# 10/2011 EC - Statement of Compliance

**Manufacturer**: Arjobex Limited
10 Stephenson Road.
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Essex
CO15 4NS
United Kingdom

**Date:** January 25th 2019

**Product:** Standard Coated Polyart

## Product Description

A biaxial orientated film composed primarily of High-Density Polyethylene, Calcium Carbonate, and Titanium Dioxide.
The monomers, polymers and additives used to manufacture this product are listed in EU Regulation 10/2011.

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 condition three times to comply with repeat use requirements as defined in EU Regulation 10/2011.

## Direct Food Contact Testing

Direct food contact testing was carried out by Intertek, an external UKAS accredited laboratory in October/November 2018, in accordance to the test methods for the "Examination of Consumer Goods" corresponding to the directives B 80.30, 1 to 3 (EG) of the Official Collection of Analytical Methods according to § 64 LFGB and according to the rules of the series of standards EN1186 and CEN/TS 14234 "Materials and articles in contact with foodstuffs – Plastics".
The testing is also in compliance with EU directives 10/2011, EC 1935/2004 and the product is manufactured in compliance with EC 2023/2006

## Overall Migration Limit Test Results

| Simulant | Test Conditions | Migration |
|---|---|---|
| Acetic Acid (3% w/w) | 10 days 40°C | 157.5 mg/dm$^2$ |
| Ethanol (20% v/v) | 10 days 40°C | 4.2 mg/dm$^2$ |
| Olive Oil | 10 days 40°C | n/a* |
| Ethanol (95% v/v) | 6 hours 60°C | 4.88 mg/dm$^2$ |

***** The sample absorbed the olive oil into it. Therefore, it was not possible to get a reliable measurement. 95% Ethanol is an acceptable substitute for olive oil as per EC 10/2011.

This product should **not** be used with acidic foodstuffs, as it exceeds the global migration limit of 10 mg/dm$^2$.


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**Monomer Analysis Results**

Constituent monomers and additives used to manufacture this product were found to have the have the following migration values;

| Monomer | Result | CAS Number |
|---|---|---|
| Methylacrylate | Not Determinable < 0.2 mg/dm$^2$ | 96-33-3 |
| Ethylacrylate | Not Determinable < 0.2 mg/dm$^2$ | 140-88-5 |
| Butylacrylate | Not Determinable < 0.2 mg/dm$^2$ | 141-32-2 |
| 2-Ethylhexylacrylate | Not Determinable < 0.05 mg/dm$^2$ | 103-11-7 |
| Methylmethacrylate | Not Determinable < 0.2 mg/dm$^2$ | 80-62-6 |
| Butylmethacrylate | Not Determinable < 0.2 mg/dm$^2$ | 97-88-1 |
| Isobutylmethacrylate | Not Determinable < 0.2 mg/dm$^2$ | 97-86-9 |
| Styrene | Not Determinable < 0.2 mg/dm$^2$ | 100-42-5 |
| Alpha methyl styrene | Not Determinable < 0.05 mg/dm$^2$ | 98-83-9 |
| Acrylic Acid | Not Determinable < 0.01 mg/dm$^2$ | 79-10-7 |



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**Specific Migration of Aluminium** (regulatory limit of 1 mg/kg)

| Simulant | Test Conditions | Migration |
|---|---|---|
| Acetic Acid (3% w/w) | 10 days 60°C | <0.1 mg/kg |
| Ethanol (95% v/v) | 10 days 60°C | <0.1 mg/kg |

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

- N,N-Bis (2-hydroxy-ethyl) alkyl (C8-C18) is an anti-static additive used in the manufacture of the base film and has an specific migration limit of 1.2 mg/kg
- Butyl acrylate 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.
- 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.

All 3 of the above substances were not detected during the migration testing.

**Dual use Additives**
The following materials used in the manufacture of Standard Coated Polyart are classified as dual use additives;

| | | |
|---|---|---|
| Calcium Carbonate | E170 | CAS 1317-65-3 |
| Titanium Dioxide | E171 | CAS 13463-67-7 |

There are no specific migration limits for either of these materials.

The composition of the Standard Coated Polyart also complies with all purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC.


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Standard Coated Polyart 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 Intertek Standard Coated Polyart fully complies with the regulations indicated and may stand in direct contact with dry, aqueous, non-acidic and fatty foodstuffs.

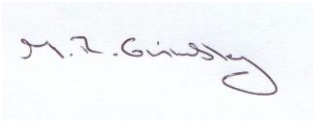
The product Standard Coated Polyart can be used in direct contact with dry, aqueous, non-acidic and fatty foodstuffs for the following durations;

For refrigeration or freezer conditions (5°C or lower) storage time is 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 Polyart product as supplied, that the final product stills meets the appropriate legislation.

Signed:



**Dr Mark Grimbley**
**Quality & Technical Manager**

January 25th 2019.

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