

Declaration of Compliance with legislation(s) for articles intended to come into contact with foodstuffs.

In compliance with the Union Guidelines on regulation (EU) No 10/2011 and its amendments as regards information in the supply chain.

Polyolefin film transparent / colored Printed and unprinted

1. DoC issued by:

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E-MAIL: sales@huchem.nl
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2. Manufactured/imported by:

HUCHEM BV
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TEL: +31 (0) 887 877 799
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3. Identity of the product or representative sample

Polyolefin film transparent / colored (hereafter addressed as Polyolefin film) is a product, mainly consisting of the basic polymers polyethylene and polypropylene.

4. Issued date

04-12-2020

5. EU regulatory status of the article Polyolefin film

EC Regulation 1935/2004

Polyolefin film complies with the safety aspects set out in Article 3 (1) (a) and (1) (c) community authorization according to Article 11 paragraph 5 and Article 15 labelling of the Framework Regulation (EC) 1935/2004.

GMP

Polyolefin film has been manufactured in accordance with the relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Traceability

Manufacturer/importer has systems in place fulfilling the relevant aspects on traceability as required in article 17.1 of Regulation (EC) No. 1935/2004.

5.a Used monomers and additives.

Product has been manufactured only with monomers, other starting substances and additives that are authorized under the Plastics Regulation EU 10/2011 (up to and including the amendment EU 2020/1245).

5.b Other substances used in the formulation of Polyolefin film

Other substances used in the manufacturing of **Polyolefin film** are listed in:

Dutch Regeling Verpakkingen- en Gebruiksartikelen (Warenwet).

Chapter 1 – Kunststoffen.

<https://zoek.officielebekendmakingen.nl/stcrt-2014-8531.html>

Pigments and colorants

Colorants and/or pigments used in the formulation of **Polyolefin film**, that are not regulated by

EU 10/2011 (up to and including the amendment EU 2020/1245), are in compliance with:

Dutch Regeling Verpakkingen- en Gebruiksartikelen (Warenwet).

Chapter XI – Colourants and pigments

<https://zoek.officielebekendmakingen.nl/stcrt-2014-8531.html>

Resolution AP (89) 1 of the Council of Europe "On the use of colourants in plastic materials coming into contact with food", II, 2 (purity).

The French positive list on pigments and colorants, published in "*Circulaire n° 176 consolidée du 2 décembre 1959 modifiée relative aux pigments et colorants des matières plastiques et emballages*", as amended.

Printed products

The ink complies with the Annex 6 of the Swiss Ordinance. Ink formulations are produced with compliance with the EuPIA (CEPE) Exclusion List 1st Edition of September 2015. The printed side of the film is always intended for indirect food contact.

5.c Overall Migration

Polyolefin film complies with the overall migration limit tested under the following conditions:

Simulant	Test conditions	Value	Limit
A (Ethanol 10% v/v)	OM2	<2,5 mg/dm ²	10 mg/dm ²
B (Acetic acid 3% v/v)	OM2	<2,5 mg/dm ²	10 mg/dm ²
D2 (Vegetable oil)	OM2	<2,5 mg/dm ²	10 mg/dm ²

Note 1: It should be noted that the representative samples have been tested for the above mentioned conditions only. It is the responsibility of the legal entity responsible for placing on the market of the article to ensure that the usage of the articles is safe, lawful and technically suitable and can **determined** through **mutual** consultation and **agreement**.

Note 2: To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed. Testing other simulants (C, D1 and E) is not required in this case.

5.d Polyolefin film is not yet in contact with food and/or intended for direct use by consumers.

It has therefore not been determined if the product induces an unacceptable change in the composition of the food or organoleptic changes of the food.

6. Regulatory status of used substances

6.a Used substances subject to restrictions in national legislation

Not applicable

6.b Monomers

Monomer(s) used in the formulation of **Polyolefin film** are listed in EU regulation EU 10/2011 (up to and including the amendment EU 2020/1245).

Restrictions of substances in Polyolefin film mentioned complied with, based on worst case calculations, migration modeling or migration testing.

FCM no	SML (mg/kg)	
231	12	Compliant
264	15	Compliant
356	3	Compliant

6.c Additives

Additives used in the formulation of **Polyolefin film** are listed in EU regulation EU 10/2011 (up to and including the amendment EU 2020/1245).

Restrictions of substances in Polyolefin film mentioned complied with, based on worst case calculations, migration modeling or migration testing.

FCM no	SML (mg/kg)	
19	1.2 as tertiair amine	Compliant
20	1.2 as tertiair amine	Compliant
53	60	Compliant
69	30	Compliant
129	<1mg/kg in final product	Compliant
132	5	Compliant
176	6 as acrylic acid	Compliant
227	30 as ethyleneglycol	Compliant
263	30 as ethyleneglycol	Compliant
282	Undetectable	Compliant
411	Max 2.5% (m/m) carbon black in polymer	Compliant
433	6	Compliant
483	0.05	Compliant
500	0.6	Compliant
689	6	Compliant
715	6	Compliant
716	30	Compliant
771	5	Compliant
779	0.05	Compliant
783	60 sum of all materials	Compliant
793	NIAS	Compliant
923	5	Compliant

6.d Substances listed in Annex II (1), metals

Substances listed in Annex II (1), to the Plastics Regulation are present. These substances cannot be released above the limit specified.

Restrictions of substances in Polyolefin film mentioned complied with, based on worst case calculations, migration modeling or migration testing.

FCM no	SML (mg/kg)	
106	5 expressed as zinc	Compliant
402	5 expressed as zinc	Compliant
Zn	5	Compliant
Ba	1	Compliant
Fe	48	Compliant
Cu	5	Compliant

6.e PAAs (Primary Aromatic Amines) covered by Annex II (2) to the Plastics Regulation

Polyolefin film does not contain intentionally added PAAs. PAAs cannot be released above the detection limit.

7. Presence of dual-use additives. Identity of substance as listed in the European legislation on additives or flavorings, (Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008)

FCM no	E-number	
9	E471/E470a/E470b	Compliant
10	E471/E470a/E470b	Compliant
11	---	Compliant
21	E170	Compliant
41	E471	Compliant
45	E471	Compliant
84	E552	Compliant
139	E330	Compliant
247	E363	Compliant
315	E321	Compliant
395	E529	Compliant
409	E172	Compliant
504	E551	Compliant
568	E493	Compliant
575	E900	Compliant
610	E171	Compliant
615	E553b	Compliant
638	E1521	Compliant

8. Final use of Polyolefin film

Polyolefin film is allowed to be in contact with all kinds of food.

The standard test conditions according to OM2.

OM2: Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{(T-70)/10}$ minutes.

The ratio between surface in contact with food and the volume according to the regulations is 6dm^2 in contact with 1 kg food.