

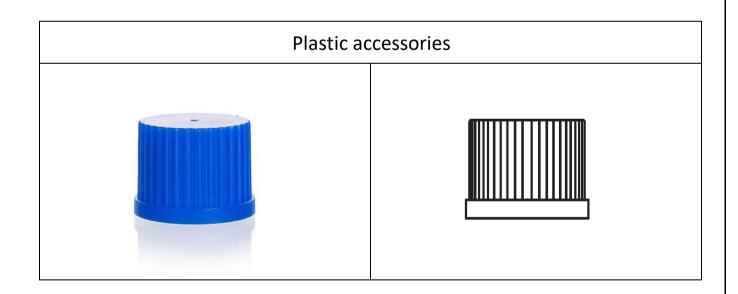
PRODUCT DATA SHEET

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

Object of the declaration:

PLASTICS USED WITH LABORATORY GLASS

Product IDN	Description	<u>Colour</u>	<u>GL Thread Size</u> (acc. DIN 168-1 (1998-04))
9180000829	Screw cap	blue	GL14
9180001201			GL18
9180001202			GL25



Material specifi	cation:		Technical data	
Screw Cap with a Pouring Ring	blue	PP MOSTEN MA 230	page 2-4	
Purpose of use sealing various products that are GL-terminated such as test tubes, flasks, etc.				
ruipose oi use				

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
<u>Regulation</u>

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 ovenup to 140°CSteam sterilization, in an autoclave121°C/ 20 min134°C/ 10 min134°C/ 10 min

**See the handling instruction below

Handling instructions:

a) Freezing substances

Freeze the bottle in a skew position (about 45°) and filled up to max ¾ (volume expansion). Temperature limit: -40°C as plastic lids 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) <u>Sterilization</u>

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) <u>Cleaning</u>

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:

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 crižová 1018/6, 150 00 prats. Czec, Skiářská 359, 285 06 prata 5 CZech Republic IC: 474 68/815 -61