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Declaration of Compliance

Food contact materials · Packaging and Packaging Waste Regulation (EU) 2025/40 (PPWR)

Issued by	Plastdurker Kft. HU-1113 Budapest, Badacsonyi utca 13/A Tax no.: 12317011-2-43 · Company reg. no.: 01-09-665605
Product	**PA/PE CO-EXTRUDED FILM AND VACUUM BAGS**, transparent, 50–200 µm (standard vacuum bags 65 and 85 µm), unprinted
Structure (outside → inside)	Polyamide (PA) – tie layer – low-density polyethylene (LDPE). The LDPE layer is in contact with food. There is no functional barrier.
Manufacturer	EU / non-EU film manufacturer as stated on the delivery note and product label; full identity and address available on request
Intended use	Vacuum packaging of all types of food, including chilled and frozen storage and cooking in the bag within the limits of section 5
Scope	Product supplied by Plastdurker Kft. from approved manufacturers whose supporting declarations are held on file
Document no.	PD-DoC-PAPE-2026-10
Date of issue	02/10/2026
Valid until	01/10/2027 (12 months from issue), or until a change in composition or legislation

1. EU food contact legislation

Plastdurker Kft. declares that the PA/PE film and vacuum bags is produced from raw materials and under conditions that comply with the relevant requirements of:

- **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;
- **Commission Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food, as last amended by Commission Regulation (EU) 2026/245;
- **Commission Regulation (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food;
- **Commission Regulation (EU) 2024/3190** on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives in food contact materials, as corrected by Regulation (EU) 2026/250;
- **Commission Regulation (EC) No 1895/2005** on the restriction of use of certain epoxy derivatives (BADGE, BFDGE, NOGE).

Compliance with Commission Regulation (EU) 2025/351, which amends Regulations (EU) No 10/2011, (EU) 2022/1616 and (EC) No 2023/2006, is based on the information currently available from our suppliers. In accordance with its transitional provisions, materials placed on the market before 16 September 2026 may continue to be placed on the market until stocks are exhausted.

2. Non-intentionally added substances (NIAS)

According to Article 3 of Regulation (EU) No 10/2011, a “non-intentionally added substance” (NIAS) is an impurity in the substances used, a reaction intermediate formed during production, or a decomposition or reaction product.

In line with Article 3 of Regulation (EC) No 1935/2004 and Articles 6(4) and 19 of Regulation (EU) No 10/2011, the manufacturer has assessed NIAS in the PA/PE film and vacuum bags according to internationally recognised scientific principles of risk assessment. Based on the available information, no safety concern has been identified under the intended conditions of use.

3. Overall migration

Overall migration was tested by an independent laboratory on a representative 150 µm PA/LDPE film (test date 22/11/2018). The results comply with the overall migration limit of Article 12 of Regulation (EU) No 10/2011. The simulants cover all types of food.

Food simulant	Test conditions	Result	Limit
Ethanol 10% (A)	10 days at 40 °C (OM2)	2.6 mg/dm²	10 mg/dm²
Acetic acid 3% (B)	10 days at 40 °C (OM2)	2.9 mg/dm²	10 mg/dm²
Vegetable oil (D2)	10 days at 40 °C (OM2)	5.3 mg/dm²	10 mg/dm²

In accordance with Annex V, Chapter 3 (Table 3) of Regulation (EU) No 10/2011, test OM2 also covers the food contact conditions of OM0, OM1 and OM3:

Test	Test conditions	Intended food contact conditions
OM0	30 min at 40 °C	Any food contact at cold or ambient temperature for a short duration (≤ 30 minutes)
OM1	10 days at 20 °C	Any food contact at frozen and refrigerated conditions
OM2	10 days at 40 °C	Any long-term storage at room temperature or below, including when packed under hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes
OM3	2 hours at 70 °C	Any food contact that includes hot-fill and/or heating up to 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes, not followed by long-term room-temperature or refrigerated storage

4. Specific migration and restricted substances

Specific migration was tested on the same film (10 days at 60 °C in 10% ethanol, 3% acetic acid and olive oil, or the alternative simulants indicated by the laboratory). Results are calculated for 6 dm² of film per kg of food:

Substance	CAS / FCM	Result (mg/kg)	SML (mg/kg)
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	1.9	6
Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester	FCM 74400	< 3.17	30
Mono- and diethylene glycol	107-21-1 / 111-46-6	< 0.11 / < 0.47	30
N,N-bis(2-hydroxyethyl)alkyl (C8–C18) amine	FCM 39090	< 0.17	1.2
1-Hexene	592-41-6	< 0.0001	3
Maleic anhydride (as maleic acid)	108-31-6	< 1.44	30
Hexamethylenediamine	124-09-4	< 0.35	2.4
Caprolactam	105-60-2	1.2	15
Zinc	7440-66-6	< 0.01	5

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Dual-use additives. The film contains vitamin E (E 307, FCM 93520) and talc (E 553b), which are also authorised food additives (Article 11(3) of Regulation (EU) No 10/2011). Their estimated migration at 6 dm²/kg is 15.6 mg/kg (10% ethanol), 17.4 mg/kg (3% acetic acid) and 31.8 mg/kg (vegetable oil), below 60 mg/kg. For packs with a higher surface-to-volume ratio (up to 11.75 dm²/kg, i.e. small bags), the conservative estimate for fatty foods is 62.3 mg/kg. The customer should check such uses with Plastdurker before use.

5. Conditions of use and cooking in the bag

- Types of food: all types of food.
- Storage: long-term storage at room temperature or below, including chilled and frozen storage (OM2 covers OM1).
- Surface-to-volume ratio used to establish compliance: 6 dm²/kg (see the note on small bags in section 4).

