



**KAVALIER**

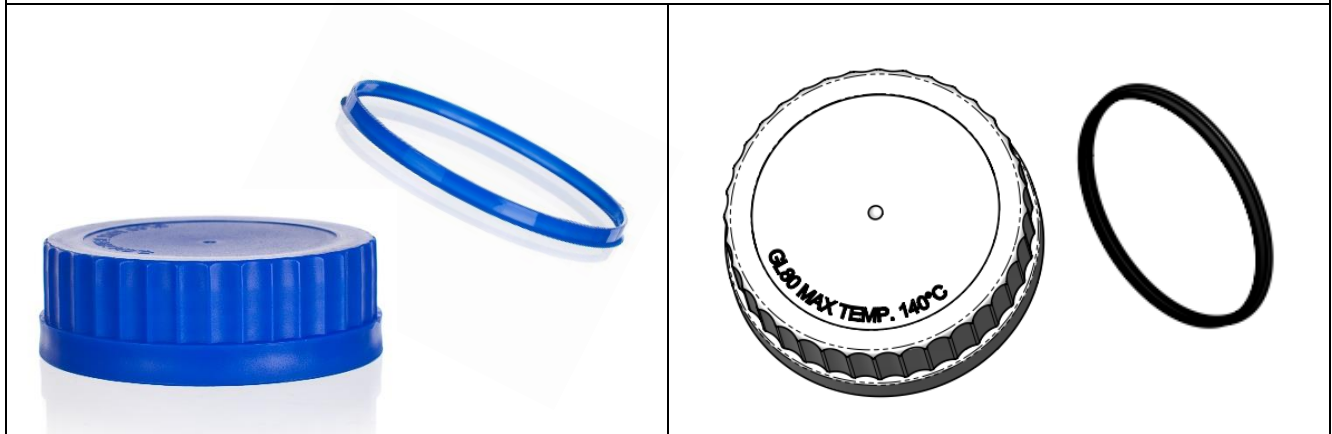
# PRODUCT DATA SHEET

Issuer's name/ producer: **KAVALIERGLASS, a.s.**  
 Issuer's address/Producer: **Křížová 1018/6, Prague 5**  
**office: Sklářská 359, 285 06 Sázava, Czech Republic**

Object of the declaration: **PLASTICS USED WITH LABORATORY GLASS**

<u>Product IDN</u>	<u>Description</u>	<u>Colour</u>	<u>GL Thread Size</u> <i>(acc. DIN 168-1 (1998-04))</i>
9180002271	Screw cap	blue	GL80
9180002272	Pouring ring		
9180003013	Screw cap	black	
9180003014	Pouring ring		

## Plastic accessories



<b>Material specification:</b>			<b>Technical data/ Declaration of compliance food contact</b>
<b>Screw Cap with a Pouring Ring</b>	blue	PP MOSTEN GB 107	page 2-4/ page 5-6
<b>Purpose of use</b>	laboratory bottles		

# The object of the certificate described above is in conformity with the requirements of the following standards and regulations:

## Technical standards for products:

- ISO 4796 Laboratory glassware, bottles

## No heavy metals (lead, cadmium, mercury and hexavalent chromium):

- **RoHS** - Directive 2011/65/EU of the European parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
- **Regulation EC No 1935/2004 of 27 October 2004**

Directive on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

- **Commission Regulation (EU) No. 2023/2006**

Good manufacturing practice for materials and articles intended to come into contact with food

- **Regulation of Czech Health Ministry Decree No. 38/2001 Coll.**

Directive on articles intended to come into contact with foodstuffs

- **US FDA 21 CFR 177.1520 » US Code Federal Regulations 21 Food and Drug Administration § 177.1520 Olefin Polymers ©, Specifications 1.1a**

Directive on articles intended to come into contact with foodstuffs

- **Commission Regulation (EU) No. 10/2011**

Relating to plastic materials and articles intended to come into contact with foodstuffs & migration limits

- **Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December - [EU REACH Regulation](#)**

In the manufacture any SVHC are not used as additives, ingredients or adjuvants in concentration more than 0,1 %.

