



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

Ö-COLAMIN XKS PA/PE 80B

3-side-seal-pouches

transparent and red printed “121°C”

Our products meet the requirements of 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) This was confirmed by the raw material supplier
- Recommendation III and X of the plastic Committee of Federal Institute for Risk Assessment (BfR)
- FDA 21 CFR 177.1500 (b), 6.1 and 6.2, 177.1500 (a) 6, 177.1390, 175.105 (a)(2), 175.105, 175.300, 175.320, 177.1520 (a)(3)(i)(a)(1), 177.1520 (c) 2.1, 2.2, 3.1a 3.2a, 177.1520 (b), 176.170 (c) table 1 and table 2, 178.3860 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.

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 Conditions for Migration Tests following to the application

Simulant	Test conditions (time/temperature)
A 10%iges Ethanol (V/V)	2h / 100°C
B 3% acetic acid (G/V)	2h / 100°C
C 20%iges Ethanol	2h / 100°C
D1 50% Ethanol (for milk products)	2h / 100°C
D2 fatt (rectified olive olive/fat stimulant HB 307)	2h / 100°C
E MPPO (Tenax)	2h / 100°C

* 2 hours / 100°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.

2.2 Overall Migration :

The results from the test conditions outlined under 2.1 complies to the overall migration limit of 10 mg/dm² of the area which is contact with the food.



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2.3 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 outlined under 2.1. 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 :

- Rules of migration testing in accordance with 10/2011/EU (including all amendments and supplements)
- Suppliers Certificate of Conformity
- Worst case calculations

This concerns the following substances in polymers :

Substance	FCM Substancenumber	PM/Ref.-No.	SML/QM/QMA (mg/kg)
Stearic acid	106	89040/24550	25
Maleic anhydride	234	19960	30
1-hexene	356	18820	3
Octadecy-3-(3,5-di-ter-butyl-4-hydrophenyl)propionate	433	68320	6
Zinc oxide	402	96240	25
Tris (nonphenyl)-phosphite	69	74400	30
Caprolactam	212	14200	15
N,N' Ethylen-bis-stearamide	250	53520	60
Hexamethylendiamin	305	18460	2,4
Isophthalic acid	291	19150	5

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

2.4 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
Glycerol	E422		
Calcium carbonate	E170		
Silicon dioxide	E551	86240	504
Polyethylenglycol	E1521		
Calciumstearate	E470a		



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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 :

- 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.

We have 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 and 2005/20EG, 219/2009/EG and Commission Regulation 2013/2/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.



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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.

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 29-01-2016
EuralPack nv

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