DuPont Teijin Films™

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DECLARATION OF COMPLIANCE FOR FOOD CONTACT ARTICLES

MYLAR® OL, OLT Polyester film,
as manufactured in the USA,

in which the basic polymer chemically consists of a polyethylene terephthalate.

European Union

The composition of the above mentioned film is compliant with Commission Regulation (EU) N° 10/2011 as amended under the condition that the finished article meets the following migration limits

OML 10 mg/dm² or 60 mg/kg food (Article 12).

PM Ref	FCM	CAS Nos.	SUBSTANCES	LIMITATIONS
16990	227	107-21-1	Ethylene glycol	SML(T) = 30 mg/kg
24910	785	100-21-0	Terephthalic Acid	SML = 7.5 mg/kg
35760	398	1309-64-4	Antimony Trioxide	SML = 0.04 mg/kg (expressed as antimony)

All monomers and additives used in the composition of the above product are listed in the Union list of authorised substances, see Annex I of Commission Regulation (EU) N° 10/2011

This film grade contains additives which are also food additives and flavouring ('Dual Use Additives'), based on the provisions of Article 11 (3) of **Regulation (EU) No 10/2011** as proprietary substances. These are present at less than 1**%** of minimum limits allowed in food identified in Regulation (EU) No 1333/2008 as amended and calculated total w/w percentage content less than 1% of any SML. These may be disclosed to an independent third party testing laboratory for performance of necessary tests, subject to secrecy obligations.

Substances listed in Annex II of the Regulation are either not intentionally added or, when used, worst case calculations and or measurement ensures compliance with the restrictions of Annex II.

The above mentioned film is produced according to our quality management systems, which comply with the requirements of the Regulation (EC) No 2023/2006, on good manufacturing practice for materials and articles intended to come into contact with food.

Traces of substances authorised as food additives can be present. If present migration into foodstuffs is not reasonably expected to exceed the limits, specified in the relevant food legislation.

The above mentioned film is compliant with the relevant requirements of the Framework Regulation (EC) No 1935/2004, presuming further appropriate processing of the film following the Good manufacturing practice Regulation (EC) No 2023/2006.

In Europe, in the case of incomplete compliance in one country, the product can, on the basis of its full compliance in at least one Member State of the European Union, be legally placed on the market for direct food contact in all Member States according to the Article 34-36 of **The Treaty on the Functioning of the European Union** (TFEU). Moreover it is our understanding that the Swiss Ordinance SR 817.023.21, for its part on plastic food contact materials and articles, is in line with the EU legislation. Therefore, compliance with the Swiss Ordinance SR 817.023.21 is implied.

Migration Data for MYLAR® OL, OLT Film
(up to 39 µ)

The basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs are harmonized at European level. Commission Regulation (EU) N° 10/2011 describes the methods to determine migration by using food simulants. The limits of specific migration for allowed monomers and additives are listed in Annex I of Commission Regulation (EU) N° 10/2011. The same Regulation sets the limit for overall migration of the finished article at 10mg/dm².

For above mentioned films migration tests have been performed on representative samples based on the conditions covered by Dir.97/48/EC. The results are shown in the table below

		Simulant B	**Simulant C**	**Simulant D**	**Simulant D**
		3% Acetic Acid	**20% EtOH**	**95% EtOH**	**Olive Oil**
	Limits	4h reflux	4h reflux	4h reflux	2h 175°C
OML	10mg/dm2	compliant	compliant		compliant
SML EG/DEG	30 mg/kg			Compliant	
SML Terephthalic Acid	7.5 mg/kg food			Compliant	
SML Antimony	0.04 mg/kg food	compliant			

Note: Compliance to OML / SML for simulants B to D is considered to also cover compliance for Simulant A (water).

Substances listed in Annex II of the Regulation are either not intentionally added or, when used, worse case calculations and or measurement ensures compliance with 10% of the restriction of annex II.

The migration tests for materials and articles intended to come into contact with food-stuffs should be carried out in accordance with Commission Regulation (EU) No 10/2011, Article 18 and with respect to the transitional provisions as expressed in article 22.

From the results shown above, we see no restrictions on the use as Food Contact Material for this product. If a customer considers his application deviating from the conditions covered by the test conditions highlighted in the table here above, they are responsible for performing the appropriate testing.

