

## Declaration of Compliance

| Description         | Material                 | Article Number |
|---------------------|--------------------------|----------------|
| Sealing film for PP | Layers: BOPA/Adhesive/PP | 151548         |

Duni declares that the article meets the requirements of:

- Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004 (Framework regulation)
- EU Regulation 2023/2006/EC (GMP)
- EU Regulation 10/2011/EC with amendments (Plastic regulation)
- EU Regulation (EU) 2024/3190 on the use of bisphenol A (BPA) and other bisphenols
- BfR recommendation XXVIII (adhesive)

This plastic product has been manufactured only with monomers, other starting substances and additives that are authorized under Regulation (EC) 10/2011 and all amendments.

### Area of use

Based on the migration tests and Declaration of Compliance, the sealing film can be used safely with all types of food under following conditions:

- any long-term storage at room temperature or below
- Temperatures:
  - 70°C for up to 4 hours, or
  - 100°C for up to 2 hours (including hotfill<sup>1</sup> conditions)
  - 121°C for up to 1 hour
- Microwave oven (make sure to puncture the film before use if sealed to a box or tray to allow the steam to ventilate).

This film is not suitable for use in conventional ovens.

---

<sup>1</sup> Definition from COMMISSION REGULATION (EU) 2016/1416: “hot-fill” means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.

The process ability and the various properties of this film (resistance of the sealing, mechanical properties, antifog effect - this one may be lost during a thermic treatment) in these conditions must be validated by the customer.

*High temperatures recommendations*

The film can be used at temperatures up to 100°C according to the migration tests performed (see Test conditions), but at high temperatures, the material loses some of its mechanical properties. The pressure created when packed under MAP (modified atmosphere packaging) may cause the sealing to break.

Remove the film from the tray if it is used in temperatures above 100°C.

*Low temperatures recommendations*

In frozen conditions, plastic sealing film generally becomes more brittle due to the low temperatures, which can affect its flexibility and potentially its sealing properties. If the film is used in frozen condition, be aware:

- The film may become less flexible and may crack or tear more easily.
- Freezing can weaken the seal of the film over time. For food packaging, this could lead to freezer burn or moisture loss if the seal breaks or weakens.
- Handle frozen packages gently.

**Overall migration (1)**

According to the above-mentioned regulations, the overall migration does not exceed 10 mg/dm<sup>2</sup> or 60 mg/kg.

**Specific migration (2)**

The product contains substances that are subject to restrictions under the plastic regulation 10/2011 and its amendments.

| Substance                      | CAS and Ref. No. | SML        |
|--------------------------------|------------------|------------|
| Caprolactam                    | 105-60-2         | 15 mg/kg   |
| 9,9-bis(methoxymethyl)fluorene | 182121-12-6      | 0,05 mg/kg |
| Acrylic acid, methyl ester     | 96-33-3          | 6 mg/kg    |
| Aluminium                      | -                | 1 mg/kg    |

### Test conditions

Migration tests on the article material performed by an independent institute showed that under the following test conditions, overall migration (see 1.) falls considerably below the limit given by regulation 10/2011.

#### Overall migration

| <i>Simulant</i>    | <i>Test conditions</i> | <i>Result (mg/dm<sup>2</sup>)</i> |
|--------------------|------------------------|-----------------------------------|
| 10 % Ethanol (A)   | 4 h 100°C              | < 10                              |
| 3% Acetic acid (B) | 4 h 100°C              | < 10                              |
| Olive oil (D2)     | 2 h 100°C              | < 10                              |

Ratio of food contact surface area to volume of component used to establish the compliance of material is 6 dm<sup>2</sup>/kg.

The plastic in this product contains additives that are subject to a restriction in food as referred to in Article 11.3 of EU Regulation 10/2011.

| <b>Substance</b>   | <b>Ref. No.</b> | <b>E-number</b> |
|--|-----------------|-----------------|
| Polyoxyethylene sorbitan monolaurate;<br>Polysorbate 20        | 79040           | E432            |
| Mono- and diglycerides of fatty acids                          | 30610/30612     | E471            |
| Magnesium oxid   |                 | E530            |
| Silica/Silicone dioxide  | 86240           | E551            |
| Talc   | 92080           | E553b           |
| Dimethyl polysiloxane;<br>Polydimethylsiloxane (Mw > 6 800 Da) | 76721           | E900            |

Recommended storage conditions: 15° C-25° C (55° F-77° F) in a dry place, away from direct sunlight.

Please be advised that Duni AB does not add anything to the product.

---

To the best of our knowledge, the information provided is accurate and reliable as of the date of publication and, where relevant, reflects the information received from suppliers. It is valid from the stated issue date until it is replaced or superseded.