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DECLARATION OF COMPLIANCE

Description	Material	Article Number
Sealing film for PP	Layers: BOPA/Adhesive/PP	107075

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)
- 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

The items can be used safely with all types of food under following conditions:

- Long term storage above 6 months at room temperature or below
- Temperatures:
 - o 70°C for up to 4 hours, or
 - o 100°C for up to 2 hours
 - o 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.

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.

Overall migration (1)

Overall migration is below 10 mg/dm² under standard testing conditions laid down in Regulation (EC) No. 10/2011.

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Specific migration (2)

The material contains substances that are subject to restrictions according to regulation 10/2011/EC.

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

Simulant	Test conditions	Result (mg/dm²)
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 dm²/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.

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

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 as received from suppliers. It is valid from the stated issue date until it is replaced or superseded.

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