

## Declaration of Compliance

Product: **ROVAC FILM (Vacuum packaging film)**

Date: 26/04/2023

### EU Food contact:

The **ROVAC 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.
- 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:

Overall migration tests carried on this film confirm that it complies with the overall migration limit (OML) of 10mg/dm<sup>2</sup> 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)

### *Regulation EU 10/2011 – Annex III:*

<i>Table 3</i>	
<b>Food simulant assignment for demonstrating compliance with the overall migration limit</b>	
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; 2. food simulant B; and 3. food simulant D2.

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

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 $70\text{ °C} \leq T \leq 100\text{ °C}$ 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 $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum of $t = 120/2^{(T-70)/10}$ minutes, which are not followed by long-term room temperature or refrigerated storage.

Test OM2 covers also food contact conditions described for OM0, OM1 and OM3.

### **Information on substances subject to restrictions:**

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:

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- Substances subject to specific migration limit (SML) <60mg/kg:

Ref. No	CAS No	SML (mg/kg)
12670	0002855-13-2	6
14200 / 41840	0000105-60-2	15
15274 / 18460	0000124-09-4	2,4
18430	0000116-15-4	ND
18820	0000592-41-6	3
19150	0000121-91-5	5
19960	0000108-31-6	30
22660	0000111-66-0	15
26140	0000075-38-7	5
68320	0002082-79-3	6
Annex II - Aluminium	0007429-90-5	1
Annex II - Zinc	0007440-66-6	5

- Dual-use additives (approved as food additives): E170, E432, E470a, E551, E553b, E1521.

### **Heavy metals:**

The film is produced with raw materials that comply with the following requirements:

- 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).

### **Other substances:**

Based on the available information on the raw materials used in the production of the film, we deem that the following substances are neither used nor intentionally added in their formulations. However, the raw materials as well as the film have not been tested for these substances.

- Allergens (as defined in Regulation (EU) No 1169/2011)
- Bisphenol A (BPA) (Regulation (EU) No 321/2011)
- BADGE, NOGE, BFDGE (Regulation (EC) No 1895/2005)

### **Notice:**

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.