

Blumberg, 17. September 2020

## Declaration of Compliance (DoC) with the legislations for materials and articles intended to come into contact with food products.

Version: 2  
Print date: 2020-04-06

Remarks on update:  
Update in regard to the latest amendments of the (EU) 10/2011

### 3. Identity of the product

Food Packaging\_80%\_R-Pet\_Transparent (Hereinafter referred to as "Product").

Product type: Final material or article  
Product description: R-Pet Trays & Lids, containing 80% Recycled Materials.

4. Issue date  
2020-04-03

### 5. Applicable legislation and purity confirmation

#### European Commission Regulation definition:

- REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, (hereinafter referred to as "Regulation (EC) No 1935/2004").
- 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, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to Commission Regulation (EU) 2019/1338 of 29 August 2019., (hereinafter referred to as "Regulation (EU) No 10/2011").
- COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, amended up to COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred to as "Regulation (EC) No 282/2008").



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Geschäftsführer: Kai Kruse, Wolfgang Eichler, Thomas Wölflein, Dr. Heinz-Joachim Reinhardt • Es gelten unsere vereinbarten Liefer- und Zahlungsbedingungen.

## A. Europe

### i. Compliance with the requirements of the Framework Regulation

- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects: YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

### ii. Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES

Plastics used to produce this Product and not separated from the food by a functional barrier are manufactured from only monomers, other starting substances and additives authorized under Regulation (EU) No 10/2011.

### iii. Compliance with the requirements of the Recycled Plastics Regulation

- Regulation (EC) 282/2008: YES

Recycled plastic materials used to produce this Product and not separated from the food by a functional barrier are obtained only from a recycling process authorized in accordance with Regulation (EC) No 282/2008 and listed in the EC Register of authorized recycling processes.

Authorized recycling process(es)			
Number	Process	EFSA question number; application number	Business operator
RECYC0126	Recycled poly(ethylene terephthalate) for direct food application	EFSA-Q-2015-00190	Coveris Rigid Deutschland GmbH Germany

### iv. Other EU legislation

Other EU legislation: NOT SPECIFIED

## B. Member State legislation and non-European legislation

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

National legislation in EU Member States and legislation for countries outside the EU: NOT SPECIFIED

## C. Non-intentionally added substances

Non-intentionally added substances in plastics, according to Article 6(4a) of Regulation (EU) No 10/2011, and in non-plastic materials, are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Adequate information on non-intentionally added substances can be found in section 6A of this document.

## D. Overall migration limit

This product complies with the overall migration limit tested under the following conditions:

### Simulants

- A: Ethanol 10% (v/v) : < 0.5 mg/dm<sup>2</sup>
- B: Acetic acid 3% (w/v) : < 0.5 mg/dm<sup>2</sup>
- D2: Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011. : < 1 mg/dm<sup>2</sup>



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Test conditions			
Test Number	Test conditions	Intended food contact conditions	Covers also food contact conditions described for
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.	Test OM2 covers also food contact conditions described for OM1 and OM3.

### E. Organoleptic properties

We have performed organoleptic tests according DIN 10955 to confirm compliance with Article 3 of Regulation (EC) No 1935/2004. However it is the responsibility of the downstream user to verify suitability in combination with the used food.

## 6. Limits, restrictions and compositional specifications

### A. Limits and restrictions of non-listed substances

Europe - Article 19: intentionally added substances PLASTICS		
Proprietary substance RamaPet	CAS number: - Reference number: -	Fat-reduction factor: unknown
<b>Maximum concentration: -</b>	<b>Maximum Use Level: n/a</b>	
<b>Restrictions and specifications</b>		
Unknown		

### B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

FCM number	EEC reference number	CAS number	Substance name	Maximum concentration	Maximum use level
398	35760	0001309-64-4	antimony trioxide	-	-
509	23170, 72640	0007664-38-2	phosphoric acid	-	-
227	16990, 53650	0000107-21-1	ethyleneglycol	-	-
263	13326, 15760, 47680	0000111-46-6	diethyleneglycol	-	-
291	19150	0000121-91-5	isophthalic acid	-	-
128	10060	0000075-07-0	acetaldehyde	-	-
785	24910	0000100-21-0	terephthalic acid	-	-

### C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

#### i. Restrictions; Annex I – table 1

FCM number	Fat-reduction factor	Restriction(s)	Restrictions and specifications	Notes
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398	no	SML:(1) 0,04 mg/kg	Notes: Note number (6): Migration limit might be exceeded at very high temperature. Other Specifications: SML expressed as antimony	Note number (6): Migration limit might be exceeded at very high temperature
509	no	No		
227	no	SML:(1) 30 mg/kg	SML(T) Remark:(1) Group 2: expressed as ethyleneglycol (89, 227, 263, 1048)	
263	no	SML:(1) 30 mg/kg	SML(T) Remark:(1) Group 2: expressed as ethyleneglycol (89, 227, 263, 1048)	
291	no	SML:(1) 5 mg/kg	SML(T) Remark:(1) Group 27: expressed as isophthalic acid (188, 291)	
128	no	SML:(1) 6 mg/kg	SML(T) Remark:(1) Group 1: expressed as acetaldehyde (128, 211)	
785	no	SML:(1) 7,5 mg/kg	SML(T) Remark:(1) Group 28: expressed as terephthalic acid (191, 192, 785)	

**ii. Group restrictions: Annex I – table 2**

No group restrictions are present.

