

1852



CELLOPHANE™ XS

DECLARATION OF COMPLIANCE for materials and articles intended to come into contact with food

I LEGAL BASIS

This declaration is issued in accordance with:

- Article 16(1) of Regulation (EC) No 1935/2004 (“Framework Regulation”)
- Article 6 of Directive 2007/42/EC (“RCF Directive”)

II ASSURANCES

1 **Identity and address of the business operator issuing the declaration of compliance:**
Applicable entity specified in Note A.

2 **Identity and address of the business operator which manufactures the material:**
Applicable entity specified in Note A.

3 **Identity of the material:**

This declaration applies to the following products made by Innovia Films at its production site in Wigton, England:

- Cellophane™ 280XS
- Cellophane™ 315XS
- Cellophane™ 340XS
- Cellophane™ 365XS
- Cellophane™ 440XS
- Cellophane™ 500XS
- Cellophane™ 600XS

subsequently referred to collectively as “Cellophane™ XS”.

Cellophane™ XS is a regenerated cellulose film covered on each surface by a coating consisting of plastics. It falls within the scope of Article 2(c) of Directive 2007/42/EC.

Cellophane™ XS can also be defined as a multi-material multi-layer (MMML) material. It is composed of a non-plastic layer (of regenerated cellulose film) and two surface coatings consisting of plastics.

Only the plastics surface coating layers fall within the scope of the EU Plastics Regulation (EU) No 10/2011 (Article 2(1)(e)). The regenerated cellulose film layer is outside the scope of the EU Plastics Regulation.

NOTE:

This and all subsequent references to Regulation (EU) No 10/2011 mean that Regulation as amended by Regulations (EU) Nos 321/2011, 1282/2011, 1183/2012 & 202/2014.

II ASSURANCES continued

4 Date of the declaration:

This declaration applies to **Cellophane™ XS** supplied in the period:

01 January 2014 to 30 June 2016

5 Confirmation that the material meets relevant requirements laid down in Regulation (EC) No 1935/2004, Directive 2007/42/EC, Regulation (EU) No 10/2011 and Directive 78/142/EEC:

Cellophane™ XS complies with the following:

- Article 3(1) (“General requirements”) of Regulation (EC) No 1935/2004
- Article 17 (“Traceability”) of Regulation (EC) No 1935/2004
- Articles 4 (“Conformity with good manufacturing practice”), 5 (“Quality assurance system”), 6 (“Quality control system”) and 7 (“Documentation”) of Regulation (EC) No 2023/2006
– as amended by Regulation (EC) No 282/2008
- Article 4 of Directive 2007/42/EC
- Article 2(1) of Directive 78/142/EEC

NOTE:

Article 4(2) of Directive 2007/42/EC foresees that plastic coatings for food contact RCFs should be formulated using substances authorised at EU level for food contact plastic materials and articles. It also foresees that the films should comply with restrictions set out for those substances in the relevant legislation.

Directive 2007/42/EC has not yet been amended to update the references to EU plastics legislation. This declaration takes account of the repeal of Directive 2002/72/EC on 1 May 2011 and assumes that the obsolete references to that directive in Directive 2007/42/EC should be read as references to Regulation (EU) No 10/2011 as amended.

The plastics surface coating layers of **Cellophane™ XS** each comply with:

- Article 14 (“Multi-material multi-layer materials and articles”) of Regulation (EU) No 10/2011

6 Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to Regulation (EU) No 10/2011 to allow downstream business operators to ensure compliance with those restrictions:

The following substances having specific migration restrictions listed in Annex I of Regulation (EU) No 10/2011 (as amended) are or could be present in the plastics surface coating layers of **Cellophane™ XS**:

