

The declaration of compliance

Nr. part: 21379

PouchEurope

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We claim that rolls called
PE-tube 800x0,05 clear

Size (+/- 2mm) 800x0,05mm

produced for the firm:

ETRA Oy
Lampputie 2
00740 Helsinki
Finland

from the following material:

Foil PE 50mic thickness **PE tube film, quantity** 500kg

meet the requirements for products that are intended to come into contact with food and meet high hygienic and production standards.

Use:

The product is intended for contact with food

Based on documents provided by our raw material suppliers we declare that our products meet the requirements of Regulation (EC) No 1907/2006 (REACH) of 18 December 2006 as amended.

The material mentioned above meets the law requirements included in the following regulations:

1. Commission Regulation (EC) No. 10/2011 – on materials and plastic intended for contact with food as amended (the last change - Commission Regulation 2017/752 on 28 April 2017)
2. 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 80/109/EEC.
3. Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste corrected by Directives 2004/12/EC and 2005/20/EC.
4. Council Directive 94/62/EC – with regard to concentration of heavy metals - the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight.
5. Council Directive No. 85/572/EC, corrected by Directive 2007/19/EC, and Council Directive 82/711/EEC and its amendment No. 93/8/EEC – laying down the basic principles of migration.
6. Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation and Authorization of Restricted Chemicals (REACH) respect for bisphenol A.
7. Regulation CE No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, and corrected by Commission Regulation (CE) No. 282/2008

Intended food contact conditions:

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.

Information about “dual-use” additives in the material:

No dual use additives were used in the manufacture of this product.

Concerning the ratio surface / volume in contact with food, specify this ratio is 6dm²/kg

The requirements concerning the use of the material:

The global migration level not exceed the limit 10mg/dm².

The sum of concentration levels of 4 heavy metals (Cd, Hg, Cr VI, Pb) not exceed 100 ppm.

The concentration of solvents not exceed 5me/m².

The product does not affect the organoleptic properties of the dedicated food. Test are made by an independent research institute.

In addition,

We declare that substances - MOSH, MOAH, Bisphenol A and Phthalates - are not deliberately used by us in the production of our products.

In our printing process, we use only low migration printing inks, which may be present in articles for contact with food. They comply with the EuPIA guidelines for printing inks.

It is only used solvent-free adhesives which comply with FDA regulations. Our production process is carried out in accordance with GMP for flexible packaging materials, minimizing the risk of substances migration from the packaging to the packed article.

Based on Regulation 10/2011, we carry out control tests, which confirm that the substances listed above do not exceed the migration limit contained in the Act. The above document is consistent with documents issued by raw material suppliers.

Limitations of the use:

Bags can not be used as toys and can not be consumed, they only apply to dedicated products.

The conditions of processing and storing:

The product must be stored in rooms which are: covered with roof, dry, far from sources of heat. It must be protected against water, dampness and exposure to the sun.

The optimal temperature is 5-30°C, wetness level 30-70%. The required time of seasoning in the production process conditions before usage the packaging – minimum 24 hours.

Obeying the above regulations guarantees effective processing of the foil and packaging, as well as preservation of the guaranteed properties of our products.

Warranty:

The warranty period is 6 months from the moment manufacture finished product.

Declaration sources:

Declarations from the raw materials suppliers

In order to provide the highest quality products, meet the current law regulations connected with safety and food, and also meet the standards for products intended to come into contact with food, as well as ecological requirements. Products are produced according to implemented and uses in practice the systems of confirming the quality with the requirements BRC Packaging, ISO 9001:2009 and HACCP

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