



EIN UNTERNEHMEN DER CLARUS GROUP

DECLARATION OF COMPLIANCE according to Regulation (EU) 10/2011 Annex IV

CLARUS[®], EXLFILM[®] und Sytec[®] Polyolefin-Shrinkfilm

Status: European Union (EU)

For the production of **Clarus, Exlfilm and Sytec Polyolefin shrinkfilm** only substances are used listed in Regulation **EU No. 10/2011 & 202/2014**. **Clarus, Exlfilm and Sytec Polyolefin shrinkfilm** complies with the migration and other requirements of EU Regulations **1935/2004** and **2023/2006**.

The Overall Migration

Tests in an accredited and independent external laboratory were carried out using the following three EU - recommended food simulants: 3% acetic acid (10 days at 40°C), 10% ethanol (10 days at 40°C) and 95% ethanol (10 days at 40°C); EC Directives **85/572/EEC** and **82/711/EEC** as amended by Directives **93/08/EEC** and **97/48/EC**.

The film passes the test - the migration from the film into each simulant being less than one third of the EU limit of 6 mg/dm² before the application of any permitted reduction factors.

Specific Migration (SM)

Following substances subject to limitations and/or specifications against EU-directive 10/2011 may be present in the film:

68320	Octadecyl
38820	Antioxidant
39090	Anti-static

The result obtained for this type substances, is below the limits defined in Regulation (EU) 10/2011.

Monomers / additives not subject to restriction: Ethylene (16950).

Dual Use Additives

In the manufacture of **Clarus, Exlfilm and Sytec Polyolefin shrinkfilm** additives maybe used which are subject to a restriction in food. Monoglycerides of fatty acids (30610) and synthetic silica (86240) are identified.

FDA

Our film complies with the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA),

CLARUS FILMS

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under: **21 CFR 177.1520 (Olefin polymers)** provided it is used subject to limitations found in 21 CFR 177.1520 and in accordance with good manufacturing practices.

Specification of the intended use

By the test values obtained, carried out in external laboratory, the film is intended to be put in contact with all types of food.

Recommendation that a temperature of 35°C not be exceeded. 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.

Ratio of food contact surface area to volume used to establish the compliance of the material or article
6 dm² per kg food.

Heavy metals content

The heavy metals cadmium, lead, mercury and chromium_{VI} are not intentionally used for the production of the unconverted and unprinted polypropylene films.

The sum of the heavy metals cadmium, lead, mercury and chromium_{VI} incidentally present in this product is below 100 ppm and the film, therefore, complies with the limits set out in EC Directive **94/62/EC** (Article 11) on packaging and packaging waste.

By observing the above regulations, the duty of care regarding the compliance of the product with legislation governing food contact applications has been fulfilled.

Although the product is intended for general food use (i.e. intended for contact with foodstuffs of all types) it is the responsibility of the user to verify its suitability for his own intended food application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular foodstuff being used.

The content of this declaration is strictly confidential and should not be passed on to third parties. However in case your customer requires this information in order to assess compliance and measuring migration as required by law, you are entitled to pass them on to the customer or a neutral institute, under the strict obligation that the information is treated strictly confidential.

CLARUS FILMS GmbH



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