

# EXTRUSA DE COLOMBIA S.A.

Kilómetro 11 Vía Mamonal, Cartagena, Colombia

Date 27-Jul-2018

## Declaration of Compliance for Articles intended to come into Contact with Foodstuffs according to Art. 16 of Regulations (EC) 1935/2004 and Annex IV of Regulation 10/2011

We hereby confirm that our product Polyolefin Shrink Film  
Codes P5ER, P5HS, P5HS Premium, P5LSF, P5LS, P3LS, P5AF, P10, Bakery and PDP-R  
Description Biaxially Oriented Multilayer Film

Complies with legal requirements laid down in EU Regulation 1935/2004, EU Regulation 2023/2006 and EU Regulation 10/2011 and its amendments (includes EU Regulations 321/2011, EU1282/2011, EU 1183/2012, EU 2018/79, EU 2018/213, EU 2018/831), EU 202/2014 and EU174/2015, EU Reg. 2016/1416 and EU 752/2017 regarding plastic materials and products for contact with food.

In order to guarantee the compliance with the Resolution, the end plastic product must be analyzed by the manufacturer concerning total migration limit, and such limit must be less than 10 mg/dm<sup>2</sup>.

This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

Traceability as defined in art. 17 of Regulation 1935/2004 is ensured by the lot number on the tube and box label - part 4: traceability applied in the plastic chain.

According to the information provided by our raw material suppliers:

Polymer	Polyethylene	CAS No	9002-88-4	26221-73-8	
	Polypropylene	CAS No	9003-07-0	25895-47-0	9010-79-1

Monomers/additives subject to restriction can be contain or included in the composition of the current products.

- Additives which are also authorized as food additives or food flavorings (so-called dual use additives) should be used as an intentional additive or ingredient in the manufacture of the current products. Material meets requirements of Regulations (EC) 1935/2004 and 10/2011 with Annex 1 as a positive list for monomers and additives.

The ingredients used in the formulation are not likely to alter the organoleptic properties of foodstuffs.

The article in question does not contain postconsumer recycled plastics, statement of compliance with Regulation 282/2008 is not required.

### Specification of the intended use or restrictions

The above article under normal and foreseeable conditions of use is suitable for contact with acid, aqueous and fatty foodstuffs, for any long term storage at room temperature or below. Films are used at room temperature and under severe conditions -refrigerated and deep-frozen storage (minus 40/maximum plus 70°C) A functional barrier plastic is not used in the product mentioned above.

### Overall migration

When used as specified, the overall migration (OM) and specific migration do not exceed the legal limits. Migration tests carried out following the Regulation 10/2011 confirm OM results below 10 mg/sq. dm or 60 mg/kg of food simulant in simulants A, B, D2 for 10 days at 40°C and 4 hr at 100°C.

	Simulant A	Simulant B	Simulant D2
All product types	<10	<10	<10

### Specific Migration Limit (SML)

SM has been evaluated in compliance with Regulation 10/2011 by calculation or, if necessarily, by conducting experiments. All calculations have been done using the worst case scenario and carried out under the condition that 1 kg of food is in contact with 6 sq.dm of packaging product in simulants A, B, D2 for 10 days at 60°C.

### Specific migration of residual monomers and others by calculations

Material	CAS No	PM Ref- No	SML, mg/kg
Octadecyl-3-(3,5 di-tert-butyl -4-hydroxyphenyl) propionate	2082-79-3	68320	6
Ethylene	74-85-1	16950	15
1-Octene	111-66-0	22660	15
1-Hexene	592-41-6	18820	3
Octadecylceramide	10094-45-8	68400	5
2,6- di-tert-butyl-p-cresol (BHT)	128-37-0	46640	3
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine (1) +	-	39090	1,20
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides (1)	-	39120	

(1) Expressed as tertiary amine

**Dual use additives** can be added to the articles according to the information provided by our raw materials suppliers with no intention of releasing them into food, imparting no odour or taste, nor should the SML be exceeded. Substances below do not exhibit technological function in the food and are present below limits subject to a restriction as defined in Regulation 10/2011

GMS	E471	Calcium stearate - Calcium salts of fatty acids	E470a
Silicon dioxide	E551	2,6- di-tert-butyl-p-cresol	E321

Synthetic silica and citric acid (< 3 %) as a coating agent	E330
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Calculation of "worst case" migration (100%) for the above substances shows that none can exceed respective SML. Calculation is based on maximum amount of substances found in raw materials according to our supplier's

Declaration of Compliance.

