VERKLARING VAN OVEREENSTEMMING

Voor materialen bestemd voor het in contact komen met voeding

Artikelnummers	70344, 70345
Benamingen	PET pot 400ml + ALU deksels PET pot 250ml + ALU deksels

Verklaring t.a.v. PET:

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 40ºC
- Surface/volume ratio: 8 dm²/ kg (surface = 24 cm² 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. de EPE inlage in de alu dop:

According to the information given us by our suppliers and our examinations, the materials which have been used in the above mentioned specification complies with the following guidelines and recommendations.
Manufacture of the above named product was done in accordance with regulation (EC) 2023/2006 relating to “good manufacturing practice for materials and articles intended to come into contact with foodstuffs”. This seal is intended for contact with all food types, when used at ambient temperatures up to hot fill at maximum of 70 °C for 2 hours or at maximum of 100°C for 15 minutes and then stored at room temperature.

The sealing material (foamed up LDPE) complies with the following requirements in their current version:

- Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) § 31., Germany
- Commission Regulation (EC) No 10/2011 on plastic materials and articles intended to come into contact with food, and amendments.
- CFR 21, § 177.1210 - „Closures with sealing gaskets for food containers“, and §177.1520 „Olefin polymers”, Food and Drug Administration (FDA), USA.
- Monography 3.1.3., ”Polyolefine”, of the European Pharmacopoeae
- The production process complies with the reproducibility and requirements of the Monograph 3.2.2. of Ph. Eur.

- Chapter 661, USP 36, “Containers-Plastics”, Monograph Low-Density Polyethylene
    - Infrared Spectroscopy and Differential Scanning Calorimetry are carried out in house against internal LDPE standards. The other tests of the requirements of the United States Pharmacopoeia class 36, chapter 661, are made extern.
- ICH Q3D (Guideline for elemental Impurities)
- Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food.

Migration tests
For the manufacture of the product no substances are used for which a specific migration limits exists.
Ratio of area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article is 30 cm²/1l.

Simulant	Conditions	results in mg/dm²
dist. water	10d, 40°C	1,4
3% acetic acid (B)	10d, 40°C	1,1
10% Ethanol (A)	10d, 40°C	0,7
20% Ethanol	10d, 40°C	1,0
50% Ethanol	10d, 40°C	1,7
Olive oil (D2)	10d, 40°C	<2 *
95% Ethanol	10d, 40°C	3,2

* value negative

In migration screening (95% ethanol, 60°C, 10 days) substances were identified and quantified, which are present as impurities or degradation products or reaction products originating from the additives or monomers used (Not Intentionally Added Substances - NIAS).
The evaluation of these substances was carried out based on OML and SML values or there were the amounts found below the 'threshold of toxicological concern' (TTC, EFSA Journal 2012 10 (7): 2750).
In summary, it should be noted that in migration and screening tests no material transitions were observed, which give rise to health concerns.

Special Substances and „Dual Use Additives“
The PE foam contains no dual use additives.

For a better processability of the product we use carbon dioxide as blowing gas and a minimal percentage of Erucamide (<0,1 %; CAS Nr. 112-84-5, EC No 2040092) as a slipping agent.
Other substances, for example BADGE, Phthalates, flame-retardant substances, or antioxidants (stabilizers) are not added to the product.
Bisphenol A was not detectable (<0,5µg/dm² with RP-HPLC)
The material contains no genetically modified organism (GMO- Directive 1830/2003).
The material does not contain any nanomaterials acc. to the definition of the EU Commission from 2011 (2011/696 / EU).

Cosmetic products

- We confirm that restricted or prohibited substances according to annex II and annex III of the Regulation (EC) No. 1223/2009 nor skin sensitizers are not intentionally used or added during manufacturing.
- For the mentioned substance/-s no chemical analyses have been performed so trace levels cannot be excluded. But a 10 ppb screening (see paragraph above) showed the absence of such kind of substances within the limits of this method.

Allergenic potential

The composition of the above mentioned products does not contain any of the substances recognized as causing hypersensibility (allergic reactions) of the Directive 1169/2011/EC.

BSE-Risk

The used raw materials are not of animal origin and can therefore be considered as risk-free concerning the topic of BSE/TSE

Environment

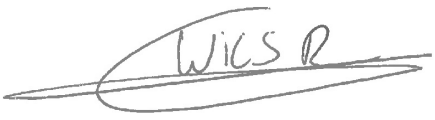
The lead, cadmium, chromium (Cr+6) and mercury concentration is less than 100 ppm (Coneg model legislation, Directive 94/62/EEC, Article 11).

Substances of the ECHA SVHC- list (REACH)

We got confirmations from our suppliers and are pleased to confirm that according to their information none of the materials what we deliver to you contain any of the SVHC substances according to http://echa.europa.eu/chem_data/candidate_list_table_en.asp >0.1%.
We know that we have to inform you of changes. If substances are present above the stated value, we will inform you in due time.

The above statements are the results of our tests and/or in accordance with the information provided by our suppliers, and they correspond to our present state of knowledge. They do not release the buyer from the duty to make his own checks on arrival of the goods and, due to the numerous possible effects in processing and application, they do not release the buyer from the duty of carrying out his own tests and examinations. The suitability of the product for the intended application and the possibility of effects on the taste and smell of the filled-in goods, must be checked by the user in the individual case. Any proprietary rights affected and statutes in force must be observed by the receiver of our products under his own responsibility.

Ondertekend door Euro Fresh NV
Datum: 01-01-2023



Robbie Wils
General Manager