- **Decree 306/2012 Coll. on conditions for the prevention and spread of infectious diseases, and hygienic requirements for the operation of medical facilities and social care institutions**

Relating the specific conditions for sterilization

- **California's Safe Drinking Water & Toxic Enforcement act of 1986 (Proposition 65)**

Products may contain trace amounts of chemicals listed on (Prop 65)

The Current Proposition 65 list can be found at:

<https://oehha.ca.gov/proposition-65/proposition-65-list>

- **Tallow/ BSE/ TSE**

We incorporate small amounts of calcium stearate derived from fatty acids. These are derived from fat, mainly from animal origin. Due to technology of the manufacturing we therefore state that these additives and our product are to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

## Technical requirements according to purpose of use

- **Pharmaceutical use**

*European Pharmacopoeia (EP)*

Eur. Ph.9 – 3.1.3; based on the statement of the supplier

- **Temperature resistance**

**Screw Cap with a Pouring Ring**      -40°C to +140°C

- **Chemical resistance of plastics\***

Classes of substances +20 °C	PP MOSTEN GB 107
Alcohols, aliphatic	+
Aldehydes	+
Alkaline solutions	+
Esters	+
Ethers	-
Hydrocarbons, aliphatic	+
Hydrocarbons, aromatic	+
Hydrocarbons, halogenated	+
Ketones	+
Acids, dilute or weak	++
Acids, concentrated or strong	+
Acids, oxidising	+

Legend:

++ = very good resistance

+ = good to limited resistance

- = low resistance

*\*More detail upon request*

- **Storage conditions of concentrated sulfuric acid in reagent bottle with screw cap GL45**

Diluted sulfuric acid up to 50% is alright, even at long-term exposure to temperatures up to 70°C.

More concentrated acid, especially at higher temperatures, causes changes in mechanical properties of the lid.

Concentration above 80% is unsuitable, because it causes oxidative degradation of the polypropylene of the lid.

- **Sterilization\*\***

Hot air sterilization, in the oven      up to 140°C

Steam sterilization, in an autoclave      121°C/ 20 min

134°C/ 10 min

*\*\*See the handling instruction below*

## Handling instructions:

After completion glass reagent bottle with a plastic screw cap and a pouring ring, they enable liquids to be easily poured out. The screw caps can be mutually interchanged.

### a) Freezing substances

Freeze the bottle in a skew position (about 45°) and filled up to max  $\frac{3}{4}$  (volume expansion). Temperature limit: -40°C as plastic lids and pouring rings do not resist to lower temperatures.

### b) Thawing of substances

Thawing of a frozen material can be carried out by submerging the bottle into liquid bath (temperature difference should not exceed 100°C). the frozen material will thus be heated up uniformly from all sides and the bottle will not be damaged. Thawing can also be accomplished slowly from the top so that the surface is first liquefied and the material can expand.

### c) Sterilization

The bottle, pouring ring and the screw cap can be sterilized. During sterilization, the screw cap can only lightly be fitted on the bottle (screw max. one rotation). Pressures are not equalized when the bottle is closed. The pressure difference created in this way can result in the bottle breakage. The bottles can be hot-air sterilized up to 140°C, or autoclaved up to 121°C, or 134°C.

### d) Pressure resistance

These laboratory bottles are not suitable for works under pressure or vacuum.

### e) Cleaning

Cleaning should be carried out manually in a soaking bath or automatically in a dishwasher. To care properly for laboratory glassware, it should be washed immediately after use at low temperature, on a short cycle and with low alkalinity.

Laboratory glassware should not be soaked for long periods in alkaline media at more than 70°C since this can have an adverse effect on the printing and may cause glass corrosion. Also, to be avoided, is severe mechanical action e.g. scraping using a metal spoon.

Abrasive cleaners and abrasive sponges should not be used on laboratory glassware as these can damage the surface of the glass.