Heating and cooking in the bag (e.g. sous-vide, pasteurisation). In terms of food safety, the film is validated for heating within the time–temperature limits below (OM2 conditions, t = 120/2^((T-70)/10) minutes):

Temperature (°C)	Maximum time (minutes)
70	120
75	85
80	60
85	42
90	30
95	21
100	15

Longer heating times at lower temperatures (for example 70 °C for 12–14 hours) have **not** been validated and are not covered by this declaration; they would require additional migration testing. Retort or sterilisation conditions (e.g. 121 °C) are not covered; for these a PA/PP structure validated up to 121 °C for 6 hours is available on request, with a separate declaration.

USA. The polyethylene component complies with US FDA 21 CFR 177.1520 (c) 3.2a; it may be used in contact with all food types of Table 1 and conditions of use A–H of Table 2 of 21 CFR 176.170(c).

6. Packaging and Packaging Waste Regulation (EU) 2025/40 (PPWR)

Regulation (EU) 2025/40 amends Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repeals Directive 94/62/EC. It sets sustainability and labelling requirements for the whole life cycle of packaging as a condition for placing packaging on the market, and has applied since **12 August 2026** (Article 71). Based on the official declarations of our suppliers and the available analytical results, Plastdurker Kft. declares the following:

6.1 Heavy metals – Article 5(4). The sum of the concentrations of lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr VI) resulting from substances present in the PA/PE film and vacuum bags does not exceed **100 mg/kg**.

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6.2 PFAS in food-contact packaging – Article 5(5). Since 12 August 2026, food-contact packaging must not be placed on the market if it contains per- and polyfluoroalkyl substances (PFAS) at or above the limits below. The PA/PE film and vacuum bags complies with these limits:

PFAS parameter	PPWR limit	Status
Any individual PFAS, targeted analysis (polymeric PFAS excluded)	< 25 ppb (µg/kg)	Compliant
Sum of PFAS, targeted analysis, with prior degradation of precursors where applicable (polymeric PFAS excluded)	< 250 ppb (µg/kg)	Compliant
PFAS including polymeric PFAS, measured as total fluorine (TF)	< 50 ppm (mg/kg)	Compliant

This is based on the film manufacturer's declaration under Regulation (EU) 2025/40 (31 August 2026) and its PFAS statement (June 2026): PFAS are not intentionally added to the raw materials or during production. The approach follows the stepwise method in the European Commission's guidance on Regulation (EU) 2025/40 (C(2026) 3702, June 2026), which starts from total fluorine. This assessment reflects current knowledge and may be revised if the guidance is clarified.

6.3 Substances of concern – Article 5(1). The presence and concentration of substances of concern in the PA/PE film and vacuum bags are minimised, as described in the REACH and other-substances sections of this declaration.

6.4 Recycled content – Article 7. The manufacturers do not use recycled material, so the product contains **no post-consumer recycled plastic**. The recycled-content targets of Article 7 apply from 1 January 2030.

6.5 Recyclability – Article 6. PA/PE is a multi-material structure. Such structures are generally assessed as having limited recyclability in polyethylene recycling streams. The recyclability performance grade will be determined once the design-for-recycling criteria are adopted in the delegated acts under Article 6 (from 2030 at the earliest).

6.6 Labelling and technical documentation. The harmonised labelling requirements of Article 12 will apply from 12 August 2028 (or 24 months after the implementing act, if later). On request, Plastdurker Kft. will give its customers the information and supplier evidence they need for the technical documentation referred to in Annex VII and the EU declaration of conformity (Article 39).

7. REACH – Regulation (EC) No 1907/2006

According to the declarations of our suppliers, no substance on the ECHA Candidate List of Substances of Very High Concern (SVHC), as updated on 4 February 2026 (253 entries), is present in the product at a concentration above **0.1% (w/w)**. No substance listed in Annex XIV is used, and the applicable restrictions of Annex XVII are respected. If this changes, Plastdurker Kft. will inform its customers in line with Article 33 of REACH.

8. Other substances

Based on the information available on the raw materials, the following substances are neither used nor intentionally added. Unless stated otherwise, the product has not been specifically tested for them.

- Allergens listed in Annex II of Regulation (EU) No 1169/2011
- Bisphenol A (BPA) and other hazardous bisphenols (Regulation (EU) 2024/3190)
- BADGE, BFDGE and NOGE (Regulation (EC) No 1895/2005)
- Ortho-phthalates as plasticisers (DEHP, DBP, BBP, DIBP, DINP, DIDP)
- Genetically modified organisms (GMO); nanomaterials
- Per- and polyfluoroalkyl substances (PFAS) – see the PPWR section

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9. Notice

It is the customer's responsibility to check that the product is suitable for the intended use, and that the final packaging and packed food comply under real conditions of use (type of food, contact time, temperature and surface-to-volume ratio).

This declaration covers only the PA/PE film and vacuum bags in its original form, as supplied by Plastdurker Kft. It does not cover later changes such as printing, lamination, conversion or the addition of other materials.

Traceability (Article 17 of Regulation (EC) No 1935/2004) is ensured through the roll, lot or box number on the product label and the Plastdurker delivery note. Supporting documents (Article 16 of Regulation (EU) No 10/2011) are available to the competent authorities on request.

This declaration is valid for 12 months from its date of issue. It will be updated earlier if there is a significant change in production, raw materials or the applicable legislation.

This declaration covers unprinted film and bags only. Printed bags need a separate declaration that includes the inks (EuPIA exclusion policy, Swiss Ordinance SR 817.023.21 Annex 10).

Budapest, 02/10/2026

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Authorised signature and company stamp