

FOOD CONTACT STATUS & SML

Product:

FLM1598 4-RL2C-12632 PE TCX GLOSS WHITE 85 / AP901 / WG62

Herewith we confirm that to our knowledge the face, TC and adhesive materials of the product listed above comply with the following European Regulations:

Regulation (EC) No. 1935/2004 (*materials and articles intended to come into contact with foodstuffs*) and amendments;

Regulation (EU) No. 10/2011 (*plastic materials and articles intended to come into contact with foodstuffs*) and amendments;

Please be aware that the product listed above is suitable for direct food contact with dry, moist and such kind of fatty foodstuffs with a correction factor of at least 3 according to the Regulation (EU) No. 10/2011.

Such information is derived from the declaration of our materials' suppliers.

Please be aware that the whole above listed product has not specifically analysed

TOP COATING: TCX

The following compounds are intentionally added into formulation, and they are not present in the final article:

Substance name	CAS n°
Oligomers hexamethylene diisocyanate (listed in BFR XXXVI/3)	28182-81-2
propylene carbonate	108-32-7

The TCX contains the following substances that are subject to limits according to Regulation (EU) 10/2011.

Substance name	CAS n°	SML (mg/kg)	SML(T) (mg/kg)
2-methyl-4-isothiazolin-3-one	2682-20-4	0.5	

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FACE MATERIAL: PE GLOSS WHITE

1. Confirmation that the plastic material meets the legal requirements

In the production of the polypropylene base film, only substances listed in Regulation (EU) No 10/2011 are intentionally used. The supplier has performed overall migration tests on a sample of film representative of the subject film under the following test conditions: total immersion for 10 days at 40°C.

Abbreviation	Simulant
A	Ethanol 10% (v/v)
B	Acetic acid 3% (w/v)
D2	Vegetable oil

2. Adequate information on the substances used for which restrictions are set out

The polypropylene film contains the following monomers and/or additives that are subject to limits according to Regulation (EU) 10/2011. The supplier can confirm that these intentionally added monomers and/or additives that are subject to a restriction comply with their respective limit values based upon worst-case calculation, mathematical modelling or experimental test data.

Substance name	CAS N°	SML (mg/kg)	SML(T) (mg/kg)
Diethyleneglycol	111-46-6	30	-
Ethyleneglycol	107-21-1	30	-
Hexafluoropropylene	116-15-4	0,01	-
Vinylidene fluoride	75-38-7	5	-
Octadecyl 3-(3,5-di-tert-butyl-4hydroxyphenyl) propionate	2082-79-3	6	-
Ethylene Oxide	75-21-8	1 in final product	-
Aluminium	-	1	-

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Other monomers and/or additives subject to a specific migration limit are or could be present within the film.

3. Adequate information relative to the substances which are subject to a restriction in food

This polypropylene film contains the following monomers and/or additives that are authorised as food additives by Regulation (EC) No 1333/2008 and which are subject to a restriction in food.

Code	Name
E170	Carbonic acids, salts
E171	Titanium dioxide
E330	Citric acid
E470a	Sodium, potassium and calcium salts of fatty acids
E551	Silicon dioxide
E553b	Talc
E471	Mono and diglycerides of fatty acid
E1521	Polyethylenglycol

Based on information provided by the supplier, the components used to make the subject film are not formulated to contain any substances authorised as flavourings by Regulation (EC) No 1334/2008.

ADHESIVE: AP901

The “Monomers and Other Starting Substances” used in the manufacture of the product are listed in the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and its amendments.

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The components with an SML or restriction are listed here following:

SML Table

Substance name	CAS #	FCM No.	SML (mg/kg)	SML(T) (mg/kg)
Acrylic acid	79-10-7	147	-	6
Methacrylic acid, monoester with ethyleneglycol	868-77-9	374	-	6
2-ethylhexylacrylate	103-11-7	206	0.05	-
Acrylic acid, 2-hydroxypropyl ester	999-61-1	385	0.05	-
Methyl acrylate	96-33-3	176	-	6
Methyl methacrylate	80-62-6	156	-	6
Sodium monoalkyl dialkylphenoxybenzendisulfonate	---	88	9	-
Polyethyleneglycol (EO=1-50) ethers of linear and branched primary (C8-C22) alcohols	---	799	1.8	-
Polyethyleneglycol (EO=1-50) monoalkylether (linear and branched, C8-C20) sulphate, salts	---	78	5	-
Sulphosuccinic acid alkyl (C4-C20) or cyclohexyl diesters, salts		813	5	-
Ethylene oxide	75-21-8	129	QM* 1	-
2-ethylhexanol	104-76-7	209	30	-
2-methyl-4-isothiazolin-3-one	2682-20-4	451	0.5	-
2-methyl-4-isothiazolin-3-one alone or together with 5-chloro-2-methyl-2H-isothiazol-3-one	2682-20-4		0.01 (NL Chapter 10)	-
As the sum of both components for mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one	55965-84-9		0.01(NL-Chapter 10)	-
1,2-benzisothiazolin-3-one	2634-33-5		30 (NL Chapter 10)	-

NL: Dutch Warenwet

IT: Italian Decreto Ministeriale

QM: Maximum permitted quantity on the residual substance in the material or article

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SML: specific migration limit in food or simulant

SML(T): specific migration in food or in food simulant expressed as total of moiety or substance(s) indicated.

The information of this Statement is derived from the declaration of our materials' suppliers.

However, the above regulations relate to the finish material ready to use. Therefore, this statement cannot take into account

- **Any process able to change the nature of the material**
- **The verification of compatibility between the material and the packaged foodstuffs or the foodstuffs and of the non-modification of the organoleptic characteristics of the latter.**

Fedrigoni Self-Adhesives does not specifically analyze for the presence of the substances referred to above and cannot guarantee the absence or level of these substances to any specific limit or threshold value. The suitability of the articles for the application concerned, including their observance of any given limitations must be tested and ensured in each case by the user of our products.

This statement is valid for the product as such, as supplied by our Company and **does not cover subsequent transformations** (printing, die cutting, further coating or lamination) for which the suitability for food contact needs to be re assessed.

The suitability of the articles for the application concerned and observance of the appropriate regulations should be verified. As well as any given limitations must be tested and ensured in each case by the person who places the finished food contact article on the market.

Please note that it is the responsibility of the Producer of the final article to verify the suitability of the product for its intended use.

REGULATORY AFFAIRS OFFICE

Disclaimer:

This information is for guidance only, it is based on our most up-to-date knowledge and experience and we cannot assume any liability for damage caused through its use.

This statement does not constitute any warranty, express or implied and is only intended for the recipient and cannot therefore be transferred to any third party. We cannot assume any liability for using our products in conjunction with other materials.

All our products are sold subject to Fedrigoni Self-Adhesives general sales conditions and please additionally note that you should ensure that any existing laws are observed. This publication replaces all previous versions published and any and all information is subject to change without notice.

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