

ASEPT

Declaration of Compliance

For articles intended to come into contact with food

We hereby declare that our article:

Dispenser Pump 9880 (part of 11272 UNI Dispenser for BÄHNKE)

Fulfill the European food contact legislative requirements as described in the below cited regulations.

These article(s) comply with the regulation **1935/2004/EC**, including Articles 3 & 17 in valid version at the time of the distribution of this declaration and corresponds as well to the regulation over good manufacturing practice for materials and articles intended to come into contact with food (GMP) **2023/2006/EC**. They do not contain allergens listed in Annex II of the EU Food Information for Consumers Regulation No. **1169/2011**. The formulations of the articles further comply with the requirements set in the Commission Regulation **(EU) 10/2011** incl. amendments.

Migration Limits:

The overall migration of the articles is -within intended use- under the legal limit values in accordance with the regulation EU **10/2011**. The used raw materials and additives comply with the consumer article regulation (and/or correspondences) into the European plastic regulation EU **10/2011** as well as the transition periods and changes of this guideline valid at the time of the distribution of this declaration.

- simulant A – 10 per cent ethanol (for foods with hydrophilic character)
- simulant B – 4 per cent *) acetic (acid, for foods with a pH below 4.5)
- simulant D2 – vegetable oil, with a regulation specified fatty acid distribution (for fatty foods)

*) 4% acetic acid for additional demonstration of compliance with Italian Ministerial Decree, Title II

The absence of migration of metals according to Annex II of Reg. (EU) 10/2011 using 4% Acetic Acid and of Primary aromatic amines (PAA) has additionally been demonstrated.

Specifications to the intended use or restrictions:

1. All types of food, Acidic and fatty foods which are intended for long term contact with the product at room temperature or below, including packaging under hot-fill conditions.
2. The ratio of food contact surface area to volume used to establish the compliance of the articles was 6 dm² per kg food.
3. Migration analysis test conditions:
 - Overall migration 10 days with +40°C
 - Specific migration 10 days at +60°C

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This product contains monomers, additives or other components which have SMLs or QMAs as specified by Regulation EU **10/2011**:

- TMCD (FCM 881) CAS no.: 3010-96-6 (SML 5mg/kg)

The product follows **EC-Directive 94/62** as amended to date ("Packaging Directive").

The product does not contain more than 0.1% (w/w) of substances listed in the **REACH Substances of Very High Concern (SVHC) candidate list**.

The user has to assure the suitability of the product regarding the intended filling goods and the operating conditions, since these can deviate from the standardized conditions in the directives and regulations. The responsibility regarding the suitability of the product(s) for the intended use and the preservation of migration values under condition of use remains at the user!

Any additional requests for further documentation can be sent to Quality@asept.com

Lund 2024-11-26

Jonas Nilsson
Quality Manager