MKF-ERGIS

ERGIS
ENVIRONMENT-FRIENDLY PLASTIC

FOOD AND PHARMACEUTICAL PACKAGING FILMS AND LAMINATES
SPOŻYWCZE I FARMACEUTYCZNE FOLIE OPAKOWANIOWE I LAMINATY

LLDPE STRETCH FILMS
PET STRAPS
INDUSTRIAL PACKAGING OPTIMISATION
FOLIE STRETCH LLDPE
TAŚMY PET
OPTYMALIZACJA OPAKOWAŃ PRZEMYSŁOWYCH

CONSTRUCTION AND SPECIAL APPLICATION PVC FILMS
FOLIE BUDOWLANE I SPECJALISTYCZNE Z PVC

PVC COMPOUNDS
GRANULATY PVC

PET FLAKES
PŁATKI PET

ISO 50 001
ISO 22 000

BRC

ISO 9 001
ISO 14 001

Declaration of compliance

in accordance with Annex IV of Regulation (EU) No 10/2011 of 14 January 2011

§ 1 Identification

Declaration of compliance for PET films (all types and combinations) issue RFD-W3

§ 2 Identity and address

Company	MKF-ERGIS Sp. z o.o.
Address	ul. Dąbrowskiego 2 87-200 Wąbrzeźno Poland

§ 3 Identity of products

Trade name	PET film (all types and combinations)
Details	Three-layer co-extruded PET film, which consists of outer layers from virgin PET and an inner layer of PET from recycled post-consumer material or virgin PET.

§ 4 Date of the declaration and remarks

Date	2023-04-20
Remarks	This declaration of compliance is intended only for your company and is only valid if signed by us. Any former declarations issued by us for the above-mentioned types are null and void. This declaration expires on the day a new issue is released. You will be informed about changes in the formulation of our films if they relate to compliance obligations for materials with food contact. We advise that if one side of the film is metallized, foodstuff should not be put in contact with that side. MKF-ERGIS Sp. z o. o. has no influence on the further processing of the above-mentioned film types. The customer is obliged to test the final product by relevant analysis to determine whether they are suitable for the goods for which they intend to use them. We cannot be held responsible for any damage if the buyer has not fulfilled his obligations in this regard.

§ 5 Compliance confirmation

The products described above meet the relevant requirements of the following documents:

- European Parliament abd Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (*)
- Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (*)
- Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (*)
- COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (*)
- Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008(*)
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (*)

(*) as amended on the above-mentioned date

Pursuant to Article 6 of Regulation (EU) No 10/2011 no rules have been set yet at EU level for the use of colorants in the manufacture of plastic layers in plastic materials. All used colorants fulfil the requirements of BfR Recommendation IX. “Colorants for Plastics and other Polymers Used in Commodities” of 1 February 2015 as well as “Resolution AP (89) 1 on the Use of Colorants in Plastic Materials Coming into Contact with Food” of the Council of Europe of 13 September 1989.

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§ 6 Compliance statement

The products can have food contact (all types of food). Their intended application is food packaging.

The migration limits for PET films are met using a surface to volume ratio of 6 dm² per kg of food per Regulation (EU) No 10/2011 Article 17(2) point (c) under the following conditions:

Food simulant	Time and temperature	Food type	Parameter ≤ 10 mg/dm²	Food contact condition
Acetic acid 3 % (w/v)	10 days at 40°C	aqueous, acidic	compliant	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 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.
Ethanol 10 % (v/v)		aqueous, alcoholic	compliant	
Olive oil (*)		fatty	compliant	

(*)done using ethanol 95 % and isooctane if not technically feasible

Migration is dependent on the packaging design and the goods for the intended use and therefore has to be determined for the specific packaging.

List of substances with specific migration limit [SML], non-intentionally added substances [NIAS], and dual-use additives

For proper information on substances with SML we necessarily rely on adequate information of our suppliers. Per the motivations 18 und 20 of Regulation (EU) No 10/2011 impurities and reaction and degradation products should be taken into consideration as NIAS if they are relevant for the risk assessment, which is why relevant substances are included in the following table:

Substance	FCM substance No	CAS No	SML in mg/kg	Dual use additive	NIAS
acetaldehyde	128	0000075-07-0	SML (T) = 6*1)	-	-
1,1,1-trimethylolpropane	141	0000077-99-6	6	-	-
ethyleneglycol	227	0000107-21-1	SML (T) = 30*2)	-	-
1,4-butanediol	254	0000110-63-4	SML (T) = 5*3)		
diethyleneglycol	263	0000111-46-6	SML (T) = 30*2)	-	-
isophthalic acid	291	0000121-91-5	SML (T) = 5*4)	-	-
antimony trioxide	398	0001309-64-4	0,04 (expressed as antimony)	-	-
terephthalic acid	785	0000100-21-0	SML (T) = 7,5*5)	-	-
silicon dioxide	504	0007631-86-9	-	E 551	-
phosphoric acid	509	0007664-38-2	-	E 338	-
titanium dioxide	610	0013463-67-7	-	E 171	-
1,4-benzenedicarboxylic acid, diethyl ester	-	0000636-09-9	60	-	NIAS
1,4-benzenedicarboxylic acid, ethyl methyl ester	-	0022163-52-6	7,5	-	NIAS
isophthalic acid, ethyl 3-pentyl ester	-	1000343-99-8	1,8	-	NIAS

*1) SML (T) means that the limit must not be exceeded by the sum of FCM substance 128 and 211.
*2) SML (T) means that the limit must not be exceeded by the sum of FCM substance 89, 227, 263, and 1048.
*3) SML (T) means that the limit must not be exceeded by the sum of FCM substance 254, 344, and 672.
*4) SML (T) means that the limit must not be exceeded by the sum of FCM substance 188 and 291.
*5) SML (T) means that the limit must not be exceeded by the sum of FCM substance 191, 192, and 785.

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The products comply with the requirement of Directive 94/62/EC that the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present shall not exceed 100 ppm by weight.

The products comply with the requirement of Annex II (1) of Regulation (EU) No 10/2011 that they shall not release the following substances in quantities exceeding the specific migration limits below:

Metal	SML in mg/kg
Aluminium	1
Ammonium	-
Antimony	0,04
Arsenic	not detectable
Barium	1
Cadmium	not detectable (specified limit of detection 0,002)
Calcium	-
Chromium	not detectable
Cobalt	0,05
Copper	5
Europium	0,05
Gadolinium	0,05
Iron	48
Lanthanum	0,05
Lead	not detectable
Lithium	0,6
Magnesium	-
Manganese	0,6
Mercury	not detectable
Nickel	0,02
Potassium	-
Sodium	-
Terbium	0,05
Zinc	5

The products comply with the requirement of Annex II (2) of Regulation (EU) No 10/2011 that primary aromatic amines listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 and for which no migration limit is specified in Table 1 of Annex I of Regulation (EU) No 10/20 shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They are not detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine.

The sum of primary aromatic amines not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I of Regulation (EU) No 10/2011, does not exceed 0,01 mg/kg in food or food simulant.

Renata Żebrowska
Quality Manager

Wojciech Gadomski
Managing Director