

- Polyester : Hostaphan® • Melinex® • Mylar® • Lumirror®
- OPP • TI-Films® • Treofan® • Bio-Folien • PLA
- Zellglas: Cellophan® • NatureFlex™ • PS
- PEN: Teonex® PI: Kapton® • Upilex®
- Hart-/Weich-PVC • Polyamid
- Di-/Tri-Acetat • Tyvek®
- Rollen • Formate • Lohnschneiden



Pütz GmbH + Co. Folien KG • Postfach 1465 • D-65222 Taunusstein

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**DECLARATION ON COMPLIANCE WITH FOOD CONTACT REGULATIONS**

**Product: Transparent BOPP film 20 µm**

The manufacturer declare that the above listed bioriented polypropylene films, when leaving from our Dubai and Oman factories, have a composition that complies with the following requirements for food contact applications:

**1. EUROPEAN UNION:** Regulations (EC) No. 1935/2004 and Regulation (EU) No. 10/2011 (including its amendments up to Regulation (EU) 2018/831).

Monomers, additives and other starting substances 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 and D2 at the condition of 10 days at 40°C), confirm an Overall migration results below to 10 mg/dm<sup>2</sup>, as reported here below:

	Simulant A (mg/dm <sup>2</sup> )	Simulant B (mg/dm <sup>2</sup> )	Simulant D2 (mg/dm <sup>2</sup> )
All film types	1.2	< 1	2.3

Overall migration test, made in simulants A, B and D2 at the condition of 2 hours at 100°C, confirm values within law limit.

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 way (assuming that 1 kg of food is packaged with 6 dm<sup>2</sup> 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 PM Ref.: 39090 + FCM Nr.: 20 PM Ref.: 39120 SML (T): 1.2 mg/kg	< 0.1	0.3	< 0.1
FCM Nr.: 157 CAS Nr.: 84-74-2 PM Ref.: 74880 SML: 0.3 mg/kg	< 0.1	< 0.1	< 0.1
FCM Nr.: 587 CAS Nr.: 10094-45-8 PM Ref.: 68400 SML: 5 mg/kg	< 1.0	< 1.0	< 1.0
Aluminium SML : 1 mg/kg	< 0.1	0.3	< 0.1
Zinc SML : 5 mg/kg	< 1	< 1	< 1

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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 film thickness of 350 µm (assuming that 1 kg of food is packaged with 6 dm<sup>2</sup> of film):

FCM Nr.: 760	CAS Nr.: 119345-01-06	PM Ref.: 83595	SML : 18 mg/kg
FCM Nr.: 652	CAS Nr.: 26741-53-7	PM Ref.: 38820	SML : 0.6 mg/kg
FCM Nr.: 433	CAS Nr.: 2082-79-3	PM Ref.: 68320	SML : 6.0 mg/kg
FCM Nr.: 283	CAS Nr.: 117-81-7	PM Ref.: 74640	SML : 1.5 mg/kg
FCM Nr.: 500	CAS Nr.: 7128-64-5	PM Ref.: 38560	SML : 0.6 mg/kg
FCM Nr.: 661	CAS Nr.: 27676-62-6	PM Ref.: 95360	SML : 5.0 mg/kg
FCM Nr.: 779	CAS Nr.: 182121-12-6	PM Ref.: 39815	SML : 0.05 mg/kg
FCM Nr.: 783	CAS Nr.: 736150-63-3	PM Ref.: 55910	SML(T) : 60 mg/kg

In accordance with Regulation 1935/2004/EC Art. 17 the manufacturer has implemented an appropriate system which allows the traceability of OPP films up to the single reel.

In accordance with Regulation 2023/2006/EC OPP films are manufactured in compliance with general rules on good manufacturing practice (GMP).

**2. DUAL USE ADDITIVES:** The following dual use additives (food additives or flavourings) subject to a restriction in food as defined in regulation (EU) No. 10/2011 are present in the above mentioned film:

- Na, K & Ca salt of fatty acids E470a
- Mg salt of fatty acids E470b
- Mono- & Diglycerides of fatty acids E471
- Polyglycerol esters of fatty acid E475
- Silicon dioxide E551
- Citric acid E330
- Polydimethylsiloxane E900

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

**3. HEAVY METALS:** Directive 94/62/EC (incl. its amendments up to Directive 2013/2/EU), D.L. n.152/2006 and U.S. CONEG legislation. Lead, Cadmium, Mercury, Chrome Hexavalent are not intentionally added on the films. The manufacturer have total heavy metal content, due to incidental sum of concentration, lower than 100 ppm.

#### 4. BADGE,

substances BADGE, BFDGE, NOGE are not intentionally used in the manufacture or formulation of the films.

**5. ALLERGENS:** Substances listed in Annex II of Regulation (EU) No. 1169/2011 are not intentionally added to film formulations of the manufacturer (Dubai and Oman) that includes as well substances belong to the eight major foods or food groups as identified in Sec. 202 (2) of FDA food allergen labelling and consumer protection act of 2004.

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**6. PHTHALATES:** The phthalates are not intentionally added in the above mentioned films. However DIBP, DBP, DEP and ethyl isobutyl phthalate could be as minor components; maximum residuals are not more than 15 ppm.

**7. OTHER ABSENCES:** The manufacturer declares that in the recipes of films, the substances listed below are not intentionally added:

Acetyl acetone	Biocides	Formaldehyde	PFOA/PFOS
Acryl amide	Bisphenol A	ITX	PVC/PVDC
Aromatic amines	CMR Substances	Latex	Triclosan
Asbestos	Dimethyl fumarate	Melamine	Vinyl Chloride
Azocolorants	Dioxins & furans	Nanoparticles	
Benzophenone	ESBO	Nonylphenol & nonylphenol ethoxylate	
BHA, BHT	Flame Retardants	Organotin Compounds	

**8. USA:** The subject BOPP transparent films are suitable for use in food contact applications in compliance with applicable U.S. FDA food packaging regulations. Specifically, the raw materials used in the composition of the subject the manufacturer products are in compliance with the requirements of Title 21 of the U.S. Code of Federal Regulations (21 CFR) 21 CFR 177.1520 (c) 3.1a and other applicable regulations in 21 CFR referenced therein.

**9. RECYCLABILITY:** BOPP transparent films are suitable for recycling and can be effectively disposed of through incineration. Full combustion of polypropylene yields almost entirely carbon dioxide and water. Waste reduction by energy recovery yields 24 MJ/Kg polypropylene.

Customer 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 the manufacturer customers.

Declaration is valid starting from the above issue date and will be modified in the case of significant modification in the manufacturer product's formulation, 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

The information contained in this document must be intended as confidential. Any type of divulgation, copy or modification not expressly authorized by the manufacturers is prohibited.

This information is taken from the original manufacturer's certificate