FCM Substance No.	Substance Name	Specific Migration Limit (mg/kg)
16	alkyl(C ₈ -C ₂₂)sulphonic acids	6
98	formaldehyde	(T) = 15 (Group Restriction 15)
127	vinyl chloride	ND (LoQ = 0.01 mg/kg)
130	vinylidene chloride	ND (LoQ = 0.01 mg/kg)
150+	methacrylic acid + esters	(T) = 6 (Group Restriction 23)
225	acrylonitrile	ND (LoQ = 0.01 mg/kg)
239	2,4,6-triamino-1,3,5-triazine (= melamine)	2.5
246	tetrahydrofuran	0.6
248	maleic acid	(T) = 30 (Group Restriction 3)

continued

II ASSURANCES continued

continued

FCM Substance No.	Substance Name	Specific Migration Limit (mg/kg)
312	methacrylonitrile	ND (LoQ = 0.01 mg/kg)
315	2,6-di- <i>tert</i> -butyl- <i>p</i> -cresol	3

Innovia Films confirms that when **Cellophane™ XS** is used in accordance with Section 8 (“Specifications on use of the material”) migration of the substances complies with these Specific Migration Limits.

- 7 Adequate information relative to substances in the plastic coating layer which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria to enable the user of the material to comply with relevant EU provisions or, in their absence, with national provisions applicable to food: The following substances authorised as food additives by Regulation (EC) No 1333/2008 are or could be present in the plastic coating layers of **Cellophane™ XS**:

E Number	Additive Name	Restriction in Food	Migration ^(f) (mg per kg food)
E 321	butylated hydroxytoluene	maximum quantity: 100 mg/kg	< 0.03
E 471	mono- and diglycerides of fatty acids	quantum satis	—
E 526	calcium hydroxide	quantum satis	—
E 559	kaolin	maximum quantity: 10 000 mg/kg	< 2
E 570	fatty acids	quantum satis	—
E 902	candelilla wax	quantum satis	—
E 903	carnauba wax	maximum quantity: 200 mg/kg	< 1.5

^(f) assuming complete migration from one surface and a surface area : food mass ratio of 6.00 dm² per kg food

Based on information provided by suppliers, the components that Innovia Films uses to make the plastic coating layers of **Cellophane™ XS** are not formulated to contain any substances authorised as flavourings by Regulation (EC) No 1334/2008.

8 Specifications on use of the material:

a Types of food with which it is intended to be put in contact.

Cellophane™ XS meets the applicable legal requirements for contact with the following types of foods:

- water-containing foods (pH > 4.5)
- acidic foods (pH ≤ 4.5)
- alcoholic foods (alcohol content ≤ 50 % v/v)
- fat-containing foods
- milk, fermented milk products and cream
- dry foods

On the basis of the film’s physical properties Innovia Films does not recommend **Cellophane™ XS** for use as a monoweb material for the holding of liquid foods.

II ASSURANCES continued

b Time and temperature of treatment and storage in contact with the food.

Cellophane™ XS meets the applicable legal requirements for contact with food under the following conditions:

- at temperatures up to 40°C without restriction on contact time, including refrigerated and frozen storage conditions
- at temperatures between 40°C and 70°C for periods up to 2 hours
- at temperatures between 70°C and 100°C for periods up to 15 minutes, including “hot fill”

Cellophane™ XS is intended for contact with food under temperate and chilled conditions (temperature range: 0 to 40°C).

Low Temperature Applications:

Innovia Films has not evaluated the performance of Cellophane™ XS at very low temperatures. On the basis of the film’s physical properties, Innovia Films recommends that Cellophane™ XS should not be used for food contact applications at temperatures below –30°C (for example, blast freezing).

Elevated Temperature Applications:

Cellophane™ XS is suitable for short-term contact with many warm foods (food temperature: up to 100°C) in ordinary “hot fill” food packing operations.

Innovia Films has not evaluated the performance of Cellophane™ XS at high temperatures. We recommend the film is not used to hold or store food for prolonged periods (> 15 minutes) at temperatures above +70°C.

c Ratio of food contact surface area to volume used for establishing compliance of the material.

6.00 dm² of contact surface per kg of food

NOTE:

For containers and other articles intended to contain less than 500 mL or 500 g of food – including small packs – relevant legislation states that it is permissible to apply a ratio of 6 dm² per 1 kg of food irrespective of the actual ratio in real life.

This is also permissible for sheets and films not yet in contact with food.

9 Functional barrier:

Innovia Films has not evaluated Cellophane™ XS to verify whether it performs as a functional barrier in any specific food contact application.