Also, calculation of "worst case" migration (100%) shows that OML of 10mg/dm<sup>2</sup> or 60 mg/kg food cannot be exceeded. It is valid for above simulants.

The final item producer is responsible for the evaluation of overall/specific migration at the real time/temperature conditions or used under conditions deviating from test conditions.

<b>We states that the conditions under which the food contact suitability is guaranteed are:</b>	<b>Yes</b>	<b>No</b>
For use with every type of foodstuff except fatty food	+	
For use with every type of foodstuff including fatty food	+	
For use up to -40°C	+	
For use up to +40°C	+	
For use up to +140°C		+
For use in a freezer	+	
For use in a refrigerator	+	+
For use at room temperature (~20°C)	+	+
For use in a conventional oven		
For use in a grill		
For use in a microwave without contact with food	+	
For use in a microwave with contact with food	+	

#### *Additional information*

**Phthalates:** Phthalates are not intentionally added to our product formulations. Further, none of the constituent raw materials is specified by its supplier to contain phthalates as an impurity. Maximum residuals are not more than 15 ppm.

**Nanoparticles:** Nanoparticles are not intentionally added to our product formulations and neither constitute part of our raw materials component

#### **Polycyclic Aromatic Hydrocarbons (PAHs) Directive 2005/69/EC**

We do not intentionally use the following polycyclic aromatic hydrocarbons (PAHs) in the manufacture of or formulation of this product. However, we do not test this product for this chemical substance.

#### **Bisphenol A (Regulation 321/2011)**

We do not intentionally use the following Bisphenol A in the manufacture of or formulation of this product. However, we do not test this product for this chemical substance.

#### **Primary Aromatic Amines (PAA) Regulation 10/2011**

We do not intentionally use the following PAA in the manufacture of or formulation of this product. However, we do not test this product for this chemical substance.

**Allergens:** Substances listed in Annex II of Regulation 1169/2011 are not intentionally added to product formulation.

**Triclosan** - 2,4,4-trichloro-2-hydroxydiphenyl ether (**Directive 2010/169/EC**) Biocide is not used as intentional additive or ingredient. However, this product has not been tested for this chemical substance.

#### **Declaration of other substances**

We certify, that during manufacturing of this product, we do not intentionally incorporate into this product any of the substances listed below and therefore are not expected to be present in this product. However, this product has not been tested for these chemical substances.

- Azo-dye - Azocolorants (restricted by Directive 2002/61/EC)
- \* Dispersion paint
- \* Tartrazine -yellow azo dye
- Acrylamide [CAS No. 79-06-1]
- \* resorcinol [CAS No 108-46-3]

#### **Heavy metals: RoHS, WEEE, Packaging Waste, CONEG**

This product meets the relevant requirements of the following Directives or Regulations:

10/2011/EU as amended	Regulation (EC) 1907/2006, annex XVII, as amended
2002/95/EC (RoHS) as amended	Directive 94/62 as amended; USA CONEG Regulation
2002/96/EC (WEEE) as amended	2000/53/EC on end-of life vehicles (ELV)

#### **NOTE**

The present declaration is updated with the amendments EU Regulations 2018/79, EU Regulations 2018/213, EU Regulations 2018/831 which are not applicable for heat shrink films POF

#### **Conclusion**

We also declare that should we on any occasion change the composition of our products in a way that would interfere with the declaration, we will inform your company.

This declaration is valid for a period of 12 months. It should be renewed in the case of a change of the raw materials, composition of the product, the legal regulations or new toxicological realizations.

*Signed for Extrusa of Colombia*

*Production Manager*

*Javier Julio R*

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