



## Declaration of Compliance

with the legislation for materials and articles intended to come into contact with food

---

This declaration is intended for: **Eurobottle B.V.**

Food safety is fully integrated in the business policy of Flectic B.V. A review of the ISO22000 Food Safety Management System (FSMS) takes place every year.

All materials we use for producing bottles and closures are food safe prime materials. We are active in controlling and monitoring this on a frequent base. Additional testing for global migration limits is done on a group of base materials. Testing is performed by an independent lab, according to 82/711/EEC.

The article as described in the statement meets the relevant requirements of the framework (EC) 1935/2004.

### PRODUCT

“**Water bottle, transp. yellow, 0.5 liter**”, is a coloured article, mainly consisting of the basic polymers Low Density Polyethylene.

Item number		
Flectic B.V.	Eurobottle & Design BV	Description
20020902120007	I0209010481	500 ml. activity yellow transparant - K481
20085202120173	I10852010385	Activity dop bruin - K385
20085502120203	I0855010385	Activity nippel bruin - K385

### EU REGULATORY STATUS OF USED SUBSTANCES

Supplied information is based on specifications of the raw material.

#### 1. Monomers

Monomer(s) used in the formulation of “**Water bottle, transp. yellow, 0.5 liter**” are listed in EC Commission Directive 10/2011/EC effectively replacing Directive 2002/72/EC as amended (by 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC, and 2009/975/EC).

**Presence of monomer (s) subject to SML or QM restrictions.**

None of the monomers present are subjected to a SML.

#### 2. Additives

Additives used in the formulation of “**Water bottle, transp. yellow, 0.5 liter**” are listed in EC Commission Directive 10/2011/EC effectively replacing Directive 2002/72/EC as amended (by 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC, and 2009/975/EC).

**Presence of additives subject to SML or QM restrictions.**

None of the use additives present are subjected to a SML.

2013-006 Eurobottle	pagina 1 van 3
version 2011-03	



## Declaration of Compliance

with the legislation for materials and articles intended to come into contact with food

---

**Presence of dual use additives which are subject to disclosure of adequate information as described in Annex VI of Directive (EC) 10/2011, article 11.3.**

None of the dual use additives present are subjected to a SML.

### **3. Other substances**

The other substances used in the manufacturing of **“Water bottle, transp. yellow, 0.5 liter”** are listed in:

Dutch Regeling Verpakkingen- en Gebruiksartikelen (Warenwet), Chapter 1 - Kunststoffen.

### **4. Pigments and Colorants**

The other pigments and colorants used in the manufacturing of **“Water bottle, transp. yellow, 0.5 liter”** have been assessed in accordance with internationally recognized scientific principles and are regarded as safe under the restrictions and/or conditions of use specified under supporting documents.

### **MIGRATION**

Migration testing (OML and SML) with a representative sample made of 3020K Lupolen, EXXONMOBIL LD653, BOREALIS FT5230, carried out with food simulants during 3 days at 40 °C have shown that under these test conditions (according to 82/711/EEC) the specific and overall migration limits were not exceeded in 3% acetic acid. The foodstuffs corresponding with the food simulants are stated in EU Directive 85/572/EEC.

under the following provisions:

Restriction for 72 hours

Restriction on temperature for 40°

It should be noted that the products have been tested by a similar range of products for the above mentioned forms of usage and conditions. Therefore, it will be the sole responsibility of the downstream user to determine that the usage of the products complies with the information given in this document and is safe, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occurs. In case the products will be used in a different manner than tested, the information in this declaration of compliance will not apply and the downstream users shall be responsible for the compliance with the specific legislation and regulations.

**No noticeable amounts of heavy metals, phthalates were detected in representative samples.**

### **GMP**

**“Water bottle, transp. yellow, 0.5 liter”** 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.



## Declaration of Compliance

with the legislation for materials and articles intended to come into contact with food

---

### TRACEABILITY

Manufacturer has systems in place fulfilling the relevant aspects on traceability as required in article 17.1 of Regulation (EC) No. 1935/2004.

### LABELLING

The product is or could be labeled “for food contact” or bear the symbol with a glass and fork.



Information concerning correct use:

This product is not tested to be food safe with temperatures higher than 40 °C and for use in microwave.

In addition, it is the responsibility of our customers (downstream user(s)) to determine that their use of our product(s) is safe, and according to the information given in this document, lawful and technically suitable so that no change in flavour, taste or organoleptic properties occur. Because use conditions and applicable laws may differ from one location to another, the customer is responsible for determining whether products and information in this document are appropriate for the customers use. The purchaser remains responsible for determining whether the use complies with all relevant regulations.

The information included in this document is valid from the stated version date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We therefore recommend our customers to verify the regulatory status periodically.

Company	Name and position	Signature and date
Flectic B.V. Pioniersweg 32 8251 KN Dronten Netherlands	J.P. Vaartjes Quality Manager	2013-01-22 