### Additional information:

**Individual declaration will be provided upon request.**

**The producer declares that the products are safe when used in usual and proper way.**

The producer has installed the Quality Assurance System according to ISO 9001 and thus guarantees that all products delivered to the market are in full conformity with the technical documentation and with all fundamental requirements to such products. Certificate No. 04 100 940602 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.



**KAVALIER**

# DECLARATION OF COMPLIANCE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

In acc. to:

- Regulation EC No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

1. the identity and address of the business operator issuing the declaration of compliance

## **KAVALIERGLASS, a.s.**

**Křížová 1018/6, Prague 5**

**office: Sklářská 359, 285 06 Sázava, Czech Republic**

2. the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles: **see art. 1**
3. the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles:

Plastic accessories	SAP No.	Colour	Material
Screw cap GL80	918 000 2271	blue	PP MOSTEN GB 107
Outlet ring GL80	918 000 2272		PP Bormed TM HF840MO
Screw cap GL80	918 000 3013	black	PP MOSTEN GB 107
Outlet ring GL80	918 000 3014		BOREALIS HF 700 SA

4. the date of the declaration: 05.03.2020
5. We confirm hereby that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet hygienic requirements for the products made of plastics given by
- Czech Health Ministry Decree No. 38/2001 Coll., relating to hygienic requirements for the articles intended to come into contact with foodstuffs, as amended
  - Commission Regulation (EU) 10/2011 of 14th January 2011 on plastic materials and articles intended to come into contact with food, as amended
  - Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food in an article 3; article 11 paragraph 5 and in an article 15 and 17
  - US FDA 21 CFR 177.1520 » US Code Federal Regulations 21 Food and Drug Administration § 177.1520 Olefin Polymers ©, Specifications 1.1a. Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.
6. adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;

The evaluated sample meets requirements for the substances limited by their specific migration limits (SML):

- in acc. to Annex I of Commission Reg. 10/2011/EU:

Colour	Name of the Substance	SML [mg/kg]
black	Confidential substance A	6 mg/kg
	Confidential substance B	6 mg/kg

- in acc. to Annex II of Commission Reg. 10/2011/EU: metals (Al, Ba, Co, Cu, Fe, Li, Mn, Ni, Zn) and primary aromatic amines
7. adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
- **not applicable – used materials do not contain substances which are subject to a restriction in food**
8. specifications on the use of the material or article:

The product is suitable for contact with food –*laboratory bottle*

- (i) **Contact with all foodstuff types**
- (ii) **At temperatures up to 140°C for up to 30 minutes, with following storage for up to 6 months at room or lower temperatures including hot-fill conditions and/ or heating up to 70°C for up to the maximum contact time 2 hours.**
- (iii) **Ratio: 60 cm<sup>2</sup> of product area/ 500g (ml) or more of food.**

**The evaluated sample does not cause a deterioration in organoleptic characteristics of food.  
The products do not require any restriction according to the test results.**

9. when a functional barrier is used – **not used**

*Additional information:*

**The producer declares that the products are safe when used in usual and proper way.**

**This declaration was issued on the basis of the accredited Test Report Ref. No. 472112195-01 and Test Report Ref. No. 4721122549-02 by ITC Zlín, CZE.**

**The validity of the declaration is ending if the requirements are changed.**

**The producer declares that the products are safe when used in usual and proper way.**

The producer has installed the Quality Assurance System according to ISO 9001 and thus guarantees that all products delivered to the market are in full conformity with the technical documentation and with all fundamental requirements to such products. Certificate No. 04 100 940602 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.

The certificate is issued for the customer: -

Sázava, 29. 04. 2021  
*Place and date of issue*

Ing. Kristýna Machová  
*Project Quality Engineer*

**KAVALIERGLASS, a.s.**  
Křtžová 1018/6, 150 00 Praha 5  
office: Sklářská 359, 285 06 Sázava  
Czech Republic  
IČ: 474 68 815  
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