

0303-xxxx Narrow-necked bio-bottles PE

Declaration of Compliance

Food regulatory assessment

European Union

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 202/2014). The analytical tolerance of the method is ± 2 mg/dm².

The investigated samples are in compliance with the overall migration limit for all types of food for any long term storage at room temperature and below, including hot fill and high temperature applications up to 121 °C.

USA

For materials produced according to 21 CFR § 177.1520 paragraph (a) (3) (i) the limit for the maximum extractable fraction in n-hexane is 2.6 % at 50 °C and the limit for the maximum soluble fraction in xylene is 30 % at 25 °C according to 21 CFR § 177.1520 paragraph (c) 3.2.a.

The investigated samples are in compliance with the limit for the maximum extractable fraction and the maximum soluble fraction according to 21 CFR § 177.1520.

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.

06. October 2021



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

