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## **Declaration of compliance for materials and articles intended to come into contact with food**

### **Pentaclear® SmartCycle® APET BX-E660F04-1160000-100\_0-ZZZ**

The films are suitable for food contact in compliance with the following European Regulations:

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, as amended.

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, last amended by Regulation (EU) 2019/37.

According Regulation (EC) No 1935/2004 specific substances not regulated in Regulation (EU) No 10/2011 like pigments comply with national regulations or applicable Recommendations of the Council of Europe.

If the films contain Post Consumer Recycling material, it complies with Regulation (EC) No 282/2008 in its current state of validity.

The products are produced using Good Manufacturing Practice in accordance with Regulation (EC) No 2023/2006.

### **Overall migration**

The overall migration limit of 10 mg/dm<sup>2</sup> area resp. 60 mg/kg of food for plastic materials and articles intended to be brought into contact with food intended for infants and young children is met under testing condition OM2, 10 d at 40°C in the food simulants A, B, D2

### **Specific migration**

For substances with subject to specific migration limits (SML) - as listed in the annex - the compliance is ensured either by worst case calculation, when the content is known, by determination of the residual content according Annex V 2.2.2. of Regulation 10/2011 or by migration measurements in contact with the appropriate food simulant for the substance under standardized testing condition according Annex V 2.1.4.: 10 d at 60°C



### **Intended food contact conditions**

Compliant for all type of foods for 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.

### **Ratio of food contact surface**

For the above mentioned films article 17 (2) c) applies. Sheets and films that are not yet in contact with food, the compliance is established by a surface to volume ratio of 6 dm<sup>2</sup> per kg of food.

### **Dual Use Additives**

Dual Use Additives according EU Regulation No 10/2011 are additives which are authorised for the manufacture of plastic materials and articles and at the same time authorised as food additive or flavouring substances. The film may contain dual use additives as listed in the annex.

### **Non-intentionally added substances – NIAS and degradation products**

Annex IV paragraph 6 of Regulation (EU) No 10/2011 refers to degradation products for which restrictions and/or specifications are set out in Annexes I and II to this Regulation. The identified substances are listed in the annex of this declaration.

### **European packaging directive**

Additionally the products are in compliance with the European packaging directive 94/62/EC, amended by the directives 2004/12/EC, 2005/20/EC and 2013/2/EU.

### **General**

The adherence to the requirements of the European Regulation (EC) No 1935/2004, particularly the suitability of the articles for the intended use, the effect to impairment of organoleptic characteristics such as smell and taste of the food as well as the compliance to all possible restrictions, must be guaranteed by the person, who brings the articles into the circulation.

It is the responsibility of the user to test the suitability of our products for the intended food application. We accept no liability for losses arising from the inadequate suitability of our products for the food.

This letter is intended for your company only and replaces previous declarations of compliance. After a break in delivery lasting more than 12 months, this letter ceases to be valid for new deliveries of the relevant product.

You will be informed of any changes in the composition of our above mentioned products which are relevant to food contact legislation.

This declaration is valid as long as no new or amended legislation comes into force and will then be updated accordingly.

Michael Otten  
Group Manager, Regulatory Affairs  
Heiligenroth, Germany

**Annex****Substances with specific migration limits (SML)**

Substance	Ref. No	SML (mg/kg food)
terephthalic acid	24910	7,50
isophthalic acid	19150	5,00
ethyleneglycol	16990/53650	30 (T) (2)
diethyleneglycol	13326/15760/47680	30 (T) (2)
antimony trioxide	35760	0,04
acetaldehyde	10060	6,00
polyethylene glycolmonoalkylether 1)	77708	1,8
chlorides of choline esters of coconut oil fatty acids 2)	43515	0,9
bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride 3)	39200	1,8

1) if film is silicone coated

2) if film is antistatic coated

3) if film is anti-fogging coated

(T): group SML

**Non-intentionally added substances – NIAS and degradation products**

The following substances are identified as NIAS or degradation products:

Substance	FCM substance No.	CAS No	Ref. No	SML (mg/kg food)
acetaldehyde	128	0000075-07-0	10060	6,00

**Dual Use Additives:**

Dual Use Additive	Ref. No	E-No.
glycerolester	-	E471
aluminium silicate	62720	E559
magnesium silicate	85601	E553a
talc	92080	E553b
silica	86240	E551
phosphoric acid	23170/72640	E338
acetaldehyde	10060	Flavouring agent
titanium dioxide 1)	93440	E171
polydimethylsiloxane 2)	76721	E900

1) if film is opacified with titanium dioxide

2) if film is silicone coated

The information about the substances is based on our current state of knowledge and on information from our raw material suppliers.