

10/2011 EC Statement of Compliance

Supplier of the product:

MDV Papier- und Kunststoffveredelung GmbH

(issueing this statement)

An der Pfingstweide 3,

D-63791 Karlstein

GERMANY

Manufacturer:

Arjobex SAS

88, rue du Dôme

92100 Boulogne Billancourt

FRANCE

Date: February 24th, 2025

Product: Robuskin PET CL5 FA

Product Description.

A biaxial oriented white opaque film composed primarily of Polyethylene Terephtalate and Barium Sulfate, both sides coated with a print receptive coating.

The product and materials used in its manufacture are also compliant within the framework defined by the Regulation 1935/2004/EC on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

The above product has been independently tested for overall migration with the simulants and test conditions listed below as defined in EC Directive 97/48 EC and EU Regulation 10/2011.

The product was exposed to each simulant and test conditions three times to comply with repeat use requirements as defined by EU Regulation 10/2011 and all subsequent amendments up to and including No 2023/1627 of 10th August 2023.

Direct Food Contact Testing

Direct food contact testing was carried out by Eurofins (France), March-April 2023, in compliance with EU directives 10/2011, EC 1935/2004. In addition, the product is manufactured in compliance with EC 2023/2006.

Overall Migration Limit Test results – Testing by Complete Immersion.

Simulant	Test Conditions	Migration
A: 10% Ethanol	10 days 40°C	$< 2 \text{ mg/dm}^2$
B: 3% acetic acid	10 days 40°C	2.6 mg/dm ²
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D2: Olive Oil	10 days 40°C	$< 2 \text{ mg/dm}^2$





Other Declarations.

Analysis of primary aromatic amines not carried out as none of the raw materials used in the manufacture of Robuskin PET CL2 FA contain these types of substances.

Barium migration (10 days 40°C using 3% acetic acid) = <0.2 mg/kg.

All other metals listed in the regulations were not detectable.

Specific Migration Limits.

Constituent monomers and additives used to manufacture this product have the following specific migration requirements:

 Acrylic acid is present from the latex binders used in the coating applied to the base film and has a specific migration limit of 6 mg/kg.

Present at levels <0.3 mg/kg food, well below the migration limit of 6 mg/kg.

The composition of Robuskin PET CL5 FA also complies with all purity criteria in accordance with Directives 95/31 EC, 95/45/EC and 96/77/EC.

Robuskin PET CL5 FA is manufactured according to Commission Regulation (EC) No 2023/2006 of 22nd December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Therefore, based on the testing carried out at Eurofins, Robuskin PET CL5 FA fully complies with the regulations indicated and may stand in direct contact with all types of foods.

The product Robuskin PET CL5 FA can be used in direct contact with the permitted foods for the following durations:

- For refrigeration or freezer conditions (5°C or lower) storage time unlimited
- Storage time at ambient temperatures (20°C-40°C) is limited to 30 days.

The end-user is ultimately responsible to ensure that after printing, varnishing, lamination, or any other process that modifies the product as supplied, that the final product still meets the appropriate legislation.

Signed:

Dr. Christian Helly

R&D Manager

MDV Papier- und Kunststoffveredelung GmbH

February 24th, 2025