Important Information: This evaluation has been performed on a typical product sample produced under standard production conditions as per our manufacturing standards. Specific conversion conditions at our customers may change the profile of potential migrants and lead to different results on the final packaging material. Such changes are beyond our knowledge. Therefore, please be informed that it is the responsibility of both the producer of the finished food-contact articles as well as the industrial food packagers to make certain that such articles, under actual conditions of use, meet the above referenced requirements.

General requirements applicable in all countries

Manufacturers using the above product for further processing, must ascertain, through the appropriate tests, that these articles comply with the above mentioned restrictions/limitations (OML, SML etc.); furthermore these articles must comply in all countries with the general regulatory requirement that they do not bring about an unacceptable change in the composition of the food-stuffs or a deterioration in the organoleptic characteristics thereof.
The present review only refers to applicable food-contact regulations. Medical and pharmaceutical applications are not considered by these regulations. DuPont Teijin Films has established specific rules for medical and pharmaceutical end-uses. Please consult your DuPont Teijin Films representative for such applications.

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Regulatory Compliance Statement for Food Contact Materials
Attachment

Abbreviations and references:
Abbreviations

FCM = Food Contact Material
Ref. No = EEC packaging material reference number
CAS No = Chemical Abstracts Service (CAS) registry number
OML = Overall Migration Limit expressed as mg/dm^2 of surface area of material or article, or expressed as mg/kg food or food simulant.
SML = Specific Migration Limit expressed as mg/kg food or food simulant.
QMA = maximum "residual" quantity on the surface of the finished article in contact with food expressed as mg/6 dm^2 of the article.

References
Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and amendments, defining the requirements for plastics materials according to the general framework Regulation (EC) No1935/2004 and replacing Commission Directive 2002/72/EC and its amendments.
Applicable to all of the EU Member States (i.e. Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom) or in countries which have adopted equivalent legislation (Norway and Switzerland).

Some polymer production aids, colorants, aids to polymerisation and solvents are governed by national regulations in countries having positive lists (Belgium, France, Germany, Italy, The Netherlands, Spain) and/or assessed in accordance with internationally recognised scientific principles on risk assessment.

The information provided concerning additives which are also food additives and flavouring ('Dual Use Additives') is based on the provisions of Article 11(3) of Regulation (EU) No 10/2011. The lack of information on this category of additives from certain of our suppliers, do not allow us to guarantee the completeness of the information.

Pigments used in film grades are compliant with European food contact regulations, meet the purity requirements as specified in the Council of Europe Resolution AP(89)l on the use of colorants in plastic materials coming into contact with food.

The migration tests for materials and articles intended to come into contact with food-stuffs should be carried out in accordance with Regulation (EU) No 10/2011, Article 18, which refers to the Annex III and Annex V, and with respect to the transitional provisions as expressed in article 22.

All resins comply with the European regulation 1895/2005 'on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food' (BADGE, BFDGE, NOGE).

The films are produced according to our quality management systems, which comply with the requirements of the Regulation (EC) No 2023/2006 on Good Manufacturing Practice.

Source for national legislations
http ://ec . europa.eu/food/food/chemicalsafety/foodcontact/documentsen.htrn
Document: "EU and National Laws"

Belgium: Koninklijk besluit/Arrêté royal of 3 juillet 2005 relating to plastics materials and articles intended to come into contact, as amended
France : Arrêté (Decree) of 2 Jauary 2003 relatif aux matériaux et objets en matière plastique mis ou destinées à être mis au contact des denrées, produits et boissons alimentaires, as amended and Regulations compiled in Brochure No 1227 of "Journaux Officiels", Edition 2005.
Germany: "LFGB (Lebensmittel und Futtermittelgesetzbuch)" (= food law) of 26 April 2006 and " BfR (ex. BgVV, ex BGA) Empfehlungen" (Recommendations) as published in 'Kunststoffe im Lebensmittelverkehr, 62. Lieferung, Stand March 2009'.
Italy: "Decreto Ministeriale" (Ministerial Decree) of 21 March 1973 as amended.
The Netherlands: "VGB (Warenwet)" (Packaging and Utensils Decree) (Stb. 1979, 558), Part Aa, Chapter I, as amended
Spain: Real Decreto número 866/2008 de 23 de mayo 2008 as amended, and the Resolución de 04/11/1982 de la Subsecretaria para la Sanidad, as amended **.**