

Compliance Declaration

Product: **RINCEL MXM FILM** (BOPP – Biaxially Oriented Polypropylene Film) Date: 26/04/2021

The **RINCEL MXM FILM** hereafter mentioned as "film", is produced with raw materials that comply with the relevant requirements of:

- The **Regulation (EC) No 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.
- The Commission **Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles to come into contact with food, as amended up to Regulation (EU) 2020/1245.
- The Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives (BADGE, NOGE, BFDGE) in materials and articles intended to come into contact with food.
- The European Parliament and Council **Directive 94/62/EC** of 20 December 1994 on packaging and packaging waste (which stipulates that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100ppm by weight).
- This product is manufactured according to the requirements of the Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Overall migration tests carried on this film confirm that it complies with the overall migration limit (OML) of 10mg/dm2 for the following food simulants and test conditions:

Food simulant	Test conditions	
Ethanol 10% (Food simulant A)	10 days at 40°C (test no. OM2)	
Acetic acid 3% (Food simulant B)	10 days at 40°C (test no. OM2)	
Isooctane (Alternative food simulant D2)	24 hours at 40°C (equivalent to test no. OM2)	

Table 3 Food simulant assignment for demonstrating compliance with the overall migration limit		
Foods covered	Food simulants in which testing shall be performed	
all types of food	1. distilled water or water of equivalent quality or food simulant A;	
	 food simulant B; and food simulant D2. 	

Regulation EU 10/2011 – Annex III:

CASFIL - Indústria de Plásticos, S.A.

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Table 3 Standardised conditions for testing the overall migration				
Column 1 Column 2		Column 3		
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing	Intended food contact conditions		
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration (\leq 30 minutes).		
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions		
OM2	10 d at 40 °C	Any long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C \leq T \leq 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.		
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C \leq T \leq 100 °C for maximum of t = 120/ 2^((T-70)/10) minutes, which are not followed by long-term room temperature or refrigerated storage.		

Regulation EU 10/2011 – Annex V – chapter 3:

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.

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According to the information provided by the raw-materials suppliers, available until now, some grades that can be used in the production of the film may contain:

 Substances subject to specific migration limit (SML), which will not be exceeded up to a thickness of 60µm (ratio 6 dm²/kg):

Ref. No	CAS No	SML (mg/kg)
38820	0026741-53-7	0,6
38840	0154862-43-8	5
39090	****	1,2
39120	****	1,2
39815	0182121-12-6	0,05
68320	0002082-79-3	6
83595	0119345-01-6	18
92560	0038613-77-3	18
95280	0040601-76-1	6
95360	0027676-62-6	5
****	0007429-90-5	1

Dual-use additives (approved as food additives): E330, E470, E470a, E470b, E471, E551.

Based on the available information on the raw-materials used in the production of the films, we deem that **Bisphenol A (BPA)** is neither used nor intentionally added in their formulations. However, the raw-materials as well as the film have not been tested for this substance.

It is the responsibility of the customer to check the suitability of the product for the intended particular purpose.

This declaration only refers to the films in their original form, as supplied by Casfil and does not extend to subsequent modifications.

This declaration shall continue in effect for one year from its issue date.

For further information, please contact a Casfil representative.

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