change in the legislation or new relevant scientific information changes the legal status of the delivered specification.

Alessandro Zurlo
Constantia Alucap Srl
Quality Assurance Manager

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