

GENERAL DATA

Manufacturer

Plásticos Francés, S.A.U.

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Product covered by this declaration

Polypropylene ST^{bio}

Biodegradable film of polypropylene



APPLICABLE LEGISLATION

This product complies with the following legislation and its subsequent modifications up to the date of issuance of this document:

- **Regulation (EC) no. 1935/2004** on materials and objects intended to come into contact with food.
- **Regulation (EC) no. 2023/2006** on good manufacturing practices for materials and objects intended to come into contact with food.
- **Regulation (EU) no. 10/2011** on plastic materials and objects intended to come into contact with food.

This product has been manufactured with raw materials whose starting substances are included in the positive lists of the Regulation (EU) no. 10/2011.

We comply the health standards in the production of the film, and the company is registered in the Food Safety General Registry (RGSEAA) with the No **39.02567/A**.

The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with **article 3.1,c of Regulation EC 1935/2004** must be verified and tested by the food packer.

Does not apply:

- **Regulation (EC) 282/2008** on recycled plastic materials and articles intended to come into contact with foods, because we don't use any recycled material in its production.
- **Regulation (EC) 450/2009** on active and intelligent materials and articles intended to come into contact with food, because this product is not considered as such.

COMPLIANCE WITH THE OVERALL MIGRATION LIMIT

The product has been subjected to tests on Overall Migration Limits (**OML**) performed on bags made of **Polypropylene ST^{bio}** film of 120µ thickness and flexographic printing. The test conditions have been those stipulated for the **OM2** test.

The tests have been carried out in the chemical laboratory of AIMPLAS (ENAC accreditation no. 56/LE156) in accordance with the UNE-EN 1186 standard, with the subsequent results:

Food simulant	Test conditions	OML	Conclusion
A (Ethanol 10%)	10 days 40°C	10 mg/dm ²	OK
B (Acetic acid 3%)	10 days 40°C	10 mg/dm ²	OK
D2 (Vegetable oil)	10 days 40°C	10 mg/dm ²	OK

Note: The ratio of food contact surface area to volume used in the test to establish the compliance of the sample is 10 dm²/kg.

INFORMATION ON SUBSTANCES WITH RESTRICTIONS

Substances with Specific Migration Limits:

This product contains the subsequent substances with Specific Migration Limit (SML) as Annexes I and II of the Regulation (EU) no. 10/2011 and its subsequent amendments. They have been tested in the simulant/s considered as the most restrictive taken the tested substances into account.

The tests have been carried out in the chemical laboratory of AIMPLAS (ENAC accreditation no. 56/LE156) in accordance with the UNE-EN 13130-1 standard with the subsequent results:

Note	Substance	Test conditions	Annex	SML	Conclusion
(1)	10120	10 days 60°C	Annex I	12 mg/kg	OK
(1)	39815	10 days 60°C	Annex I	0.05 mg/kg	OK
(1)	83595	10 days 60°C	Annex I	6 mg/kg	OK
(1)	Barium	10 days 60°C	Annex II	1 mg/kg	OK
(1)	Copper	10 days 60°C	Annex II	5 mg/kg	OK
(1)	Iron	10 days 60°C	Annex II	48 mg/kg	OK
(1)	Manganese	10 days 60°C	Annex II	0.6 mg/kg	OK
(1)	Zinc	10 days 60°C	Annex II	5 mg/kg	OK
(1)	Aluminium	10 days 60°C	Annex II	1 mg/kg	OK
(1)	68320	10 days 60°C	Annex I	6 mg/kg	OK
(2)	31920	10 days 60°C	Annex I	(*) 60 mg/kg	OK
(2)	46640	10 days 60°C	Annex I	3 mg/kg	OK
(2)	94560	10 days 60°C	Annex I	5 mg/kg	OK
(2)	95600	10 days 60°C	Annex I	5 mg/kg	OK
(2)	13380 25600 94960	10 days 60°C	Annex I	6 mg/kg	OK

Notes:

Results expressed as mg of substance per kg of food simulant applying the surface/volume ratio of 6 dm²/kg.

(*) Group restriction specification (32), expressed as the sum of the substances.

(1) Substance present in the film, (2) Substance present in flexographic inks.

Dual Use Substances:

The following substances are used in the composition of this product (dual-use additives) that are listed in Annex I of Regulation (EU) No. 10/2011 and its subsequent amendments: **E 321**

Substances not intentionally added (NIAs):

According to the information provided by our suppliers, the product does not contain substances not intentionally added, although no tests have been carried out for confirmation.

Residual solvents:

According to the results of the tests carried out, the residual content of the solvents is below 10 mg/kg, with the sum of the specific migration of all the solvents being less than 0.1 ppm (mg/kg)

CONCLUSIONS

According to the results obtained the tested sample corresponding to bags made of **Polypropylene ST^{bio}** of 120µ thickness with flexographic printing, **FULFILS** the overall and specific migration limits stated in the Regulation (EU) no. 10/2011 and subsequent amendments, for contact with all kind of food and for any long-term storage at room temperature and below, including hot-fill conditions and/or heating up to 70°C ≤ T ≤ 100°C for a maximum t=120/2 ^ [(T-70)/10] minutes (food contact conditions intended for the OM2 test)

The analysed sample has been considered representative of the total number of samples with the same composition or less restrictive and equal or less thickness, since the tested sample is the most restrictive case.

Disclaimer:

Document issued by the Quality and Product Safety Department.

The information provided in this document has been compiled based on our own information, the information provided by our suppliers and according to the latest knowledge available and applicable legal requirements.

We assume no responsibility for any misinterpretation or misuse of this document.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of Plásticos Francés' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third-party materials.