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Declaration of conformity
for plastic materials and articles intended to come into contact with food
Commission Regulation (EC) No 10/2011

According to Article 16 of Commission Regulation (EC) No 1935/2004 of 27 October 2004 and Article 15 of Commission Regulation (EC) No 10/2011 of 14 January 2011, in relevant version, including corrections and amendments, all materials manufactured by Folienwerk Wolfen GmbH are accompanied by the following Declaration of Conformity (according to annex IV of Commission Regulation (EC) No 10/2011) which permits an easy identification of the materials for which it is issued and allows the downstream user to ensure the compliance of the material to the applicable legislation in the real conditions of use. As demanded by the above mentioned regulations and directives, the appropriate documentation in support of this declaration is available to the national competent authority on request.

1) Identity of the manufacturer

Folienwerk Wolfen GmbH, Guardianstraße 4, 06766 Bitterfeld-Wolfen, Germany

2) Identity of the materials

This Declaration of Conformity is valid for the products listed in Tab. 1 (next page).

3) Compliance with Regulations (EC) No 1935/2004 and Commission Regulation (EC) No 10/2011

According to Regulation (EC) No 1935/2004 (that repeals Directives 80/590/EEC and 89/109/EEC) and Commission Regulation (EC) No 10/2011 (repealing Directive 2002/72/EC and its amendments) the above mentioned material is suitable to come into contact with food.

Compliance with article 17 of the Regulation (EC) No 1935/2004 and article 4(c) of Commission Regulation (EC) No 10/2011 concerning traceability: The full traceability of the material is assured by the information placed on the roll/pallet label.

4) Information on restricted substances

In the production of the above-mentioned material only monomers or starting substances listed in Commission Regulation (EC) No 10/2011 are used.



Tab. 1. Products related to this declaration¹⁾

Product family	Inner layer	Outer layer
Transparent, colored or white PET-A film type 100 to 140	PET-A or Bio-PET virgin material; partly postindustrial recycling (PIR)	PET-A virgin material
Transparent, colored or white PET-G film type 200 ²⁾ to 290	PET-G virgin material; partly postindustrial recycling (PIR)	PET-G virgin material
Transparent, colored or white PET-GAG film type 300 to 340	PET-A or Bio-PET virgin material; PET-A partly postindustrial recycling (PIR)	PET-G, virgin material
Transparent, colored or white R- PET Film Type 160 to 180 (PET-A) and 360 to 390 (PET-GAG)	PET-A, mainly post-consumer recycling (PCR)	PET-A, virgin material (Type 160- 180) or PET-G, virgin material (Type 360-390)
Transparent, colored or white ECO-R-PET Film Type 199 (PET-A)	PET-A, exclusively post-consumer recycling (PCR)	PET-A, exclusively post-consumer recycling (PCR)

All products may contain antiblock/slip additives (in outer layers). Colored products may contain pigments, TiO₂ masterbatch (in inner layers).

5) Information on substances for which specific migration limits (SML's) exist

Migration tests carried out with the above-mentioned material show that the migration values of the substances in the following table are lower than their respective SML's.

Tab. 2. Substances with specific migration limit (SML)

Substance	CAS number	SML (mg/kg)
Acetaldehyde ³⁾	000075-07-0	< 6
Barium sulfate ⁴⁾	007727-43-7	< 1
Di-ethylene glycol ⁵⁾	000111-46-6	< 30 (EG+DEG)
Ethylene glycol ⁵⁾	000107-21-1	
Isophthalic acid ⁵⁾	000121-91-5	< 5
Terephthalic acid ⁵⁾	000100-21-0	< 7.5
Vinyl acetate ⁵⁾	000108-05-4	< 12

According to Commission Regulation (EC) No 10/2011 article 17 (2) the migration value calculations have been done using the surface - volume correlation, product surface 6 dm² in contact with 1 kg of food.

¹⁾ not valid for films with silicone coating, and films of grey-violet colour.

²⁾ not valid for medical green coloured PET-G film type 200

³⁾ Test conditions: migration test in acetic acid, 10 days, 60°C

⁴⁾ only for white and opaque colored material of the products listed in Tab. 1

⁵⁾ Test conditions: migration test in 95% ethanol, 10 days, 60°C



6) Information about additives, which have a restriction for the using in foodstuffs (dual use additives)

In the production of the above mentioned products the following dual use additives are used:

- E 471 (Mono-and Diglycerides of fatty acids)
- E 551 (Silicon dioxide)
Only for white and opaque colored material of the products
- E 171 (Titanium dioxide)
- Inorganic matting agent
- Stearic acid and derivatives

7) Information on specified uses of the material in food packaging

7.1 Types of food intended to come in contact with the above mentioned material:

According to the performed tests the above mentioned material is suitable for food contact for the following categories of food:

- All types of food: dry, aqueous, acidic, alcoholic and fatty foods.

7.2 According to the performed tests the above mentioned material is suitable for contact with the above-mentioned types of food for the following duration and temperature:

- Any long term storage at room temperature or below, including heating up to 70°C for up to 2 hours, or heating up to 100°C for up to 15 minutes (see Regulation (EC) No 10/2011, Annex V, table 3).

7.3 The test of the above-mentioned product was carried out on representative samples under standard conditions as described in Commission Regulation (EC) No 10/2011, Annex V, using substitute test media according to Annex III of the same Regulation:

The overall migration limit of $< 10 \text{ mg/dm}^2$ has been met. The above-mentioned test conditions are generally recognized to be the most severe if the type of food the material will be into contact with and the period of food contact are not specified: Long-time contact between the above-mentioned material and the respective food simulant: 10d, 40°C.

According to Commission Regulation (EC) No 10/2011, Annex III (4), the compliance with the overall migration limit for all types of food was demonstrated using the following food simulants:

<u>Food simulants:</u>	<u>Used food simulant or substitute test:</u>
A: 10% Ethanol	10% Ethanol
B: 3% Acetic acid	3% Acetic acid
D2: Vegetable oil	95% Ethanol ("Substitute fat test") (acc. to Annex III (3) Iso-octane)





This declaration concerns only the above-mentioned products. It does not guarantee compliance with the previously stated directives and regulations when it is used in the production of any article where chemical, physical or other treatment modifies its properties. In this case, the final article must be tested by its manufacturer to confirm compliance with the existing legislation and to confirm that the final article meets the legal, technical and health and safety requirements under the actual conditions of use.

This declaration will be renewed when substantial changes in the production bring about changes in the migration properties of the above-mentioned product, when new scientific data are available or when changes in the existing legislation occur that are of relevance to the above-mentioned product or to this declaration.

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