

POLIGAL PORTUGAL UNIPESSOAL LDA, hereby declare, that the product ***CPSST LETT – CAST POLYPROPYLENE TRANSPARENT FILM*** 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, 2019/37, 2019/1338;

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.
- 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:

THIS DOCUMENT WAS ISSUED ELECTRONICALLY AND IS THEREFORE VALID WITHOUT SIGNATURE

Poligal Portugal Unipessoal, Lda

Parque Empresarial de Mogueiras Lote B5, 4970 - 685 Tabaçô - Arcos de Valdevez
Telef. +351 258 518 095 E-mail: info@poligal.pt

Table 1 – Substance Ref No / SML

Substance Ref No	SML (T) (mg/Kg)
39090	1.2
39120	1.2
21130	6
19960	30
68320	6
38820	0.6
95360	5
83595	18
39815	0.05
55910	60
Aluminium	1

Dual use
Citric Acid (E330)
Calcium, potassium and sodium salts of fatty acids (E470a)
Magnesium salts of fatty acids (E470b)
Polyglycerol esters of fatty acids (E475)
SiO ₂ (E551)

SPECIFICATION OF THE INTENDED USE OR LIMITATIONS

1. Types of food intended to come into contact with material:

OM5 conditions: aqueous, acids, alcohols (up to 10% (V / V)) and fats¹

¹ According the table 2 of Annex III in Regulation (EU) 10/2011, the migration test results of food simulant D2 may be divided by a correction factor before comparing with the migration limits. This correction factor is defined in point 4.2 of Annex V to Regulation 10/2011. In this case, a correction factor of 2, 3, 4 or 5 must be applied to ensure the compliance with the Regulation.

Test with **simulant A** (Ethanol 10 % (v/v)), **simulant B** (Acetic acid 3 % (w/v)) and **simulant D2** (vegetable oil), have been performed with compliancy results.

2. Duration and temperature of treatment and storage while in contact with the food:

The global migration (OML) has been tested in the following test conditions:

- **2 hours at 100°C (OM5).**

THIS DOCUMENT WAS ISSUED ELECTRONICALLY AND IS THEREFORE VALID WITHOUT SIGNATURE

Poligal Portugal Unipessoal, Lda

Parque Empresarial de Mogueiras Lote B5, 4970 - 685 Tabação - Arcos de Valdevez
Telef. +351 258 518 095 E-mail: info@poligal.pt

The above conditions covers:

OM5: High temperature applications up to 121°C. Test OM5 covers also food contact conditions described for OM1, OM2, OM3 and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins. JRD Scientific and policy reports: “Technical Guidelines for migration testing; Draft under consultation; point 4.4.2 Overall migration test conditions: When testing materials with a polyolefin food contact layer, OM5 allows to clear the material for any use condition even exceeding 121°C (within the limits of technical suitability and SML compliance). The reason is that from an inertness point of view (which is what OM is testing) OM5 is considered the worst case test condition to which these materials should be subjected.”

3. Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article **6 dm²/Kg**.

No post-consumer material is used in the production of this film, according definition included in Standard ISO 14021.

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.

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, 16 December 2019

THIS DOCUMENT WAS ISSUED ELECTRONICALLY AND IS THEREFORE VALID WITHOUT SIGNATURE

Poligal Portugal Unipessoal, Lda

Parque Empresarial de Mogueiras Lote B5, 4970 - 685 Tabaçô - Arcos de Valdevez
Telef. +351 258 518 095 E-mail: info@poligal.pt