



EuralPack

Declaration of compliance

For food contact materials made from plastic films

1. Preface

We confirm that the following plastic films are intended to come into contact with food :

KOK080 – KOP080

COLAMIN XKS PA/PE 80B

Tubular pouches, transparent and red printed “121°C”

Our products complies to the following regulations (each including of all additions and the version which is relevant at the moment of issue of this statement) :

- Regulation (EG) No. 1935/2004 of 27-10-2004
- Commission Regulation (EU) No. 10/2011 of 14 January 2011
- Commodities Ordinance of 23-09-2009
- European Parliament and Council Directive 94/62/EC of 20 December 1994
- German Food and Feed Code (LFGB) of 01-09-2005
- Swiss Ordinance of the EDHA on Materials & Articles in contact with food (SR 817.023.21)
- Commission Regulation (EC No. 2023/2006 of 22 December 2006
- Recommendation III and X of the plastic Committee of Federal Institute for Risk Assessment (BfR)

- FDA 21 CFR 177.1500 (b) 4.2, 6.1 und 6.2, 177.1500 (a) 6, 177.1390, 175.300, 175.105, 175.320, 178.3297, 177.1520 (a)(3)(i)(a)(1), 177.1520 (c) 2.1, 2.2, 3.1a, 3.2, 3.2a, 177.1520 (b), 177.1395, 176.170 (c) Tabelle 1 (I - IX) und Tabelle 2 (B – H) und FDA 21 CFR 178.2010 This was confirmed by the raw material supplier.

We will make changes in the composition only after an agreement and written approval of the customer, which implies this issuing of an updated Declaration of Compliance.

We are observing new publication of the relevant laws. We carefully monitor new releases to all relevant laws and will inform our customers about more important changes of laws and standards which concern the production and usage of above mentioned product.

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1.1 Application Description (if available according to customer data)

Packed Food : (condition)	Treatment with food contact		storage with food contact		ratio of contact surface to filling quantity (dm ² /kg)
	max (°C)	max (min)	°C	(h), (d)	
dry	121°C	-	see 2.1		≤ 6,0 dm ² /kg
aqueous	121°C	-	see 2.1		≤ 6,0 dm ² /kg
acid	121°C	-	see 2.1		≤ 6,0 dm ² /kg
alcoholic	121°C	-	see 2.1		≤ 6,0 dm ² /kg
milk products	121°C	-	see 2.1		≤ 6,0 dm ² /kg
fatty	121°C	-	see 2.1		≤ 6,0 dm ² /kg

This film is suitable for the packaging of dry, aqueous, acidic, alcoholic, fatty foods and dairy products.

The ratio of the area in contact with foodstuffs to the volume, on the basis of which the conformity of the material is determined as 6,0 dm²/kg.

2. Migration and residual Content

Effective January 01, 2016, all documents mentioned in Article 16 of Regulation 10/2011 (including amendments and supplements) are based on the rules for migration testing in accordance with Article 18.

2.1 Test Conditions for Overall Migration

Simulant	Test conditions (time/temperature)
A 10%iges Ethanol (V/V)	1h / 121°C
B 3% acetic acid (G/V)	1h / 121°C
C 20%iges Ethanol	1h / 121°C
D1 50% Ethanol (for milk products)	1h / 121°C
D2 fatt (rectified olive olive/fat stimulant HB 307)	1h / 121°C
E MPPO (Tenax)	1h / 121°C

The limit value of 10 mg/dm² and 60 mg/kg of foodstuff is maintained after undergoing the different tests conditions.

* 1 hour / 121°C (OM5) includes high temperature applications up to 121°C. Test OM5 covers also food contact conditions described for OM1, OM2, OM3 and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.



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2.2 Specific Migration Limits and other limitations

All SML and/or other limitations following to regulation (EU) No. 10/2011 (including all amendments under paragraph 1.) comply with the test conditions 24h/100°C + 10 days/60°C (A, B and D2). This is valid for the S/V ratio of $\leq 6,0$ dm²/kg food.

The compliance of the specific migration limits was established as follows :

- Suppliers Certificate of Conformity
- Worst case calculations
- Rules of migration testing in accordance with 10/2011/EU (including all amendments and supplements)
- Specific migrations limited are calculated with a licensed version of software ALTS-SML 5

This concerns the following substances in polymers :

Substance	Ref-No.	FCM No.	Cas-No.	SML/QM/QMA (mg/kg)
Caprolactam	14200 41840	212	105-60-2	15
Hexamethyldiamine	8460	305	125-09-4	2,4
Isophthalic acid	19150	291	121-91-5	5
Maleic anhydride	19960	234	108-31-6	30
Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	433	2082-79-3	6
Zinc oxide	96240	402	1314-13-2	5
Zinc		Annex II		5
Antimony		Annex II		0,04
Arsenic		Annex II		ND
Barium		Annex II		1
Cadmium		Annex II		ND
Chromium		Annex II		ND
Cobalt		Annex II		0,05
Copper		Annex II		5
Lead		Annex II		ND
Mercury		Annex II		ND
Nickel		Annex II		0,02
1-hexene	18820	356	592-41-6	3
Stearic acid	89040 24550	106	57-11-4	60
Polyethylene wax	80000	549	9002-88-4	60
Nepheline syenite	68125	684	37244-96-5	60
Oleamide	68960	335	301-02-2	60



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The migration limit is way below the allowed tolerance.

