ZERTIFIKAT
CERTIFICATE

Pumpen | Probenehmer | Laborbedarf
für Labor, Industrie und Wissenschaft
Pumps | Sampling | Plastic Labware
for Laboratory, Industry, Science

8606-xxxx Three-way valve, PP/PE, various size, red/white

Declaration of Conformity for food contact material

This declaration is based on the raw-material documentation available to Bürkle GmbH and on the Fraunhofer IVV test reports. The migration testing described below was performed on the supplied PP valve body, i.e. the food-contact-relevant PP valve body represented by the tested sample.

1. General

The assessment takes into account Regulation (EC) No. 1935/2004 and Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, based on the version and amendments referenced in the Fraunhofer reports. The US extraction assessment was performed according to 21 CFR § 177.1520.

2. Overall Migration

Fraunhofer IVV determined the overall migration from the supplied red PP valve body under the following conditions:

Test medium	Method	Contact conditions	Result	Limit
3% acetic acid	EN 1186-3:2002-07	10 days / 40 °C	0.3 mg/dm²	10 mg/dm²
95% ethanol (fat substitute test medium)	EN 1186-14:2002-12	10 days / 40 °C	0.3 mg/dm²	10 mg/dm²

Fraunhofer IVV food-law assessment: The tested PP valve body complies with the overall migration limit for contact with all types of food for long-term storage at room temperature or below, including hot filling and/or heating, e.g. up to 70 °C for 2 hours or up to 100 °C for 15 minutes.

The Fraunhofer IVV test report documents 3% acetic acid and 95% ethanol as the test media used for the determination of overall migration. Isooctane was not used as a test medium in the underlying Fraunhofer IVV test report. The food-law assessment stated below is the assessment issued by Fraunhofer IVV on the basis of the tests performed.

3. Specific migration

Fraunhofer IVV investigated the specific migration parameters relevant to the documented material composition:

Substance	Food simulant	Contact conditions	Result	SML
Aluminium	3% acetic acid	10 days / 60 °C	0.070 mg/kg	1 mg/kg
9,9-Bis(methoxymethyl)fluorene	Olive oil	10 days / 60 °C	< 0.02 mg/kg	0.05 mg/kg

Fraunhofer IVV food-law assessment: The tested PP valve body complies with the above specific migration limits for contact with all types of food under the stated conditions of use.

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4. US requirements - 21 CFR § 177.1520

In addition, extraction tests were performed on the PP material in accordance with the US requirements referenced by Fraunhofer IVV:

Extraction medium	Test condition	Result	Applicable limit
n-Hexane	2 h / reflux	0.6%	6.4%
Xylene	2 h / reflux; soluble fraction at 25 °C	4.1%	9.8%

Fraunhofer IVV concluded that the investigated PP material complies with the stated limits according to 21 CFR § 177.1520 (c) 1.1.

5. Intended food contact conditions

5.1 Intended type(s) of food

- All types of food, within the conditions stated below.

This statement is based on the explicit food-law assessment in Fraunhofer IVV test reports.

5.2 Intended conditions of food contact

- Long-term storage at room temperature or below
- Including hot filling and/or heating
- Up to 70 °C for a maximum of 2 hours
- Or up to 100 °C for a maximum of 15 minutes

6. Limitations and responsibility

The user is responsible for verifying suitability of the product for the specific application, particularly where the actual conditions of use differ from those stated above.

Further tests are not carried out by us.

This declaration is based on our current state of knowledge, the available raw-material documentation and the referenced test reports. Bürkle GmbH, Bad Bellingen, Germany, maintains a quality management system certified according to DIN EN ISO 9001 by DQS (certificate no. 002284-QM15).

October 5, 2026

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