

Declaration of Compliance

Introduction

OY PLASTEX AB
 VENTELANTIE 12
 8500 LOHJA

Version: 1
 Print date: 2023-01-31

Remarks on update: NOT SPECIFIED

1. Issued by

Pretium (Hereinafter referred to as "We", "Us", or "Our").
 Vossendaal 12
 4878 AE
 Etten-leur
 Nederland

2. Manufactured/imported by

Identical to the details listed under point 1 within this document.

3. Identity of the product

Virgin PET (Hereinafter referred to as "Product").

Product type: final product

4. Issue date

2023-01-30

5. Applicable legislation and purity confirmation

Based on information provided by our suppliers in their compliance statement, combined with our own assessment, we can conclude that the product complies with the requirements of the following legislations.

A. Europe

Material group	Legislation
COLOURANTS & PIGMENTS Country: Europe - CoE AP(89)1 Status: Compliant	Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.
GENERAL Country: Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) Status: Compliant	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. (Amended by REGULATION (EC) No 2019/1381). Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a), but also covers: GMP (Article 3), labelling requirements (Article 15) and Traceability (Article 17).
Country: Europe - GMP Regulation (EC) No 2023/2006	COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come

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Status: Compliant	into contact with food
PLASTICS Country: Europe - 10/2011 up to 2020/1245 Status: Compliant	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) 2020/1245 Of 2 September 2020.

The PET material used in this product contains 100% virgin PET, so no recycled PET is used.

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) - B - Acetic acid 3% (w/v) - D2 (assigned fatty food simulant) - Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.			
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 OM 2 covers also food contact conditions described for OM0, OM1 and OM3.

E. Organoleptic properties

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The sample material was exposed to the test food. The ratio was 1.1 dm² with 100 g test food.

The test food was in direct contact with the sample material.

The following side was facing the test food:

- food contact side (by filling)

The test food was:

- water

Storage was performed in a closed glass container under the following conditions:

- 10 d / 40°C (corresponds to long-term storage according to DIN 10955)

As a blank, the same test food was stored in the same way, but without sample material.

Result (rounded up) and Description (if Result ≥ 2)

Odour: 0 - not perceptible

Taste: 1 - just perceptible

6. Limits, restrictions and compositional specifications

A. Limits and restrictions of non-listed substances

Europe - Substance of Very High Concern (SVHC), Candidate List (Annex XIV), updated on 10th June 2022		
GENERAL		
Cadmium	CAS number: 7440-43-9 Reference number: 231-152-8 Maximum Use Level: n/a	Fat-reduction factor:
Restrictions and specifications	Notes:	
No	Carcinogenic (Article 57a), Specific target organ toxicity after repeated exposure (Article 57(f) - human health)	
Screening method: Migration result (calculated from members)		

Europe - Substance of Very High Concern (SVHC), Candidate List (Annex XIV), updated on 10th June 2022		
GENERAL		
Lead	CAS number: 7439-92-1 Reference number: 231-100-4 Maximum Use Level: n/a	Fat-reduction factor:
Restrictions and specifications	Notes:	
No	Toxic for reproduction (Article 57c)	
Screening method: Migration result (calculated from members)		

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

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Substance identification	Restrictions and specifications	Screening method
FCM: 263 EEC ref: 13326, 15760, 47680 CAS: 0000111-46-6 diethyleneglycol	SML: 30 mg/kg SML(T) Remark: Group 2: expressed as ethyleneglycol (89, 227, 263, 1048) FRF: no Compliance Notes:	Method= (12)
FCM: 227 EEC ref: 16990, 53650 CAS: 0000107-21-1 ethyleneglycol	SML: 30 mg/kg SML(T) Remark: Group 2: expressed as ethyleneglycol (89, 227, 263, 1048) FRF: no Compliance Notes:	Method= (12)
FCM: 291 EEC ref: 19150 CAS: 0000121-91-5 isophthalic acid	SML: 5 mg/kg SML(T) Remark: Group 27: expressed as isophthalic acid (188, 291) FRF: no Compliance Notes:	Method= (12)
FCM: 785 EEC ref: 24910 CAS: 0000100-21-0 terephthalic acid	SML: 7,5 mg/kg SML(T) Remark: Group 28: expressed as terephthalic acid (191, 192, 785) FRF: no Compliance Notes:	Method= (12)

Legend screening methods: (1) 100% migration calculation, (2) Overall migration test, (3) Migration modelling, (4) Migration testing, (5) Other (like for instance suppliers information), (12) Migration result (from 100% migration calculation, migration modelling, migration testing or all possible combinations)

C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Table 1 Annex II, Metals

Name / Element	Restriction	Screening method
Cadmium	SML: 0,002 mg/kg	Migration result (calculated from members)
Arsenic	SML: 0,01 mg/kg	Migration result (calculated from members)
Lead	SML: 0,01 mg/kg	Migration result (calculated from members)

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Mercury	SML: 0,01 mg/kg	Migration result (calculated from members)
Chromium	SML: (1) 0,01 mg/kg (2) 3,6 mg/kg	Migration result (calculated from members)
Nickel	SML: 0,02 mg/kg	Migration result (calculated from members)
Antimony	SML: 0,04 mg/kg	Migration result (calculated from members)
Cobalt	SML: 0,05 mg/kg	Migration result (calculated from members)
Europium	SML: 0,05 mg/kg	Migration result (calculated from members)
Gadolinium	SML: 0,05 mg/kg	Migration result (calculated from members)
Lanthanum	SML: 0,05 mg/kg	Migration result (calculated from members)
Terbium	SML: 0,05 mg/kg	Migration result (calculated from members)
Lithium	SML: 0,6 mg/kg	Migration result (calculated from members)
Manganese	SML: 0,6 mg/kg	Migration result (calculated from members)
Aluminium	SML: 1 mg/kg	Migration result (calculated from members)
Barium	SML: 1 mg/kg	Migration result (calculated from members)
Iron	SML: 48 mg/kg	Migration result (calculated from members)
Copper	SML: 5 mg/kg	Migration result (calculated from members)
Zinc	SML: 5 mg/kg	Migration result (calculated from members)

D. 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: NO

E. Compliance confirmation

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This Product complies with the limits and restrictions in points 6A, 6B, 6C and 6D 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:	Above 6 months at room temperature and below	Contact temperature:	10 days at 60 °C
Test time:	10 days	Test temperature:	60 °C

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.

Number (E or FL)	Name
E 173	Aluminium
E 338	Phosphoric acid

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 types of food: aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that containing fats and oils.
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Specifications for use as regards of time and temperature of treatment and storage of food

Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.

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 ² FCM/kg food of: 8,8 dm ² FCM/ kg food

PET products could be filled at maximum of 60°C and should be stored in a dry and clean storage to avoid (cross) contamination, damage and deformation. Do not expose the pallets to direct sunlight, this will cause the products to deform. Pallet handling instruction is available.

9. Functional barrier

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This Product contains a functional barrier: NO

Legend

⁽¹⁾ 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.

P.C. Redert


Vossendaal 12
Name/Signature 4878 AE Etten-Leur
The Netherlands
T +31 (0)76 5014000

Pretium
Vossendaal 12
4878 AE
Etten-leur
Nederland

Disclaimer

The information included in this document is based on the present state of our knowledge and is valid from the stated issue date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product, we cannot guarantee that the status of this document will remain unchanged. It will be renewed in all cases where the previous conformity is no longer ensured.