Declaration of Compliance

Description	Material	Article Number
Multi Sealing Film	PET/Nylon/PE	**159848**

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

Overall migration (1)
According to the above-mentioned regulations, the overall migration does not exceed 10 mg/dm² 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 No	SML (mg/kg)
Aluminum	-	1
Iron	-	48
Zinc	-	5
Terephthalic acid dichloride	100-20-9	7,5
Terephthalic acid	100-21-0	7,5
4,4 MDI (diphenylmethane-4,4′-diisocyanate)	101-68-8	ND
Ethylene glycol	107-21-1	30
Acetic acid, vinyl ester	108-05-4	12
Diethylene glycol	111-46-6	30
1-Octene	111-66-0	15
Isophthalic acid	121-91-5	5
Antimony trioxide	1309-64-4	0,04
Octadecyl 3-(3,5-di-tert.-butyl-4-hydroxyphenyl)propionate	2082-79-3	6
2,4 MDI (diphenylmethane-2,4′-diisocyanate)	5873-54-1	ND
Acetaldehyde	75-07-0	6
Propylene oxide	75-56-9	ND

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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
- hotfill[1] conditions (also when packed under these conditions)
- high temperature applications (4 hours at 100°C)
- microwave

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.

[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.

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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.

Calculation of "worst case "migration (100%) for above mentioned substances shows that none can exceed their respective SML. Calculation is based on the maximum number of substances found in raw materials according to our suppliers' Declarations of Compliance.[2]

Overall migration OM6[3]

Simulant	*Contact time*	*Temperature*	*Result (mg/dm^3)*
10 % Ethanol	*4 hours*	*100°C*	*< 1*
3% Acetic acid	*4 hours*	*100°C*	*< 1*
Olive oil	*6 hours*	*100°C*	*< 1*

Specific migration of PAA

Simulant	*Contact time*	*Temperature*	*Result (mg/kg)*
3% Acetic acid	*4 hours*	*100°C*	*< 0,01*

Specific migration of metals

Simulant	*Contact time*	*Temperature*	*Result (mg/kg)*
3% Acetic acid	*4 hours*	*100°C*	*< 0,01*

The ratio of the sample area to the volume of the simulant is 2dm^2/100ml.

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***
2,6-Di-tert-butyl-p-cresol, Butylated hydroxytoluene (BHT)	315	E321
Calcium salts of fatty acids	106	E470a
Silicon dioxide, Synthetic silica, Silica	504	E551
Phosphoric acid	509	E338
Acetic acid	115	E260
Potassium hydroxide	399	E525

[2] Regulation (EU) No 10/2011, Annex V, 2.2.2: "To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration."
[3] OM6 test conditions corresponds to intended food contacts conditions "Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C" according to EU Regulation 10/2011/EC.

Recommended storage conditions: 15^0 C-25^0 C (55^0 F-77^0 F) in a dry place, away from direct sunlight. Maximum storage time from point of unloading of goods to be 6 months, if stored as recommended.

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

This document of compliance is based on:
- Documentation from suppliers
- Migration analysis

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.

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