

## **Food Contact Certificate**

### **Declaration of Compliance for Tetra Pak Products:**

### Twist Cap OSO 30

#### I. Plastic Article

Tetra Pak supplies caps, which are applied on Tetra Rex packages. The cap is an injection molded plastic article, consisting of the following:

- 1. Cap (LMDPE)
- 2. Neck (LDPE)
- 3. White masterbatch (on a polyethylene basis)

#### II.a Compliance with European Union Food Contact Legislation

This Tetra Pak product complies with the relevant provisions of:

- Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food,
- Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food, as last amended,
- Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food,
- EC Resolution AP(89)1 on Colorants, and
- BfR Recommendation IX on Colorants for Plastics and other Polymers Used in Commodities

for use in contact with all liquid foods for long-term storage at ambient temperature (including those foods for which simulants A, B, C, D1 and D2 are assigned in Annex III of Regulation (EC) 10/2011).

The plastic used to make the cap is manufactured only with monomers, other starting substances, and additives that are authorised under Regulation (EU) 10/2011. The other intentionally and non-intentionally added substances in the cap comply with the relevant requirements of Regulation (EC) No. 1935/2004 and a risk assessment in accordance with Article 19 of Regulation (EU) 10/2011 has been performed. Additionally, the colour masterbatches comply with the relevant legislation and standards listed above. These statements are based on information derived from our suppliers' declarations as well as Tetra Pak's own safety assessments.

Tetra Pak also confirms that when this cap is used together with laminated beverage carton and other additional materials authorized by Tetra Pak to make a final package with a volume of 300 ml or more, the final package will comply with the overall migration limit of 10 mg/dm<sup>2</sup> and the specific migration limits set by Regulation (EU) 10/2011 for plastic food contact materials, provided the constraints on food type,

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packing/storage temperatures, or package size stated in this certificate and the certificates for the other authorized materials are respected.

Proof of compliance is achieved by analytical testing and/or by calculation of the worst case migration from known maximum amounts of substances in the raw materials, based on information from our suppliers. Individual component substances subject to specific migration limits or other restrictions according to Regulation (EU) 10/2011 are listed in Section II.b below.

The specified conditions represent only food contact compliance and not technical suitability.

#### II.b <u>Specific migration limits or other restrictions according to Regulation</u> (EU) 10/2011

The restricted substances listed in the following table may be present in the finished packaging material:

Restriction	CAS No.	Substance
SML (6 mg/kg)	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-
		hydroxyphenyl)propionate
SML (Zn) (5 mg/kg)		zinc*
SML (6 mg/kg)	0000077-99-6	1,1,1-trimethylolpropane
DU	0000471-34-1	calcium carbonate
DU	0001592-23-0	calcium stearate*
DU	0013463-67-7	titanium dioxide

Restrictions may be listed as a specific migration limit (SML), a "no detectable migration" requirement (ND), a total specific migration for several substances (SML (T)), or another restriction (O). Dual use additives are marked (DU. A substance marked by \* may not be present in every article.

#### III. <u>Compliance with United States Law and Code of Federal Regulations Applicable</u> to Food Packaging Materials

The composition of this product complies with the relevant requirements for materials and articles for use in contact with food of FDA, 21 CFR as follows, subject to the restrictions on food type and use conditions below:

#### Polyethylene

FDA, 21 CFR § 177.1520 Part (b), Part (c) 3.1a and 2.2, and/or relevant FCN

#### **Colorant Masterbatch**

FDA, 21 CFR § 177.1520 Part (b), Part (c) 2.1, 2.2 and 3.1a, and/or relevant FCN FDA, 21 CFR § 178.3297 and/or relevant FCN

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The material can be used for all food types when used under conditions of use C-H as described in FDA regulation section 21 CFR 176.170 (c) Tables 1 and 2 (as listed on the date of this certificate), provided it is used in accordance with current Good Manufacturing Practices.

The specified conditions represent only food contact compliance and not technical suitability.

#### IV. Disclaimer

This certificate covers the composition of the above-mentioned material. Risk of taste and odor changes in the food must be checked by the food packer. The certification given refers only to legislative compliance as a food contact material and not to technical fitness-for-use.

#### V. Signatures

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You are supplied by:

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