

DECLARATION OF COMPLIANCE

Description	Material	Article Number
<i>Sous vide</i>	PE	162016

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)

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. A risk assessment according to Article 18 and Article 19 of Regulation (EC) No. 10/2011 has been performed for this product.

Area of use

The bags can be used for aqueous, acidic, dry and fatty foodstuffs for

- Any long-term storage at room temperature or below
- Hotfill¹ conditions
- High temperature applications (2 hours at 100°C or 1 hour at 121°C)
- Microwave
- Sous-vide

Overall migration (1)

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

Specific migration (2)

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

Substance	CAS	Ref. no. (10/2011)	SML
1-hexene	592-41-6	18820	3 mg/kg
Octadecyl 3-(3,5-di-tert-butyl-4- hydroxyphenyl)propionate	2082-79-3	68320	6 mg/kg
Aluminium	-	-	1 mg/kg
Iron	-	-	48 mg/kg
Maleic anhydride	108-31-6	19960	30 mg/kg
Caprolactam	105-60-2	14200 /41840	15 mg/kg
Vinylidene fluoride	75-38-7	26140	5 mg/kg
Hexafluoropropylene	116-15-4	18430	ND

*ND (No migration is permitted)

¹ 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.

Test conditions

Migration tests on the material of the article performed by an independent institute showed that under the following test conditions overall migration (see 1.) and specific migration (see 2.) fall below the respective limits given by regulation 10/2011.

Overall migration OM5²

10 % Ethanol	2 hours at 100°C
3% Acetic acid	2 hours at 100°C
95 % Ethanol	4 hours at 60°C
Isooctane	2 days at 60°C

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	CAS No	E-number
Calcium carbonate	471-34-1	E170
Magnesium oxide	1309-48-4	E530
Polyethylene glycol	25322-68-3	E1521
Silica	7631-86-9	E551

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.

This document was issued electronically and is therefore valid without signature.

² Test OM5 covers food contact conditions “High temperature applications up to 121 °C.”