



PROVISIONAL DECLARATION OF COMPLIANCE

FOR FOOD CONTACT MATERIALS AND ARTICLES

Poligal PORTUGAL UNIPessoal LDA, hereby declare, that the product **CATE SAC - FILME DE POLIPROPILENO BIORIENTADO** is produced according to Good Manufacturing Practice (GMP) for materials and articles intended to come into contact with food and complies with the European Union (EU) legislation for food contact materials and articles.

EU

Regulation (EC) No 1935/2004 of 27th October 2004 (articles 3, 11 (5), 15 and 17) and its amendments;

Regulation (EC) No 2023/2006 of 22nd December 2006 and its amendments;

Regulation (EU) No 10/2011 of 14 January 2011 and its amendments: Regulation (EU) 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 174/2015, 1416/2016, 2017/752, 2018/79, 2018/213, 2018/831 and 2019/37;

PORTUGAL

Decreto-lei n.º 62/2008 of 31 March, amended by Decreto-lei n.º 29/2009 of 2 February;

Decreto-lei n.º 366-A/97 of 20 December.

USA

Regulations FDA 21 CFR 177.1520

It also states that:

- Raw materials used in the production of the film meet the conditions outlined in the EU legislation, the lists of approved monomers and additives for plastic materials and articles intended to come into contact with foodstuffs;
- Product traceability is ensured;
- The sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium present in the product is not more than 100ppm by weight.

THIS DOCUMENT WAS ISSUED ELECTRONICALLY AND IS THEREFORE VALID WITHOUT SIGNATURE

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- The polymeric materials are used in proportions that ensure the overall provision to the food product will not produce specific migrations values exceeding the limits defined in EU legislation. The following table shows the possible substances with Specific Migration Limits (SML) , which may be present in the film:

Table 1 – Substance Ref No / SML

Ref. No	SML (mg/Kg)
19960	30
38820	0,6
39090	1,2
39120	1,2
39815	0,05
68320	6
74880	0,3
83595	18
95360	5
Aluminium	1

Dual use
Aluminium (E173)
Citric acid (E330)
Calcium, potassium and sodium salts(E470a)
Magnesium salts of fatty acids (E470b)
SiO ₂ (E551)

SPECIFICATION OF THE INTENDED USE OR LIMITATIONS

No migration tests have been done yet.

This declaration of compliance is valid for a period of 2 years from the date mentioned below and is subject to revision if changes occur in legislation, raw materials, production process or the scientific data that may change the conditions of product conformity.

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The statement does not contemplate any change made to the product, resulting from adding any other kind of substances (adhesives and adhesion promoters, printing inks, pigments and dyes, solvents, etc.) or application of the product under conditions not covered in the specification of the intended use or limitations. The person responsible for the alteration of the product must not place it on the market without first ensuring that it complies with relevant legislation of materials and articles intended to come into contact with food.

The issue of this declaration of compliance was based on the EU legislation applicable to materials and articles intended to come into contact with food, in compliance statements from our suppliers of raw materials and product testing.

Arcos de Valdevez, February 2019.

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