



DECLARATION OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS *(according to Commission Regulation (EU) 10/2011, Annex IV, and subsequent amendments)*

According to Article 16 of Regulation (EC) No. 1935/2004 of the European Parliament and Council of 27th October 2004, and Article 15 of Commission Regulation (EU) 10/2011 of 14th January 2011, all materials manufactured by Folienwerk Wolfen GmbH are accompanied by the following Declaration of Conformity 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 Compliance is valid for the following products:

A) Transparent or white PET-A film Type 100 to 180

- Composition of materials: PET-A, partly from PIR (post-industrial recycling) materials; outer layers of the film: PET-A, virgin material, antiblock/slip additives

B) Transparent or white PET-G film Type 200 to 240

- Composition of materials: PET-G, Virgin material; partly PIR (post-industrial recycling) materials; outer layers of the film: PET-G, virgin material, antiblock/slip additives

C) Transparent, white or colored opaque PET-GAG film Type 300 to 380

- Composition of materials: PET-GAG, Virgin material; PET-A partly PIR (post-industrial recycling) materials; outer layers of the film: PET-G, virgin material, antiblock/slip additives

White material A to C may contain: TiO₂ masterbatch

3) Compliance with European Regulations 1935/2004 and 10/2011

According to EU Regulation 1935/2004 (that repeals EU Directives 89/109/EC and 80/590/EC) and Commission Regulation (EU) 10/2011 (repealing EU Directive 2007/19/EC) the above mentioned material is suitable to come into contact with food.

Compliance with article 17 of EU Regulation 1935/2004 and article 4(c) of Commission Regulation (EU) 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 (EU) 10/2011 are used.



5) Information on substances for which specific migration limits (SMLs) 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 SMLs.

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

The migration value calculations have been done using the surface – volume – correlation, product surface 6 dm² in contact with 1 kg of food, according to Regulation (EU) 10/2011. 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 brown material A to C

- E 171 (Titanium dioxide)

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

A: 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

B: 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:

- Period of food contact not specified (t > 24 h)
- Room temperature (20 °C) or below.

C: The test of the above-mentioned product was carried out on representative samples under standard conditions as described in Commission Regulation (EU) 10/2011, Annex V, using substitute test media according to Annex III of the same Regulation:

The overall migration limit of < 10 mg/dm² 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 (EU) 10/2011, Annex III (4), the compliance with the overall migration limit for all types of food was demonstrated using the following food simulants:

Food simulants:	Used food simulant or substitute test:
A: 10% Ethanol	Simulant A: 10% Ethanol
B: 3% Acetic acid	Simulant B: 3% Acetic acid
D2: Vegetable oil	95% Ethanol ("Substitute fat test") (acc. to Annex III (3))

This declaration concerns only the above-mentioned product. 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 & 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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