

STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Film BOPP Standard - 24 my ***Film BOPP Standard - 27 my***

Taghleef Industries S.L declares that the above listed bioriented polypropylene films, when leaving the factory, have a composition that complies with the following requirements for direct food contact applications:

1. **EUROPEAN UNION:** Articles 3, 11 (5), 15 and 17 of Regulation (EC) No. 1935/2004 and Regulation (EU) No. 10/2011 (including its amendments up to Regulation (EU) 2023/1627) and Resolution AP (89)1. Monomers and additives are listed in the Annex I of the Regulation (EU) No. 10/2011. Migration tests, carried out following the Regulation (EU) No. 10/2011 (simulants A, B, D2 at the condition of 10 days at 40°C), confirm an Overall migration results below to 10 mg/dm² (as reported here below):

Simulant A (mg/dm ²)	Simulant B (mg/dm ²)	Simulant D2 (mg/dm ²)
0.2	0.4	1.4

The above listed films can contain some substances for which a specific migration limit (SML) is established. Specific migration has been evaluated in compliance with Regulation (EU) No. 10/2011 in a theoretical (assuming that 1 Kg of food is packaged with 6 dm² of film) or, if necessary, in experimental way (simulants A, B and D2 for 10 days at 60°C). Herewith we report the analysis' results.

SML substances	Simulant A (mg/Kg)	Simulant B (mg/Kg)	Simulant D2 (mg/Kg)
FCM Nr: 19 Ref Nr: 39090 + FCM Nr: 20 REF Nr: 39120 SML(T): 1.2 mg/Kg	<0.5	<0.5	<0.5
FCM Nr: 231 CAS Nr: 108-05-4 Ref Nr: 10120 SML : 12 mg/kg	<1	<1	<1
FCM Nr.: 325 CAS Nr.: 141-32-2 Ref Nr: 10780 SML: 6.0 mg/Kg	<1	<1	<1
FCM Nr: 356 CAS Nr: 592-41-6 Ref Nr: 18820 SML : 3 mg/kg	<1	<1	<1
FCM Nr: 779 CAS Nr: 182121-12-6 Ref Nr: 39815 SML: 0.05 mg/Kg	<0.02	<0.02	<0.02

In order to verify the compliance of annex II of Regulation (EU) 10/2011, a specific migration analysis has been carried out concerning the metals (simulant B for 10 days at 60°C). Herewith we report the analysis' results.

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Metals	Simulant B (mg/Kg)	Metals	Simulant B (mg/Kg)
Aluminium	<0.1	Iron	<1
Antimony	<0.01	Lanthanum	<0.01
Arsenic	<0.002	Lead	<0.005
Barium	<0.1	Lithium	<0.1
Cadmium	<0.002	Manganese	<0.1
Chrome	<0.01	Mercury	<0.002
Cobalt	<0.01	Nickel	<0.01
Copper	<1	Terbium	<0.002
Europium	<0.01	Zinc	<1
Gadolinium	<0.01		

The above listed films can contain some other substances for which a specific migration limit (SML) is established. For these substances the SML will not be exceeded even to a maximum thickness of 100 µm (assuming that 1 Kg of food is packaged with 6 dm² of film):

FCM Nr: 132	CAS Nr: 75-38-7	Ref Nr: 26140	SML	5	mg/kg
FCM Nr: 264	CAS Nr: 111-66-0	Ref Nr: 22660	SML	15	mg/kg
FCM Nr: 282	CAS Nr: 116-15-4	Ref Nr: 18430	SML	0.01	mg/kg
FCM Nr: 292	CAS Nr: 122-20-3	Ref Nr: 94560	SML	5	mg/kg
FCM Nr: 315	CAS Nr: 128-37-0	Ref Nr: 46640	SML	3	mg/kg
FCM Nr: 402	CAS Nr: 1314-13-2	Ref Nr: 96240	SML	5	mg/kg (expressed as zinc)
FCM Nr: 433	CAS Nr: 2082-79-3	Ref Nr: 68320	SML	6	mg/Kg
FCM Nr: 661	CAS Nr: 27676-62-6	Ref Nr: 95360	SML	5	mg/Kg
FCM Nr: 688	CAS Nr: 38613-77-3	Ref Nr: 92560	SML	18	mg/Kg
FCM Nr: 760	CAS Nr: 119345-01-6	Ref Nr: 83595	SML	18	mg/Kg
FCM Nr: 974	CAS Nr: 939402-02-5	Ref Nr: 74050	SML	10	mg/kg

In accordance with Regulation (EC) No. 2023/2006 TI S.L films are manufactured in compliance with general rules on good manufacturing practice (GMP).

2. DUAL USE ADDITIVES: The following dual use additives subject to restriction in food as defined in Regulation (EC) No. 1333/2008 and Regulation (EU) No. 10/2011 are present in the above mentioned film:

- Calcium carbonates E170
- Alpha Tocopherol E307
- Butylated hydroxytoluene E321
- Citric Acid E330
- Sodium, potassium and calcium salts of fatty acids E470a
- Magnesium salts of fatty acids E470b
- Mono and diglycerides of fatty acid E471
- Silicon dioxide E551
- Magnesium silicates E553b
- Fatty acids E570
- Dimethyl polysiloxane E900
- Polyethylene glycol E1521

Their migration is lower than the overall migration reported at point 1

3. PHTHALATES: Phthalates are not intentionally added in the above mentioned films. However, traces of phthalates may be present as impurities from the catalytic system used to manufacture some of the base polyolefin resins used for BOPP production; maximum residuals are no more than 15 ppm.

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4. **USA:** The above listed films are suitable for use in food contact applications with the following restrictions based on the composition of the film and the U.S. FDA regulation applicable:

Base film: The raw materials used in the composition of the BOPP film are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 177.1520 (c) 1.1a, 3.1a, 3.2a and other applicable regulations in 21 CFR referenced therein.

Adhesive: The raw materials used in the composition of the olefin copolymer (adhesive) are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 175.320 and other applicable regulations in 21 CFR referenced therein.


Adhesion promoter: The raw materials used in the composition of the adhesion promoter are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations 21 CFR 175.105 and other applicable regulations in 21 CFR referenced therein.

Customers must check that their use of our films is safe and technically suitable in their applications. The final item producer is responsible for the evaluation of global/specific migration at the real time/temperature conditions.

This document is in compliance with the art. 16 of Reg. 1935/2004/EC and it is specifically made for Taghleef Industries

S.L customers. Declaration is valid starting from the below issue date, and will be modified in the case of significant modification in our products formula structure or in the case of legislation amendments.

The Customer has the responsibility to check periodically the update of the present document. Film guarantee: please refer to the product specification.

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