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Declaration of Compliance for materials and articles intended to come into contact with food

- Item: **F1084 (PET-burk 50 ml)**
- F1085 (PET-burk 75 ml)**
- F1086 (PET-burk 200 ml)**
- F1087 (PET-burk 450 ml)**
- F1088 (PET-burk 200 ml)**
- F1185 (PET-burk 150 ml)**
- F1186 (PET-burk 400 ml)**

Opella AB, declares that the PET containers stated above in this document meet the requirement norms and directives:

- **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 89/ 109/EEC;
- **Regulation Commission (EC) No 10/2011** of 14 January 2011 as amended by (EU) 1282/2011, (EU) 1183/2012, (EU) 202/2014, (EU) 865/2014, (EU) 2015/174 and (EU) 2016/1416 on plastic materials and articles intended to come into contact with food;
- **Regulation Commission (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The chemical composition of the PET containers stated above consist of:

- One or more monomers and/or additives which are regulated with a specific migration limit (SML) or a quantitative maximum (QM).

The following substances subject to limitations and/or specifications:

Component	CAS	Specific migration limit (mg/kg food)
Terephthalic acid	100-21-0	7.5 / 5
Isophthalic acid	121-91-5	
Mono-ethylene glycol	107-21-1	(T) 30
Di-ethylene glycol	111-46-6	
Antimony trioxide	1309-64-4	0.04 (expressed as Antimony)
Phosphoric acid (E338)	7664-38-2	60

Table 1: Substance subject limitations

This material does contain intentionally incorporated dual use additive (E 338) which are subject to disclosure of adequate information as described in Annex VIa of Directive 2007/19/EC.

Migration tests of the above-mentioned product were performed and have shown that under these conditions of use migration limits where not exceeded:

- Type of food intended to come in contact with material/article: all |

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- Shelf-life and material/article temperature: any long storage (> 6 months) at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes (Please be aware of the properties of PET concerning the hot fill temperature. PET products shall degrade at approximately 60 °C, which is an indication under ideal circumstances.)
- Surface/volume ratio: 6.3 dm² contact area / 1 kg food

Simulants	Test conditions
3% acetic acid	10 days at 60 °C
10% ethanol	10 days at 60 °C
Olive oil	10 days at 60 °C

Table 2: Test conditions overall and specific migration

This Declaration of Compliance is valid for the product delivered by us as specified above. The information included in this document is valid from stated version 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. It will be renewed in all cases where the previous conformity is no longer ensured.

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.

REACH SVHC - Our suppliers of raw materials or components have a duty to inform us if their products contain *substances of very high concern* (SVHC) on the SVHC candidate list at a concentration above 0.1% w/w. In the event of notification by our suppliers of the existence of one of the substances exceeding the 0.1% w/w threshold, we will inform you as soon as possible, if the products you purchase are impacted. The above information is based upon the certificates provided by our suppliers of raw materials/components. Opella AB has no access to the detailed composition of raw materials, and does not, routinely, carry out any chemical analysis of these materials. The presence of non-intentionally added substances cannot therefore be totally excluded. This document does not exempt the client from ensuring the compatibility of the packaging requested with his product and verifying that the finished product conforms to the analytical requirements (specific and/or global migration, restriction and/or specification) according to the expected conditions of use of the product. This statement is based on our current state of knowledge and related to products currently sold by Opella AB.

Stockholm, 20 November, 2017



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