

7506-xxxx Graduated cylinders, SAN

Declaration of Conformity

Food regulatory assessment

Compliance with General Food Contact Legislation

We declare under our sole responsibility that the products listed above meet the present requirements of the Ordinance on Materials and Articles and Regulation (EC) No 1935/2004 and Commission Regulation (EU) Nr. 10/2011 in their actual version (inclusive of their amendments), too.

Analyses by an independent, accredited laboratory according to the overall migration limit of the final article validates no overstepping of the regulated limits. Also during the organoleptic tests no negative interaction with the food (change of taste and odor of the food) could be discovered. The testing has been performed according to article 17 and 18 of Commission Regulation (EU) No 10/2011 in conjunction with Annex V. Therefore the above named products comply with the requirements of Commission Regulation (EU) No. 10/2011 and could be used related to the specified limitation of migration limits in contact with food.

According to statement provided by our raw materials supplier we could declare, that the material currently used for production of the above named products, has been manufactured in accordance with the relevant requirements of good manufacturing practice for articles intended to come into contact with food, according to Commission Regulation (EC) No. 2023/2006.

Unless the raw material used for the production of the above named products contains substances with specified limitation (SML / QM) the defined limiting values according to Commission Regulation (EU) No. 10/2011 were observed.

Specification for envisaged use or limitations:

All types of foodstuffs (dry, aqueous, sour, fatty) except alcoholic beverages - tested according to table 3 annex III with listed food simulants (1. distilled water or water of equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2 - with 95% ethanol and isooctane alternatively according to annex V, chapter 2 paragraph 2.1.3 Conditions of contact when using food simulants.).

Kind of food, which should not come into contact with the used material:

alcoholic beverages

Contact time and contact temperature for using and storing food:

The applied testing conditions relate to short-term hot contact for a maximum of 30 minutes not exceeding 70°C. This also includes a shorter contact as well as contact at lower temperatures.

Overall migration Limiting value: max. 10.0 mg/dm² determined:

with Acetic acid 3%	for 2 h, at 70°C by S:V of 2.55 dm ² : 50 ml	- measured: < 1 mg/dm ²
with Ehtanol 10%	for 2 h, at 70°C by S:V of 2.55 dm ² : 50 ml	- measured: < 1 mg/dm ²
with Ethanol 95%	for 2 h, at 60°C by S:V of 2.55 dm ² : 50 ml	- measured: < 1 mg/dm ²
with Isooctane	for 0.5 h, at 40°C by S:V of 2.55 dm ² : 50 ml	- measured: < 1 mg/dm ²
with Olive oil	for 2 h, at 70°C by S:V of 0.4 dm ² : 100 ml	- measured: < 3 mg/dm ²

According to information provided by our raw material supplier monomers or additives are used, which are controlled by a specific migration limit:

Barium SML:	Limiting values: max. 1.0 mg/kg	- measured: < 0.01 mg/kg
Cobalt SML:	Limiting values: max. 0.05 mg/kg	- measured: < 0.01 mg/kg
Iron SML:	Limiting values: max. 48.0 mg/kg	- measured: < 0.1 mg/kg
Copper SML:	Limiting values: max. 5.0 mg/kg	- measured: < 0.01 mg/kg
Lithium SML:	Limiting values: max. 0.6 mg/kg	- measured: < 0.01 mg/kg
Manganese SML:	Limiting values: max. 0.6 mg/kg	- measured: < 0.01 mg/kg
Zinc SML:	Limiting values: max. 5.0 mg/kg	- measured: < 0.1 mg/kg
Aluminium SML:	Limiting values: max. 1.0 mg/kg	- measured: < 0.01 mg/kg
Nickel SML:	Limiting values: max. 0.02 mg/kg	- measured: < 0.01 mg/kg

each determined with Acetic acid 3% for 0.5 h, at 70°C by S:V of 5.1 dm² : 100 ml

Acrylnitril [FCM material 225; Ref. No. 12100]

SML: Limiting value: max. -- mg/kg - measured: detection limit < 0.02 mg/kg
determined with Olive oil for 0.5 h, at 70°C by S:V of 5.1 dm² : 100 ml

"Dual-Use-Additives":

The raw material does not contain substances also authorised as direct food additives ("Dual use additives") according to Regulation (EG) No. 1333/2008 in its actual version.

No functional barrier of plastic material is used.

It is in the scope of the end-user to validate the product for applications which differ from the guidelines of the regulations.

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.

25. August 2020



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

