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DECLARATION OF COMPLIANCE FOR FOOD CONTACT ARTICLES

MYLAR® OLAF, OLAF[®] polyester film as manufactured in the USA

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

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.

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.

Regulation (EU) No 10/2011, as amended, is a Regulation for all EU countries that applies to plastic food contact materials and articles.

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 placed on the market for use 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.

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) No 10/2011.

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 10% of the restrictions of Annex II.

Intentionally added substances not subject to listing in the Union list comply with relevant requirements of the Framework regulation. Relevant risk assessments have been carried out, considering the specific conditions of use described below, in accordance with Article 19 of Regulation (EU) No 10/2011. These risk assessments can, but not necessarily, refer to national legislation and or European Resolutions.

To the best of our knowledge we can confirm that, for the aforementioned Films, reaction intermediates, impurities, decomposition or reaction products, commonly called non-intentionally added substances (NIAS), as far as they are known to us today, comply with the relevant requirements of the Framework Regulation. Relevant risk assessments have been carried out, considering the specific conditions of use described below, in accordance with Article 19 of Regulation (EU) No 10/2011. These risk assessments can, but not necessarily, refer to national legislation and or European Resolutions.

Migration Data for MYLAR® OLAF (up to 39µ)

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) No 10/2011 describes the methods to determine migration by using food simulants and lists the limits of specific migration for allowed monomers and additives. The following limits are applicable to the above product.

The same Regulation sets the limit for overall migration of the finished article at 10mg/dm² (or 60mg/kg food intended to be brought into contact with infants and young children).

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.

Migration testing has been performed on representative samples based on the conditions covered by Annex V of Commission Regulation (EU) No 10/2011, as below. It is the responsibility of both the producer of the finished food-contact articles as well as the industrial food packagers to ensure that these test conditions cover the actual conditions of use. Please refer to Commission Regulation (EU) No 10/2011 as amended.

OM Testing

OM Test Number	Simulant		Condition	Result
OM6	Simulant A	10% ethanol	4 hours at reflux	<10mg/dm ²
OM6	Simulant B	3% acetic acid	4 hours at reflux	<10mg/dm ²
OM7	Simulant D2	vegetable oil	2 hours at 175°C	<10mg/dm ²

The composition of the above mentioned film is compliant with Commission Regulation (EU) No 10/2011 as amended under the condition that the finished article meets the 10 mg/dm² (or 60 mg/kg food) migration limit.

SML Testing

Substance	Simulant	Condition	Limitation	Result
Ethylene glycol CAS 107-21-1 FCM 227	95% ethanol	8 hours @ reflux	SML(T) = 30 mg/kg	< 30 mg/kg
Terephthalic acid CAS 100-21-0 FCM 785	95% ethanol	8 hours @ reflux	SML = 7.5 mg/kg	< 7.5 mg/kg
Antimony trioxide CAS 1309-64-4 FCM 398	3% acetic acid	8 hours @ reflux	SML = 0.04 mg/kg (expressed as Sb)	< 0.04 mg/kg
Isophthalic acid CAS 121-91-5 FCM 291	95% ethanol	8 hours @ reflux	SML = 5 mg/kg	< 5 mg/kg

Based on worst case calculations, we can confirm that any proprietary substances, should they be present, are calculated to be at concentrations below 10% of the respective specific migration limit and are therefore considered to be compliant in all Food Simulants listed in Regulation (EU) No 10/2011.

Proprietary substances may be disclosed to an independent third party testing laboratory for performance of necessary tests, subject to secrecy obligations.

This film grade contains additives which are also food additives and flavourings ('Dual Use Additives'), based on the provisions of Article 11 (3) of Regulation (EU) No 10/2011.

Listed here: Silicon Dioxide E551

Some of the additives are proprietary substances, we can confirm that these would be present at less than 10% of minimum limits allowed in food in Regulation (EU) No 1333/2008 as amended and calculated total w/w percentage content less than 10% of any SML.

Based on the results reported above for OML and SML tests. our conclusion is that the aforementioned films can be used for 2 hours, with all food types at high temperature up to 225 °C:

In our experience those testing conditions also cover:

- a) 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.
- or
- b) retort / sterilisable applications up to 121 °C for up to 2 hours.

If a customer considers his application deviating from the conditions covered by the test conditions highlighted in the table above, they are responsible for performing the appropriate testing.

Compliance has been established using the standard surface area to volume ratio of $6\text{dm}^2 / 1\text{ kg}$ food (EU cube).

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.

This Declaration is provided for your company only, is valid for material supplied to you by DuPont Teijin Films without further modification and replaces previous Declarations of Compliance.

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.



Mr Keith Kilmartin
Regulatory Affairs Manager & Product Steward Europe
DuPont Teijin Films

This statement applies to products as supplied by DuPont Teijin Films and without any further modification.

Since conditions of use are outside DuPont Teijin Films's control, DuPont Teijin Films makes no warranties, express or implied, and assumes no liability in connection with any use of this information.

Regulatory Compliance Statement for Food Contact Materials Attachment

Abbreviations and references:

Abbreviations

FCM = Food Contact Material

CAS No. = Chemical Abstracts Service (CAS) registry number

OML = Overall Migration Limit expressed as mg/dm² 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 dm² 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) No 1935/2004 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) 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.

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/documents/en.htm>

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

Belgium: Koninklijk besluit/Arrêté royal of 3 juillet 2005 relating to plastics materials and articles intended to come into contact, as amended

France : Regulations compiled in Brochure No 1227 of "Journaux Officiels", Edition 2005.

Germany: "LFGB (Lebensmittel und Futtermittelgesetzbuch)" (= German Food and Feed Code) of 01-09-2005 as amended and "BfR (ex. BgVV, ex BGA) Empfehlungen" (Recommendations) https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp.

Italy: "Decreto Ministeriale" (Ministerial Decree) of 21 March 1973 as amended.

The Netherlands: Commodities Act Regulation on packagings and consumer articles coming into contact with foodstuffs (Commodities Act (Packagings and Consumer Articles) Regulation) - Chapter I Plastic articles and materials (Table I-1 Polymerisation auxiliaries and their decomposition products that are still permitted for use at the national level).

Spain: Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos.

Switzerland: Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen / Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Decree on materials and articles coming into contact with food) of 16 December 2016, – SR 817.023.21 Stand 16 December 2016. , section 5: Plastic Materials and articles and annex 2