

6214-xxxx Screw cap tube, PP white

Declaration of Compliance

Food regulatory assessment

Compliance with General Food Contact Legislation

Bürkle GmbH confirms that the products listed above are in compliance with the applicable requirements Regulation (EU) No. 1935/2004 and Regulation (EU) No. 10/2011.

OML - overall migration limit

The overall migration limit is set at 10 mg/dm² contact surface according to Article 12 of the European Plastics Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 2018/831). The analytical tolerance of the method is ± 2 mg/dm² for the used simulants.

The investigated tubes with screw caps ("series 6214") are in compliance with the overall migration **in contact with all kinds of food for any long term storage at room temperature and below, including hot-fill conditions and/or heating up to e.g. 70 °C for up to 2 hours, or 100 °C for up to 15 minutes.**

Conformity has been established by:

Determination of overall migration (contact area/volume: 1.38 dm²/80 ml; testing period: 12.06. - 26.06.2018). The migration tests were carried out in quadruplicate.

SML - specific migration limit

The specific migration limit of aluminium is set at 1 mg/kg and of zinc at 5 mg/kg food (simulant) according to Regulation (EU) No 10/2011 (last amendment by Regulation (EU) No 2019/1338).

According to Art. 17 Section 1 of Regulation (EU) No 10/2011, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use. For containers and other articles intended to contain less than 500 millilitres, the specific migration values shall be expressed in mg/kg applying a surface to volume ratio of 6 dm²/kg (EU cube model) in accordance with Art. 17 Section 2 (a) of this Regulation.

The investigated tubes with screw caps with capacities of 12 - 250 ml and 625 ml / 1000 ml are in compliance with the specific migration limits given above **in contact with all kinds of food for any long term storage at room temperature and below, including hot-fill conditions and/or heating up to e.g. 70 °C for up to 2 hours, or 100 °C for up to 15 minutes.**

Conformity has been established by:

Determination of the specific migration of metals (contact area/volume: 1 dm²/100 ml (total surface)*; testing period: 06.11. - 26.11.2019).

* For the specific migration of metals, the total surface is considered for the calculation of migration values.

A functional barrier made from plastic is not used in the above mentioned products.

FDA

According to the "Product Regulatory Information Document" (Polychim Industrie, dated January 2018), the base material of the investigated tubes with screw caps is a homopolymer polypropylene product compliant with the regulatory specifications as stated in 21 CFR § 177.1520 (a) (1) (i).

The following extraction limits are laid down in 21 CFR § 177.1520 (c) 1.1 a for polypropylene described in (a) (1) (i): the limit for the maximum extractable fraction in n-hexane is set at 6.4 % at reflux temperature. The limit for the maximum soluble fraction in xylene is set at 9.8 % at 25 °C.

The investigated tubes with screw caps ("series 6214") are in compliance with the limit for the maximum extractable fraction in n-hexane as well as with the limit for the maximum soluble fraction in xylene according to the requirements of 21 CFR § 177.1520 (c) 1.1a.

Conformity has been established by:

Determination of the total extractives and the maximum soluble fraction according to US regulatory requirements (Testing period: 12.06. - 26.06.2018).

The user has to convince himself of the suitability of the product for the intended filling material which goes beyond the requirements of the directives.

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 2284-08.

13.12.2019



Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director

