

# VERKLARING VAN OVEREENSTEMMING

Voor materialen bestemd voor het in contact komen met voeding

Article numbers	
69007	PET FLES SQUEEZER 250ML. + FLIPTOP DOP ZWART

## Verklaring t.a.v. PETFLES250:

The manufacturer declares that the product described complies with the relevant requirements as laid down in:

- Framework Regulation (EC) 1935/2004 (dated 27-10-2004).
- EU Commission Regulation (EU) 10/2011 relating to plastic materials (tested according to EC Directive 97/48/EC; Migration testing (2nd amendment of 82/711/EEC) and EC Directive 85/572/EC; List of simulants).

has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The chemical composition of the PET bottle F522 – 30ml - N1(S) consists of:

- One or more monomers and/or additives which are regulated with a specific migration limit (SML) or a quantitative maximum (QM). The identity of this substance(s) can be disclosed for testing purposes upon special request and under maintaining secrecy.
- The following substances subject to limitations and/or specifications:

Name of substance	CAS no.	Ref. nr.	Limitations / Specification
Antimony trioxide	309-64-4	35760	SML(T) = 0.04 mg/kg
Isophthalic acid	121-91-5	19150	SML = 5 mg/kg
Terephthalic acid	100-21-0	24910	SML = 7.5 mg/kg
Ethylene glycol	107-21-1	16990	SML(T) = 30 mg/kg
Diethylene glycol	111-46-6	13326	SML(T) = 30 mg/kg
Phosphoric acid	2466-09-3	83440	SML = 60 mg/kg
Component A	*	/	SML = 60 mg/kg
Component B	*	/	SML = 60 mg/kg

\* This component is released under secrecy agreement to the lab.

This material does contain phosphoric acid as dual use additive which is subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC.

Migration tests of the above-mentioned product are performed according to EC directive 85/572/EC and EC Directive 97/48/EC and according to Commission Regulation (EU) 10/2011 and have shown that under these conditions of use migration limits were not exceeded.

The specifications of the product are:

- type of food intended to come in contact with material/article: all foodstuffs
- Shelf-life and material/article temperature: Long time storage (more than 6 months) at a temperature up to 40°C
- Surface/volume ratio: 8 dm<sup>2</sup>/ kg (surface = 24 cm<sup>2</sup> and volume = 30 ml)

Traceability of the product is ensured according to Regulation (EC) No. 1935/2004 (via the number of the Pallet in conjunction with the date of production).

The Commission Regulation (EU) 10/2011 provides a guideline for the selection of test conditions to be used for various food products. According to that and under considerations of the food contact stated, the product complies with the stipulations of this Regulation regarding the packaging of food products to be packed. The user shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Regulation.

## **Verklaring t.a.v. PETFLES250D:**

We confirm that this product fulfils the applicable requirements on substances used for the manufacturing of materials and articles or components of articles intended to come into contact with food as described in the below cited legislation and standards.

EU

The below listed regulations represent harmonised EU legislation and are directly applicable in all EU member states. National legislation implementing such regulations is therefore not separately cited in this document.

We would like to stress that this product is a Plastic Intermediate Material as defined in chapter 4.3.1. of Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain, from 28.11.2013. Therefore this confirmation is restricted to the requirements as applicable for Plastic Intermediate Materials used for the manufacturing of materials and articles or components of articles intended to come into contact with food.

- Commission Regulation (EC) No 1935/2004. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 §1,c must be verified and tested by the producer of the final packaging material.
- Commission Regulation (EU) No. 10/2011 as amended. All used monomers and additives are listed in Annex I of this regulation.
- For any relevant restriction, as set by the Annexes I and/or II see chapter "migration testing".
- Commission Regulation (EC) No. 2023/2006. This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the "Borealis AG responses to customer inquiries" on Borealis' homepage.
- Commission Regulation (EC) No. 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade.

- Commission regulation (EC) No. 450/2009 on active and intelligent materials and articles is not applicable to Borealis' polymer resins.

## Migration limits

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Article 6.3.a and Annex II), Mercosur (Res. 39/2019 Annexo 4.3.b) and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al).

Representative worst case tests (3% acetic acid; 4h/100°C; S/V-ratio 6) did not show any migration above 0,04 mg/kg (limit of detection).

Other used monomers and additives are not regulated with specific migration limits.

Substances also authorised as direct food additives ("Dual use additives") are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of the limits as set in the applicable food legislation.

## Migration testing

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21 and article 2.12 of Chinese standard GB4806.1 the overall migration shall not exceed 10 mg/dm<sup>2</sup> from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg); (Mercosur GMC Res No. 56/92 - 8 mg/dm<sup>2</sup> and 50 mg/kg food).

A representative sample from this or a comparable material, tested for 2d at 20°C in isooctane (1 mm plate / total immersion) did not exceed the limit of 10 mg/dm<sup>2</sup> for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.

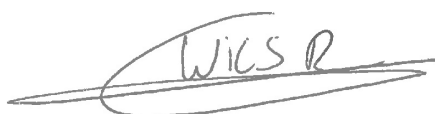
Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 10/2011; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8-2016; Mercosur GMC Res No. 32/2010. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

## Non-intentionally added substances – NIAS

To our present day knowledge, this product does not contain any intentionally added or known non-intentionally added substances for which genotoxicity has not been ruled out.

Ondertekend door Euro Fresh NV

Datum: 01-01-2023



Robbie Wils  
General Manager