**iii. Notes on verification of compliance; Annex I – table 3**

No notes on verification of compliance are present.

**D. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals**

Name / Element	Restriction	Maximum concentration
Cobalt (Co)	SML:(1) 0,05 mg/kg	-
Manganese (Mn)	SML:(1) 0,6 mg/kg	-

**E. Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines**

This Product may contain Primary Aromatic Amines according to Annex II: YES

**F. Compliance confirmation**

This Product complies with the limits and restrictions in points 6A, 6C, 6D and 6E within this document, based on worst-case calculations, migration modeling or migration testing.

Specific migration is tested under the following conditions:

Test conditions			
Contact time:	3 days < t ≤ 30 days	Contact temperature:	10 days at 40 °C
Test time:	10 days	Test temperature:	40°C

The following substances with limitations in this Product have not yet been risk assessed by Us and therefore need to be evaluated by the downstream user based on the information listed below:



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### **i. Non-listed substances**

All substances comply with the applicable limitations.

### **ii. Substances listed in Regulation (EU) No 10/2011, Annex I**

All substances comply with the applicable limitations.

### **iii. Substances listed in Regulation (EU) No 10/2011, Annex II, Metals**

All metals comply with the applicable limitations.

### **iv. Substances listed in Regulation (EU) No 10/2011, Annex II, Primary Aromatic Amines**

It is up to the downstream user to determine compliance with the applicable limitations.

### **G. Inks, coatings or adhesives**

In case this Product is printed on, covered by a coating, or if different layers are held together by adhesives, We confirm that substances listed in Annex I, coming from inks, adhesives or coatings used in this Product, comply with the relevant restrictions.

This Product may contain substances with limitations listed in the tables under 6A or 6B within this document coming from inks, adhesives or coatings but may not be identified as such by Our suppliers.

### **7. Dual Use Additive(s)**

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

<b>Number (E or FL)</b>	<b>Name</b>	<b>Maximum concentration</b>
E 211	Sodium benzoate [14]	0,020 %
E 260	Acetic acid	0,020 %
E 338	Phosphoric acid	(unknown)
E 435	Polyoxyethylene sorbitan monostearate (polysorbate 60)	0,300 %
E 900	Dimethyl polysiloxane	2,100 %

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

### **8. Specifications for use**

#### **Specifications of use as regards of type or types of food**

All type of foods

#### **Specifications for use as regards of time and temperature of treatment and storage of food**

Maximum contact time equals 30 days.

#### **Any other limitations of use**

Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children: NO

Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: NO

A surface/volume ratio expressed in dm<sup>2</sup> FCM/kg food of: 6 dm<sup>2</sup> FCM/ kg food



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## 9. Functional barrier

This Product contains a functional barrier: NO

### Legend

If the compliance assessment is based on a worst-case family strategy, the identity of the product on which the compliance assessment is based will be indicated here.

\* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source.

\*\* Substances marked with a double asterisk in this document are not present in this Product. However, they are included in this document due to compliance assessment of a worst-case product.

\*\*\* Substances marked with a triple asterisk in this document are substances to which both remarks \* and \*\* apply.

For all substances with a single asterisk, \*, you are advised to contact your supplier before carrying out any specific migration tests to verify the concentration of the substance within this Product.

EXCP<sup>1</sup>: If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

EXCP<sup>2</sup>: If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

### Disclaimer

It should be noted that the product(s) has been tested for the above mentioned forms of usage and conditions. Therefore, it will be the sole responsibility of the customers to determine that the usage of the product(s) complies with the information given in this document and is safe, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occurs. In case the product(s) will be used in a different manner than tested, the information in this declaration of compliance will not apply and the customer shall be responsible for the compliance with the specific legislation and regulation(s).

In addition, it is the responsibility of our customers to determine that their use of our product(s) is safe, and according to the information given in this document, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occur. Because use conditions and applicable laws may differ from one location to another, the customer is responsible for determining whether products and information in this document are appropriate for the customers use. The purchaser remains responsible for determining whether the use complies with all relevant regulations.

The information included in this document is valid from the stated version date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We, therefore recommend our customers to verify the regulatory status periodically by accessing our Sales Department. It will be renewed in all cases where the previous conformity is no longer ensured and in case of changes in the regulations.

Mit freundlichen Grüßen

  
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