

0525-x000 StopCock angled/straight through, PP

Declaration of Compliance

Food Contact Compliance Assessment

Compliance with General Food Contact Legislation

Bürkle GmbH confirms that the products listed above are manufactured from polypropylene (PP) and, based on the available compliance documentation and migration assessment, comply with the applicable requirements of Regulation (EC) No 1935/2004 and Commission Regulation (EU) No 10/2011, as amended and applicable.

The products are manufactured in accordance with the applicable principles of Good Manufacturing Practice pursuant to Commission Regulation (EC) No 2023/2006.

The migration tests were performed by the Fraunhofer Institute for Process Engineering and Packaging (IVV) on a finished T-connector manufactured from polypropylene and colour masterbatch. The results are used as supporting evidence for the compliance assessment of article 0525-x000, provided that the material composition and relevant manufacturing and use conditions are equivalent.

OML - overall migration limit

Test medium	Test conditions	Result	Limit
3% acetic acid	10 days / 40 °C	0.5 mg/dm ²	10 mg/dm ²
95% ethanol (fat substitute)	10 days / 40 °C	0.1 mg/dm ²	10 mg/dm ²

The overall migration limit is set at 10 mg/dm² of food contact surface according to Article 12 of Commission Regulation (EU) No 10/2011, as amended. The analytical tolerance of the method is ± 2 mg/dm².

Food Contact Suitability

Based on the available compliance assessment, the products are suitable for contact with all types of food, including:

- Dry foods
- Aqueous foods
- Acidic foods
- Alcoholic foods
- Fatty foods
- Milk and dairy products

The stated suitability applies to long-term contact at room temperature or below, including hot filling and heating up to 70 °C for up to 2 hours or 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

Substance	Test medium / conditions	Result	Limit
Aluminium	3% acetic acid / 10 days at 60 °C	At the limit of quantification (LOQ: 0.030 mg/kg)	1 mg/kg
9,9-bis(methoxymethyl)fluorene	Olive oil / 10 days at 60 °C	Below 0.01 mg/kg	0.05 mg/kg

The specific migration results obtained from the tested T-connector comply with the applicable specific migration limits for aluminium and 9,9-bis(methoxymethyl)fluorene under the tested conditions, according to Fraunhofer test report.

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The specific migration of aluminium and 9,9-bis(methoxymethyl)fluorene was investigated in accordance with test report.

The tested PP component complies with the applicable specific migration limits for both substances for contact with all types of food under the specified conditions of use.

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.

Test	Result	Applicable limit	Test conditions
n-Hexane extractables	0.4%	6.4%	2 hours at reflux
Xylene soluble fraction	3.1%	9.8%	2 hours at reflux, followed by cooling to 25 °C

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.

Bisphenol A (BPA)

Based on the available supplier documentation, we confirm that the above-mentioned products are BPA-free and that Bisphenol A (BPA) is not intentionally used in their manufacture.

Dual Use Additives

This product contains one or more Dual Use Additives as defined in Commission Regulation (EU) No 10/2011:

E 470a Calcium salts of fatty acids

No additional application-specific testing is performed by Bürkle GmbH. The user is responsible for verifying the suitability of the product for the intended application and conditions of use.

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 002284-QM15.

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