

## PRODUCT DATA SHEET

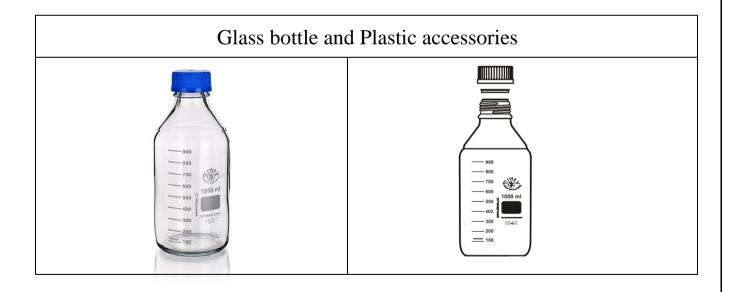
Issuer's name/producer: KAVALIERGLASS, a.s.

Issuer's address/Producer: Křížová 1018/6, Prague 5

office: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration: REAGENT BOTTLES with Screw Cap and a Pouring Ring

| Product IDN & Description |               | Capacity/ ml | GL Thread Size (acc. DIN 168-1 (1998-04)) |
|---------------------------|---------------|--------------|---|
| 2070                      | clear bottles | 100          | GL45                                      |
|                           |               | 250          | GL45                                      |
|                           |               | 500          | GL45                                      |
|                           |               | 1000         | GL45                                      |
|                           |               | 2000         | GL45                                      |
|                           |               | 3800         | GL45                                      |
|                           |               | 5000         | GL45                                      |
|                           |               | 10000        | GL45                                      |
|                           |               | 20000        | GL45                                      |



| Material specification:       |                             |  |  |  |
|-------------------------------|-----------------------------|--|--|--|
| Bottle body                   | clear                       | Borosilicate glass SIMAX®                        |  |  |
| Screw Cap with a Pouring Ring | blue, yellow, orange, green | PP MOSTEN GB 107                                 |  |  |
| Print                         | white                       | in fired-on, chemically resistant ceramic enamel |  |  |
|                               |                             |  |  |  |
| Purpose of use                | laboratory bottles          |  |  |  |

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

#### Glass characteristics:

• ISO 3585 Borosilicate glass 3.3 – properties

#### **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

• Directive 84/500EEC of 15 October 1984

Directive on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

• ISO 7086-1:2000 Glass hollowware in contact with food

Release of lead and cadmium - Part 1: Test method

• ISO 7086-2:2000 Glass hollowware in contact with food

Release of lead and cadmium – Part 2: Permissible limits

BS EN 1388-2:1996

Materials and articles in contact with foodstuffs. Silicate surfaces. Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware.

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

Glass Products do not contain any substance from the REACH Candidate list of Substances of Very High Concern (SVHC).

**Screw Cap with a Pouring Ring** 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)

Glass Products do not contain chemicals, which are listed on (Prop 65)

Screw Cap with a Pouring Ring Products may contain trace amounts of chemicals listed on (Prop 65)

The Current Proposition 65 list can be found at: <a href="https://oehha.ca.gov/proposition-65/proposition-65-list">https://oehha.ca.gov/proposition-65/proposition-65-list</a>

• Tallow/ BSE/ TSE

Glass We do not use any animal derived materials in the manufacture or formulation of this product

**Screw Cap with a Pouring Ring** 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

### Characteristics of Borosilicate glass SIMAX®

• Acid resistance Class I. (to ISO 1776)

• **Hydrolytic resistance** Class I. (HGB1 to ISO 719; HGA1 to ISO 720)

• Alkali resistance Class II. (to ISO 695)

#### • Pharmaceutical use

European Pharmacopoeia (EP) US Pharmacopoeia (USP) Japanese Pharmacopoeia (JP)

Glass Eur. Ph.9 – 3.2.1 USP <660> JP16

**Screw Cap with** Eur. Ph.9 - 3.1.3; based on the statement of the supplier **a Pouring Ring** 

#### 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.

#### • Temperature resistance

Glass The maximum permissible short-term operating temperature is 500°C

The maximum thermal shock resistance is  $\Delta T=100$  K.

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

#### • Sterilization\*

Hot air sterilization, in the oven Steam sterilization, in an autoclave up to  $140^{\circ}$ C  $121^{\circ}$ C/20 min  $134^{\circ}$ C/10 min

\*See the handling instruction below

#### **Handling instructions:**

After completion with a plastic 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 ¾ (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.

Sázava, 22. 07. 2019

Place and date of issue

Ing. Kristýna Machová i

Product Development