DECLARATION OF COMPLIANCE

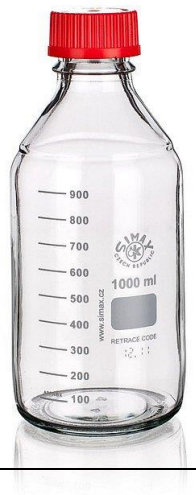
KAVALIER

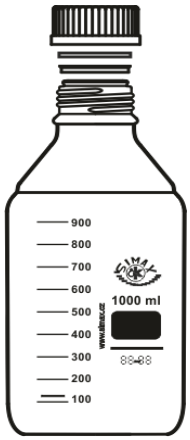
Issuer´s name/ producer: **KAVALIERGLASS, a.s.**
Issuer´s address/Producer: **Křížová 1018/6, Prague 5**
office: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration: **REAGENT BOTTLES**
with Screw Cap and a Pouring Ring
with PTFE sealing liner

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

Glass bottle and Plastic accessories





Material specification:			**Technical data/ Declaration of compliance food contact**
Bottle body	clear	Borosilicate glass SIMAX®	Page 2-5/ page 6-7
Screw Cap with a Pouring Ring	red	PBT - Celanex® 2401 MT® NATURAL	
Sealing liner	grey	silicone + one-sided layer of PTFE	
Print	white	in fired-on, chemically resistant ceramic enamel	Not applicable
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):

- **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

- **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. 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

- **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 10993-1:2018 Biological evaluation of medical devices – part 1:** Evaluation and testing within a risk management process

- **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

- **DMF 10047 (US) / 10033 (EU)**
  Listed in Drug Master File

- **MAF 443 (US) / 1078 (EU)**
  Listed in Device Master File

- **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 %.

- **Directive 2011/65/EC (RoHS II), amended by 2015/863/EC, on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Annex II - extension of limitation regarding 4 additional substances.**

Glass Products do not contain any substance restricted by the EU Directive 2011/65/EU and EU Directive 2015/863/EU

Screw Cap with a Pouring Ring Products do not contain any substance restricted by the EU Directive 2011/65/EU and EU Directive 2015/863/EU

- **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)

The Current Proposition 65 list can be found at:
https://oehha.ca.gov/proposition-65/proposition-65-list

- **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 do not use any animal derived materials in the manufacture or formulation of this product
Sealing liner The material does not contain any melamine, phthalates, latex allergens, BSE/TSE risk materials or conflict minerals.

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)
- **Coefficient of mean linear thermal expansion α: 3,3 x10-6 K-1 (to ISO 7991; 20/300 °C)**
- **Pharmaceutical use**

	European Pharmacopoeia (EP)	*US Pharmacopoeia (USP)*	*Japanese Pharmacopoeia (JP)*
Glass	Eur. Ph.10th – 3.2.1	USP <660>	JP16

Supporting data:

TEST / European Pharmacopoeia 10, Art. 3.2.1	**UNIT**	**LIMIT**	**RESULT**
Hydrolytic resistance - inner surfaces, test A	**ml 0,01 mol/l HCl/100ml of leachate**	**max 0,40**	**0,04**
Hydrolytic resistance - glass grains, test B	**mol 0,02/l HCl/g**	**max 0,1**	**0,038**
Arsenic content	**µg As/g**	**max 0,1**	**< 0,001**

Screw Cap & Pouring Ring	USP <88> Class VI; USP <87> Cytotoxicity
Sealing liner	Eur. Ph.9 – 3.1.9; based on the statement of the supplier

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

Due to sealing liner, which consists of silicone and one-sided layer of PTFE, there´s no problem with storing including highly concentrated acids.

- **Temperature resistance**

Glass	The maximum permissible short-term operating temperature is 500 °C The maximum thermal shock resistance is ΔT=100 K.
Screw Cap with a Pouring Ring	-40 °C to +180 °C

- **Sterilization***

Hot air sterilization, in the oven	up to 180 °C
Steam sterilization, in an autoclave	121 °C/ 20 min 134 °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 200 °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.

f) Purpose of use

Laboratory reagent bottles are intended for storage of chemical substances and mixtures. We recommend rinsing the bottles with distilled water before use. In the case of grinded containers, there may occur glass dust on the sides and bottom of the bottle from grinding process. Such bottles must be rinsed before use. We recommend rinsing with a 2% acetic acid solution followed by distilled water.
If bottles are intended for food and beverage storage, the beverage / food manufacturer must rinse the bottles properly with drinking water or water with low % alcohol before filling!
Grinded bottles and stoppers are recommended to be rinsed first with 2% acetic acid solution followed by drinking water or water with low % alcohol! Absolute tightness cannot be guaranteed for grinded bottles with grinded stoppers. Therefore we do not recommend to transport liquids. Any use of waxes and sealing material to ensure better tightness is solely the responsibility of the user of the sealing material.

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:

Name	Colour	Accessories	Material
Screw cap and a pouring ring GL45 with PTFE sealing liner	**red**	**screw cap and a pouring ring**	**PBT - Celanex® 2401 MT® NATURAL**
	grey	**sealing liner**	**silicone + one-sided layer of PTFE**

4. the date of the declaration: 19.02.2020

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 in an article 3; article 11 paragraph 5 and in an article 15 and 17**

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:**

Name of the Substance	PM/Ref. No.	CAS No.	SML [mg/kg]
terephthalic acid	24910	100-21-6	7,5 mg/kg
1,4-butanediole	13720	110-63-4	5 mg/kg
tetrahydrofurane	25150	109-99-9	0,6 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 180 °C for up to 30 minutes, including hot-fill conditions and/ or heating up to 70 °C for up to the maximum contact time 2 hours.
   With following storage for up to 6 months at room temperature or exposure for 168 hours at -40 °C.

   (iii) Ratio: 8,55 cm^2 of product area/ 100g (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. 412211077-01 and Test Report Ref. No. 472112791-01 by ITC Zlín, CZE.
The validity of the declaration is ending if the requirements are changed.

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: **-**

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Sázava, 07. 03. 2021 — Ing. Kristýna Machová

Place and date of issue — *Project Quality Engineer*