Supplementary Information

10 Compliance of the plastics surface coating layers with the Overall Migration Limit:

Innovia Films has performed overall migration tests on a sample consisting of a plastic layer applied to an inert substrate. The plastic layer in that sample was of the same formulation used for the plastics coating layers of Cellophane™ XS. Its thickness was greater than that of each plastic surface coating layer in Cellophane™ XS (i.e. a more severe case). Test conditions were as follows:

exposure technique	total immersion
time & temperature	10 days at 40°C
test methods	EN 1186:2002 Parts 1, 2 & 3

NOTE:

10 days at 40°C = standardised test condition “OM2” (Table 3 of Annex V, Regulation (EU) No 10/2011)

The results were as follows:

Abbreviation	Simulant	Result (mg/dm ²)	Limit Value (mg/dm ²)
A	ethanol 10% (v/v)	< 0.8	10
B	acetic acid 3 % (w/v)	< 0.6	10
C	ethanol 20% (v/v)	0.9	10
D1	ethanol 50% (v/v)	0.9	10
D2	vegetable oil	< 1.4	10

III COOPERATION WITH COMPETENT AUTHORITIES / ENFORCEMENT AUTHORITIES

Addressed to downstream business operators in EEA States (EU-28 + NO/IS/LI)
and stated in respect of Article 16(1) of the Framework Regulation (EC) No 1935/2004.

Innovia Films undertakes to make available to the food control authorities any supporting documentation that they may reasonably require, to demonstrate that **Cellophane™ XS** complies with the applicable legal requirements.

IV OTHER PROVISIONS

This declaration applies to **Cellophane™ XS** as placed on the market by Innovia Films.

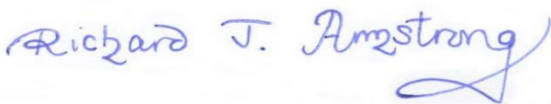
It remains the responsibility of the food packer to verify the suitability of the final material or article for the intended food contact application, including:

- checking that the physical properties of the final material or article make it suitable for the intended application
- verifying compliance of the final material or article with any applicable migration limits
- checking for the possible influence of the final material or article on the composition and organoleptic properties of the contacted food

The content of this declaration is subject to the INNOVIA FILMS – TERMS AND CONDITIONS OF SALE governing the applicable sales contract, which are incorporated by reference.

Cellophane™ is a trademark of the Innovia Films Group.

V AUTHOR, PLACE, DATE & REFERENCE

This declaration was prepared by: Richard J Armstrong <i>Global Regulatory Affairs Group Manager</i>	Signature: 
Place of issue: Date of issue:	Wigton, England 20 March 2014

Document Reference – for Innovia Films use only:

RegAff-DoC-1852/C6-A1/FC-EU/EN/MultiMat/-/-/XS/Wig/Wig/global/200314

NOTE A:

Legal Entity	Company Registration Number	Registered Office Address	Address for Correspondence
Innovia Films (Asia Pacific) Pty Ltd	A.B.N. 96 007 415 714	19 Potter Street Craigieburn 3064 Victoria Australia.	19 Potter Street / PO Box 341 Craigieburn 3064 Victoria Australia.
Innovia Films BVBA	R.C.B. 0867242950	Sluisweg 8 B-9820 Merelbeke Belgium.	Sluisweg 8 B-9820 Merelbeke Belgium.
Innovia Films Inc	E.I.N. 20-1647507	290 Interstate North Cir SE Suite 100 Atlanta, GA 30339-2401 USA.	290 Interstate North Cir SE Suite 100 Atlanta, GA 30339-2401 USA.
Innovia Films Ltd	No. 271998. Registered in England and Wales.	The Coach House West Street Wigton Cumbria, CA7 9PD United Kingdom.	Station Road Wigton Cumbria CA7 9BG United Kingdom.
Innovia Films, SA de CV	IFI 0409286G1	Ave. D #1111 Col. Hacienda Los Morales San Nicolas de Los Garza, NL CP 66495 Mexico.	Ave. D #1111 Col. Hacienda Los Morales San Nicolas de Los Garza, NL CP 66495 Mexico.

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