

0525-x000 StopCock angled/straight through, PP  
0530-1000 Compact spigot, PP  
0600-0020 Thread adapter 3/4 outer - Kautex outer, blue, 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/dm<sup>2</sup> 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  $\pm 2$  mg/dm<sup>2</sup>.

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

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

