



# KOLON INDUSTRIES, INC

## FILM QA Team

1002, Ungmyoung-dong, Gimcheon-city Gyung-sangbuk-do, 740-180, KOREA

TEL : 82-54-429-7616, FAX : 82-54-429-7666

Date 2014. 01.03

### Declaration of Compliance

according to Regulation (EU) 10/2011 Annex IV

#### General Product Information

1. Manufacturer : Kolon Industries, Inc
  - Head Office : Kolon Tower, Byeolyang-dong 1-23, Gwacheon, Gyeonggi-Do, Korea
  - Gumi Plant : 212, Gongdan-Dong, Gumi, Gyeongsangbuk-Do
  - Gimcheon Plant #1 : 1002, Eungmyeong-Dong, Gimcheon, Gyeongsangbuk-Do
2. Name(s) of product(s): Astroll(PET Film) - CD9(@) Grade
  - (@) = replace two digit(CD900 ~ 03, CD910 ~ 13, CD950~53)
3. Description of Product(s): Biaxially Oriented PET Film

#### Status : European Union

Status: European Union (EU)

For the production of Kolon Industries, Inc only substances are used listed in Annex I of Regulation EU No 10/2011. Kolon Industries, Inc complies with the migration and other requirements of EU Regulations 1935/2004 and 2023/2006. When tested for overall migration using the following three EU - recommended food simulants: 3% acetic acid (10days at 40°C), 95% ethanol (10 days at 40°C) and Isooctane(2 days at 20°C); EC Directives 85/572/EEC and 82/711/EEC as amended by Directives 93/08/EEC and 97/48/EC; the film passes the test - the migration from the film into each simulant being less than one third of the EU limit of 10 mg/dm<sup>2</sup> before the application of any permitted reduction factors.

The following substances subject to limitations and/or specifications may be present in the film.

Substance name	FCM substance No	SML (mg/kg)	SML(T) (mg/kg) (group restriction No)	Restrictions and specifications	SM (mg/kg)
Terephthalic acid	785		(28) 7.5mg/kg expressed as Terephthalic acid		< 0.5
Ethylene glycol	227		(2) 30mg/kg expressed as Ethylene glycol	1mg/kg in final product	<10
Antimony Trioxide	398	0.04		SML expressed as antimony	ND





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Regarding antimony trioxide the film is formulated that the specific migration limits cannot be exceeded under the normal recommended conditions of use even if all of the substances in it migrate into the food. According to Annex V Chapter 2 2.2.2 the verification of compliance with the limitations is not compulsory.

Regarding Terephthalic acid and Ethylene glycol tests have been carried out on the film by accredited laboratory confirming that the specific migration limit is met.

Contact Condition : 10 Days @ 40 °C

Simulants :           A 3% acetic acid  
                          B 95% ethanol

### **Status : Dual Use Additives**

In the manufacture of Kolon Industries, Inc up to one additives are used which are subject to a restriction in food.

Substance name	FCM substance No / Cas No	E-number	Remakr
Silicon Dioxide	504 / 7631-86-9	E 551	Due to the chemical nature of the additive no potntial migration into the food is to be expected

### **Specification of the intended use or limitations**

Type or types of food with which it is intended to be put in contact

Indirect food contact

Time and temperature of treatment and storage in contact with the food

Overall migration: 10 days, 40 °C, tested

Ratio of food contact surface area to volume used to establish the compliance of the material or article

### **Status : United States of America (US FDA)**

The unconverted and unprinted PET Film Kolon Industries, Inc complies with the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under: 21 CFR 177.1630 (PET) provided it is used subject to limitations found in 21 CFR 177.1630 and in accordance with good manufacturing practices.





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Please note that the film should not be used for packaging or holding food during cooking.

#### **Status : Heavy metals content**

The heavy metals cadmium, lead, mercury and chromiumVI are not intentionally used for the production of the unconverted and unprinted PET films.

The sum of the heavy metals cadmium, lead, mercury and chromiumVI incidentally present in this product is below 100 ppm and the film, therefore, complies with the limits set out in EC Directive 94/62/EC (Article 11) on packaging and packaging waste (as amended by date); the UK Packaging (Essential Requirements) Regulations 1998 (SI 1998 No. 1165 - Regulations 7, 8 and 9); the French Décret n° 2007-1467 (Article 4) and the US CONEG Model Toxics Legislation.

By observing the above regulations, the duty of care regarding the compliance of the product with legislation governing indirect food contact applications has been fulfilled.

Although the product is intended for general food use (i.e. intended for indirect contact with foodstuffs of all types) it is the responsibility of the user to verify its suitability for his own intended food application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular foodstuff being used. The content of this declaration is strictly confidential and should not be passed on to third parties. However in case your customer requires this information in order to assess compliance and measuring migration as required by law, you are entitled to pass them on to the customer or a neutral institute, under the strict obligation that the information is treated strictly confidential. This declaration shall continue in effect for 1 year from its effective date unless it is modified before. If further information is required please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Yun-Hee, Lee", positioned above a horizontal line.

**Yun-Hee, Lee**

Team Manager of **KOLON** Film Quality Assurance Team

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