

## **Declaration of Compliance**

in accordance with EU Regulations 1935/2004. and 10/2011.  
Plastic materials and articles to come into contact with food.

### *The identity of the product*

virgin PET bottles

### *Date of declaration*

30. August 2024.

### *Confirmation*

PET bottles covered by this DoC comply with the following requirements and all of its amendments in force:

- Commission Regulation (EU) 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
- 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.
  
- 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) 2023/1627 of 10 August 2023.
- Commission Regulation (EU) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
- Directive (EU) 2018/852 of the European Parliament and of the council of 30 May 2018 amending Directive 94/62/EC on packaging and packaging waste

The following substances are subject to a specific migration limit set out in the Union list of Commission Regulation (EU) No. 10/2011:

Substance	CAS number	SML
Terephthalic acid (PTA)	000100-21-0	7.5 kg/kg
Isophthalic acid (IPA)	000121-91-5	5 mg/kg
Mono-ethylene glycol (MEG)	000107-21-1	MEG + DEG 30 mg/kg
Diethylene glycol (DEG)	000111-46-6	
Antimony trioxide (Sb <sub>2</sub> O <sub>3</sub> )	001309-64-4	0.04 mg/kg

*Conformity with overall migration limits*

Overall migration has been performed as described in Commission Regulation (EU) No. 10/2011 (including amendment) relating to plastic materials and articles intended to come into contact with food.

Test methods according to the parts of EN 1186 and where applicable updated by the provisions of the Regulation, which is more recent.

Products to which is referring this declaration are meeting global migration limits according to Regulation 10/2011, in following testing conditions, and are compliant with test results.

Food simulant	Test conditions	Migration criterias (mg/dm <sup>3</sup> )
„A” simulant - 10% ethanol	10 days in 40°C	≤ 10
„B” simulant - 3% acetic acid	10 days in 40°C	≤ 10
„D2” simulant - Olive oil	10 days in 40°C	≤ 10

*Conformity with specific migration limits*

Specific migration has been performed in accordance with Commission Regulation (EU) No. 10/2011 (including amendment) relating to plastic materials and articles intended to come into contact with food.

Test methods according to the parts of EN 1186 and where applicable updated by the provisions of the Regulation, which is more recent.

Food simulant	Test conditions	Migration criteria (mg/dm <sup>2</sup> )	Result (mg/dm <sup>2</sup> )
„D1” simulant - 50% ethanol	10 days in 40°C	≤ 10	3.3

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

Solutions containing max. 50% alcohol, flavours, sweeteners, vegetable oils, water based solutions (2,5<pH<9)

*Specifications for use as regards of time and temperature of treatment and storage in contact with the food*

Handling of the packaging material:

- storage temperature: -10 - +40 °C
- shelf life unfilled: 5 years
- shelf life filled: 2 years.

The product could be filled at maximum of 50°C and should be stored in a dry and clean storage to avoid contamination, damage and deformation.

The product must be protected from radiant heat and sunlight.

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

- „A”, „B”, „D1” simulants: 1.14 dm<sup>2</sup> / 100 ml
- „D2” simulant: 1.0 dm<sup>2</sup> / 40 ml

Dated in Budapest, 30 August 2024.



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# TEST REPORT

ÉMI-TÜV SÜD Kft.  
Central Laboratory  
KERMI Department  
Budapest, 29 08 2024  
Test report No.:  
R-200320001976\_1\_M  
1 / 2 pages

**Date of application:** 01 08 2024

**Subject of application:** Test of mini PET bottle according to the Client's request.

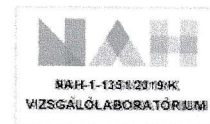
**Receipt date of test samples:** 01 08 2024

**Testing period:** 01 08 2024 – 23 08 2024

**Description of the sample:** Sample 1. mini PET bottle  
PHARMA 100, PP18(vt)  
Pharma100 típusú 100 ml-es PET palack, tömege 9 gramm,  
menet PP18, anyaga virgin PET

The samples were submitted by the Applicant.

Remark: The result relates only to the items tested  
No extract, abridgment or abstraction from a test report may be published or used to advertise a product without the written consent of the Director of ÉMI-TÜV SÜD Ltd KERMI Department. The results contained herein apply only to the particular sample tested and to the specific test carried out and not to samples of the current production line.



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**Description of the sample:**

Sample 1. mini PET bottle  
 PHARMA 100, PP18(vt)  
 Pharma100 típusú 100 ml-es PET palack, tömege 9 gramm,  
 menet PP18, anyaga virgin PET

**Test results:****1. Overall migration test**

Test method:

MSZ EN 1186-3:2023

Overall migration "A", "B", "D1" simulants

Area : Volume ratio [1.14 dm<sup>2</sup> : 100 ml]

MSZ EN 1186-2:2023

Overall migration "D2" Olive oil simulant

Area : Volume ratio [1.0 dm<sup>2</sup> : 40 ml]

Test parameters	Test results [mg/dm <sup>2</sup> ] ± 5 rel. %	Requirement
Overall migration Test circumstances OM5	mini PET bottle PHARMA 100, PP18(vt)	Regulation 1935/2004/EC and 10/2011/EU
"A" simulant 10% ethanol, 40°C, 10 days	<1	<10 mg/dm <sup>2</sup>
"B" simulant 3% acetic acid, 40°C, 10 days	<1	<10 mg/dm <sup>2</sup>
"D1" simulant 50% ethanol, 40°C, 10 days	3.3	<10 mg/dm <sup>2</sup>
"D2" simulant Olive oil, 40°C, 10 days	<5	<10 mg/dm <sup>2</sup>

LOQ: 1 mg/dm<sup>2</sup>; D2: 5 mg/dm<sup>2</sup>**Evaluation:**

The tested sample with registration number R-200320001976\_1 complies with the current legislation with regard to the tested parameters.

The tested samples are waste and accordingly are disposed.

ÉMI-TÜV SÜD Kft.  
 KERMI Department



ÉMI-TÜV SÜD Kft.  
 KERMI Osztály

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