

GENERAL DATA

Manufacturer	Plásticos Francés, S.A.U. Pol. Ind. La Casilla, C/Ministre Chapaprieta, s/n 03460 Beneixama (Alicante) Spain
Product covered by this declaration	Polypropylene EC Special film of polypropylene for low temperatures

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 EC** film of 120 μ thickness, with flexographic printing, zipper closure and closure with adhesive tape, both removable and permanent, antifog varnish and paper-touch varnish. 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)(2)	Aluminium	10 days 60°C	Annex II	1 mg/kg	OK
(1)(2)	68320	10 days 60°C	Annex I	6 mg/kg	OK
(3)	31920	10 days 60°C	Annex I	(*) 60 mg/kg	OK
(3)	46640	10 days 60°C	Annex I	3 mg/kg	OK
(3)	94560	10 days 60°C	Annex I	5 mg/kg	OK
(3)	95600	10 days 60°C	Annex I	5 mg/kg	OK
(3)	13380 25600 94960	10 days 60°C	Annex I	6 mg/kg	OK
(4)	38560	10 days 60°C	Annex I	0.6 mg/kg	OK
(4)	91530	10 days 60°C	Annex I	5 mg/kg	OK
(5)	93760	10 days 60°C	Annex I	(*) 60 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 the zipper, (3) Substance present in flexographic inks, (4) Substance present in the anti-fog varnish, (5) Substance present in the paper-touch varnish.

Other substances subject to restrictions:

The test of the following substances, which are part of the sample's formulation (film + inks + zipper + tapes) has been omitted at first due to the following reasons:

Substances	Reasons
18430, 22660, 24550/89040, 26140, 17020, 16990/53650, 13326/15760/47680 y 96240	According to the Declaration of Compliance from zipper, the supplier guarantees by means of a calculation method (considering the worst case), that the SML of these substances are not exceeded for ratio of 1dm of zipper/kg of food (1 dm ³ model bag)

Note: These calculations have been made in accordance with Regulation (EU) no. 10/2011 and its subsequent modifications and they are included in the report of the laboratory mentioned above.

Dual use substances:

Substances also authorised as direct food additives ("Dual use additives") are used in the composition of this product. They are listed in the Annex I of the Regulation (EU) no. 10/2011 and its amendments:

- Film: E321
- Zipper: E170, E551, E553b, E559 y E1521

Substances not intentionally added (NIAs):

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

- Film: Contains no NIAs.
- Zipper: 95883-E905a

Residual solvents:

According to the results of the tests carried out, the residual content of solvents is bellow 10 mg/kg and the specific migration of all the solvents is lower than 0,1 ppm (mg/kg)

CONCLUSIONS

According to the results obtained the tested sample corresponding to bags made of **Polypropylene EC** film of 120 μ thickness, with flexographic printing, zipper closure and closure with adhesive tape, both removable and permanent, anti-fog varnish and paper-touch varnish, **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 $70^{\circ}\text{C} \leq T \leq 100^{\circ}\text{C}$ for a maximum $t=120/2 \wedge [(T-70)/10]$ minutes.

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:

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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.

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