

## Declaration of Compliance for food contact materials made from plastic films

### 1. Preface

We confirm that the following plastic films delivered to **Kanjon, OÜ Kanjon** are intended to come into contact with food:

**COLAMIN PA/PE 70µ, 80 µ**  
3-side-seal-pouches, CODE 201  
Transparent and unprinted

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
- Commodities Ordinance of 23.09.2009
- Commission Regulation (EC) No. 2023/2006 of 22.12.2006
- German Food and Feed Code (LFGB) of 01.09.2005
- Recommendation III, IX and X of the Plastic Committee of Federal Institute for Risk Assessment (BfR)
- FDA 21 CFR 177.1500 (a) 6, (b) 6.1, 177.1390, 175.300, 176.170 (c) table 1 and table 2, 175.105 paragraph (c)(5), 177.1520 (c) 2.1, 2.2, 3.1a, 3.2a, 178.2010, 177.1520 (a)(2)(i), 177.1520 (b) and FDA 21 CFR 178.3297 (This was confirmed by our raw material supplier)

We will make changes in the composition only after an agreement and written approval of the customer, which implies the 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 important changes of laws and standards which concern the production and usage of abovementioned product.

#### 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 quality [dm <sup>2</sup> /kg]
	max [°C]	max [min]	[°C]	[min]	
dry					
aqueous	85°C				≤ 6,0dm <sup>2</sup> /kg <sup>1</sup>
acid	85°C				≤ 6,0dm <sup>2</sup> /kg <sup>1</sup>
alcoholic					
milk product					
fatty	85°C				≤ 6,0dm <sup>2</sup> /kg <sup>1</sup>

<sup>1</sup>The film is suitable for the packaging of aqueous, acidic and fatty foods.

## 2. Migration and Residual Content:

Following to Article 22, paragraph 2 of EU Regulation, from 1st January 2013 the supporting documents referred to in article 16 for materials, articles and substances placed on the market until December 2015, may be used on the rules for migration testing set out in Article 18 of this regulation of the basic rules for overall migration and specific migration testing set out in the Annex to Directive 82/711/EEC.

### 2.1 Conditions for Migration Tests following to application

Simulant	test conditions (time/temperature)	test results (mg/1,95dm <sup>2</sup> )
distilled water	10 days/40°C*	<1,0
3% acetic acid (G/V)	10 days/40°C*	<1,0
10%iges Ethanol (V/V)	---	---
50% Ethanol (for milk products)	---	---
fat (rectified olive oil/fat stimulant HB 307)	---	----
Alternative tests following to directive 97/48/EG	10 days/40°C* (ethanol 95%)	1,2
Isooctan	2 days/20°C (isooctane)	2,7
Ethanol 95%		
MPPO (Tenax)	---	---

\* 10 days/40°C (OM2) includes any long-term storage at room temperature or below, including heating up to 70°C for up to 2 hours or heating up to 100°C for up to 15 minutes. The test OM 2 covers also food contact conditions described for OM 1 and OM 3.

The inner layer of our COLAMIN PA/PE films is Polyethylen, which has a softening point of 85°C. If a PE/PA/PE film is subjected to higher temperatures, this can impair the mechanical values such as seal strength. The user of our film is responsible to test the technical properties of our film.

### 2.2 Overall Migration:

The overall migration limit of 10 mg/dm<sup>2</sup> of the area which is in contact with the food, complies with the test conditions outlined under 2.1

### 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 ration of ≤ 6,0dm<sup>2</sup>/kg food.

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

- Migration test in accordance to Directives 82/711/EWG (including amending directives 93/8/EG and 97/48/EG) and directive 85/572/EWG (including amending directive 2002/72/EG) and after 10/2011/EU including of all additions and amendments
- Suppliers Certificate of Conformity
- Worst case calculations

This concerns the following substances in polymers:

Substance	Ref-No.	FCM-Substance-No.	SML/QM/QMA [mg/kg]
Caprolactam	14200	212	15
Stearic acid and zinc salts	89040	106	25
Maleic anhydride	19960	234	30
1-hexene	18820	356	3
Octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	68320	433	6
Zinc oxide	96240	402	25
Tris(nonphenyl)-phosphite	74400	69	30
Hexamethyldiamine	18460	305	2,4
2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	38560	500	0,6
isophthalic acid	19150	291	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-No.	FCM-Substance-No.
Talc	E553b	92080	615
Glycerol	E422		
Silicone oil	E900		
Calcium carbonate	E170		
Silicon dioxide	E551	86240	504
Calcium stearate	E470a		

## 2.5 Functional Barrier

Providing that the plastic layers must be 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

Not applicable

## **5. Hygiene**

A concept for hygiene and pest control has been focused and can be audited on request. The production of packaging materials is subject to the requirements of good hygiene practice 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 materials is free from micro organisms, moulds and yeast (<50 CFU/100 cm<sup>2</sup>).

## **7. Heavy Metals**

We meet the requirements of Directive 94/62/EG (including amending Directive 2004/12/EG and 2005/20/EG) regarding heavy metal content.

## **8. Powder**

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

## **9. Good manufacturing practice**

We confirm, that the products are manufactured according to the requirements of 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.

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, table3, column 3 of Regulation 10/2011).

Urmas Algpeus  
Manager  
Kanjon OÜ