

0304-xxxx UN-bottle, HDPE, various size, without a lid

DECLARATION OF COMPLIANCE

for plastic materials and articles intended to come into contact with food.

Product description

HDPE containers: UN bottles, narrow-neck bottles, round bottles, rectangular bottles, square containers, wide-neck containers, cans and canisters, with tamper-evident closure.

Material

High-density polyethylene (HDPE)

Compliance statement

We hereby confirm that the above-mentioned products comply with:

- Regulation (EU) No. 10/2011 and its amendments
- Framework Regulation (EC) No. 1935/2004
- Good Manufacturing Practice Regulation (EC) No. 2023/2006

Intended use

Type of food:

Suitable for all types of foodstuffs according to Regulation (EU) No. 10/2011, including aqueous, acidic, alcoholic and fatty foods.

Conditions of use:

- Long-term storage up to 40°C
- Suitable for hot filling up to 70°C (max. 2 hours)
- Suitable for hot filling up to 100°C (max. 15 minutes)

Testing conditions (worst-case conditions)

The compliance has been verified using the following simulants and conditions:

- 3% acetic acid: 10 days at 40°C
- 10% ethanol: 10 days at 40°C
- Olive oil: 10 days at 40°C

Surface to volume ratio:

1 dm² per 100 ml simulant

Migration

Overall migration complies with the limits set out in Regulation (EU) No. 10/2011 under the specified testing conditions.

ZERTIFIKAT CERTIFICATE

Pumpen | Probennehmer | Laborbedarf
für Labor, Industrie und Wissenschaft

Pumps | Sampling | Plastic Labware
for Laboratory, Industry, Science



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Substances with restrictions (SML)

The following substance with specific migration limit (SML) may be present:

- Octadecyl 3(3,5-di-tert-butyl-4-hydroxyphenyl) propionate
SML: 6 mg/kg

Dual-use substances

No dual-use additives are intentionally added.

Additional regulatory compliance

The product/material complies with the following requirements:

- REACH Regulation (EC) No. 1907/2006 (Annex XVII & SVHC)
- RoHS Directive 2011/65/EU (incl. (EU) 2015/863)
- FDA 21 CFR §177.1520 (where applicable)
- BSE/TSE – EMEA/410/01
- Phthalates: not intentionally used
- GMO: not present
- Allergens: not present
- Nanomaterials: not used
- POP Regulation (EU) 2019/1021

Declaration

This declaration is based on our current knowledge and on information provided by our raw material suppliers.

Further tests are not carried out by us.

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.

October 13, 2026

A handwritten signature in blue ink, appearing to read "M. Saint-Denis".

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