The used pigments comply with Resolution AP (89)1 “on the use of colorants in plastic materials coming into contact with food”.

2.3 Substances, having restrictions (“dual use additives”)

The used polymers can contain the following dual use additives :

Substance	E-number	Ref-Number	FCM-Substance-Number
Talc	E553b	92080	615
Silicon dioxide	E551	86240	504
Calciumstearate	E470a	24550/89040	106

2.4 NIAS (Non intentionally added substances)

A migration of from NIAS into the food can not be excluded (detection limit of 0,01 mg/kg food). In order to ensure that the material/article complies with the requirements noted in article 3 of Regulation (EC) No. 1935/2004 a risk assessment was carried out, in line with the international accepted principles (compare article 19, Regulation (EU No. 10/2011)). The risk-assessment is based on the following, underlying data (f.e; analysis, scientific findings, statements/assessments of recognized authorities, declarations/specifications of pre-suppliers).

*NIAS : non intentionally added substances – chemical compounds that are introduced unintentionally at the manufacturing/marketing of materials and articles intended to come into contact with food.

Sources for NIAS:

- a) reaction- or degradation products based on interactions between material/article and food
- b) Contamination of substances used in manufacturing
- c) Reaction-interim-products that are formed during production or disintegration

2.5 Functional barrier

Providing that plastic layers are separated from the food with a functional barrier, our films comply with the requirements of art. 13 no. 2,3 and 4 or art. 14 no. 2 and 3 of Regulation (EU) nr. 10/2011.

3. Adhesives

Not applicable.

4. Printing

The printing inks are applicable and approved for the printing of food packaging in terms of the mentioned and legal regulations. With the aspect the raw materials have been carefully selected.

We comply to the requirements stated in the “Exclusion list for printing inks and related products” of the European council of paint, printing ink and artists colours industry (CEPE) in their current version.

Our packaging materials are not printed with UV-cured inks. They are free from the following photoinitiators :



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- Benzophenon
- 4-Hydroxybenzophenon
- 4-Methylbenzophenon
- 2,2'-Dimethoxy-2-phenylacetophenon
- ITX (Isopropylthioxanthon)

5. Hygiene

A concept for hygiene and pest control has been focused and can be audited on request. The production of packaging material is subject to the requirements of good hygiene practise in particular the identification of potential hazards, the assessment of related risks and a system for controlling of identified risks (chemical, physical and micro biological risks following to HACCP) for use with foodstuff.

The production has a hygiene certification following to HACCP and BRC/IoP.

6. Microbiology

The material is free from micro organisms, moulds and yeast (<50CFU/100 cm²).

7. Heavy metals

We meet the requirements of Directive 94/62/EG (including amending Directive 2004/12/EG, 2005/20EG, 219/2009/EG and Commission Regulation 2013/2/EU and Commission Regulation 2015/720/EU) regarding heavy metal content.

8. Powder

We do not use any powder hence all our films are powder free.

9. Allergens, nuts and genetically modified materials

All raw materials are free from allergens, including nuts, and genetically modified materials. Similarly, no genetically modified materials are used in the manufacturing processes. This was confirmed by the raw material supplier.

10. PVC, PVDC or chlorinated plastics

Not applicable. This was confirmed by the raw material supplier.

11. Phthalates, Bisphenol A or epoxidized soybean oil (ESBO)

Not applicable or below the detection limit according to the manufacturer. This was confirmed by the raw material supplier.

12. Management systems and certificates

The producer is certified according to ISO9001:2015, HACCP and BRC Global Standard for packaging and packaging materials.



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13. Traceability

The product traceability according to Regulation (EG) No. 1935/2004 is assured through the use of production numbers and production date.

Remarks : All provided information is true to the best of our knowledge. They are from the information we have got from our raw material suppliers and from the results of tests made by institutes.

Should the customer treat the packaging material beyond the test conditions of paragraph 2.1 and the involved food contact conditions (paragraph 3, table 3, column 3 of Regulation 10/2011), EuralPack NV gives no guarantee regarding the mechanical values and the compliance of the values given in this declaration.

Schoten 02-03-2023
EuralPack nv

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