

8714-xxxx Non-return valve, PP

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 of the Regulation (EU) No. 1935/2004 and Regulation (EU) No. 10/2011 as amended in the current version.

We hereby declare that, in the manufacture of the products, it follows the good manufacturing practice requirements according to (EC) No. 2023/2006.

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 2016/1416). The analytical tolerance of the method is ± 2 mg/dm².

The products are in compliance with the overall migration limit in contact with all kinds of food for any long term storage at room temperature and below, including hot filling and heating up e.g. to 70 °C for up to 2 hours or to 100 °C for up to 15 minutes.

The determination of the overall migration in 95 % ethanol is at least as severe as the determination of the overall migration into olive oil and can be used as an alternative to the overall migration test in olive oil according to Annex V, Chapter 3, Section 3.4 of Regulation (EU) No 10/2011.

SML - specific migration limit

The specific migration limit of octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate is set at 6 mg/kg and of 9,9-bis(methoxymethyl)fluorene at 0.05 mg/kg food(simulant) according to Regulation (EU) No 10/2011 (lastly amended by Regulation (EU) No 2016/1416).

Based on the solubility of the analytes, the fatty food simulants represent the more severe simulants compared to aqueous simulants.

The products are in compliance with the specific migration limits of octadecyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate and 9,9-bis(methoxy-methyl)fluorene in contact with all kinds of food for any long term storage at room temperature and below, including hot filling and heating up e.g. to 70 °C for up to 2 hours or to 100 °C for up to 15 minutes.

FDA

For polypropylene described in 21 CFR § 177.1520 (a) (1), the limit for the maximum extractable fraction in n-hexane is set at 6.4 % at reflux temperature and the limit for the maximum soluble fraction in xylene is set at 9.8 % at 25 °C according to 21 CFR § 177.1520 (c) 1.1.

The investigated polypropylene material is 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) 1.1.

Dual Use Additives

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC:
E 470a Calcium salts of fatty acids

Information about the balls

- PP balls:

Our supplier confirms that the raw material complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The raw material complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(1)(i) and (c)1.1a.

This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to information of our supplier, the substances used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

- PTFE balls:

Our supplier hereby certifies that the products VIRGIN PTFE can be utilized for products intended to come in contact with foodstuff, according to the requirements of: EU Directive 2002/72/EC (Food contact materials), EU Regulation 1935/2004 (Food contact, intelligent materials and others), EU Regulation 2023/2006 (GMP, Good Manufacturing Practice), FDA Directive 21 CFR sec 177.1550 (Fluoropolymers).

- stainless steel balls:

The balls made of stainless steel are manufactured from 1.4401 stainless steel. This is widely used and suitable for most foodstuffs.

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.

24. April 2019



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

