



CERTIFICATE OF CONFORMITY

KAVALIER

132/24

Issuer's name/ producer:
Issuer's address/Producer:

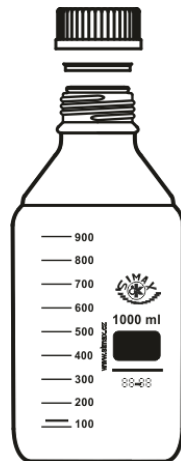
KAVALIERGLASS, a.s.
Křížová 1018/6, Prague 5
Production plant: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration:

REAGENT BOTTLES with Screw Cap and a Pouring Ring

<u>Product IDN & Description</u>	<u>Art.-Nr.</u>	<u>Capacity/ ml</u>	<u>GL Thread Size</u> <i>(acc. DIN 168-1 (1998-04))</i>
	1632414321100	100	
	1632414321250	250	
	1632414321500	500	
	1632414321940	1000	
2070 clear bottles	1632414321950	2000	GL45
	1632414321954	3800	
	1632414321956	5000	
	1632414321966	10000	
	1632414321968	20000	

Scheme of the glass bottle and Plastic accessories



Material specification:

Bottle body	clear	Borosilicate glass SIMAX®
Screw cap GL45	blue	PP BORMED™ HD850MO
Pouring ring		PP BORMED™ HF840MO
Print	white	in fired-on, chemically resistant ceramic enamel
Purpose of use	laboratory bottles Storage of chemical substances and mixtures	

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
- ISO 4794 Laboratory glassware — Methods for assessing the chemical resistance of enamels used for colour coding and colour marking
- **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
- **ISO 10993-5:2018 Biological evaluation of medical devices – Cytotoxicity Screw Cap with a Pouring Ring** Relating to plastic materials, that has been tested
- **DMF 017929 (US)**
Screw Cap Relating to plastic materials, that are Listed in Drug Master File
- **DMF 009040 (US)**
Pouring Ring Relating to plastic materials, that are Listed in Device Master File
- **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](#)**

Products do not release Substances of Very High Concern (SVHCs) above their respective threshold values listed in SVHC-Candidate List, as of the date of inclusion: 23th January 2024 as part of their formulation.

Please refer to ECHA website below for the detail of SVHC. <https://echa.europa.eu/candidate-list-table>

- **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)

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:

<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 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®

Dossier of extractables and leachables studies:

- **Acid resistance** Class I. (to ISO 1776)
- **Hydrolytic resistance** Class I. (HGB1 to ISO 719; HGA1 to ISO 720)
- **Acid resistance** ISO 1776
- **Resistance to attack by a boiling aqueous solution of mixed alkali** Class A2 (to ISO 695)

- **Coefficient of mean linear thermal expansion α : $3,3 \times 10^{-6} \text{ K}^{-1}$ (to ISO 7991; 20/300 °C)**

- **Pharmaceutical use**

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

Supporting data:

TEST / European Pharmacopoeia 10 th , 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	mg As/g	max 0,1	< 0,001

Screw Cap with a Pouring Ring Eur. Ph.10th – 3.1.3 Polyolefins; based on the statement of the supplier
 Eur. Ph.10th – 3.1.6 Polypropylene for containers and closures for parenteral preparation

- **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 permissible long-term operating temperature is 300 °C.
 The maximum thermal shock resistance is $\Delta T=100 \text{ K}$.

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

- **Sterilization***

Hot air sterilization, in the oven up to 140 °C
 Steam sterilization, in an autoclave 121 °C/ 20 min/ 2,05 bar
 134 °C/ 10 min/ 3,04 bar

*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 $\frac{3}{4}$ (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.

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.



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

KAVALIERRGLASS, 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	Material
Screw cap GL45	blue	PP BORMED™ HD850MO
Pouring ring		PP BORMED™ HF840MO

4. the date of the declaration: 23.08.2021

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:

Name of the Substance	FCM	PM/Ref. No.	CAS No.	SML [mg/kg]
Irganox 1425	715	46880	65140-91-2	

- Substances not listed in Annex I (Union list) to Commission Regulation 10/2011/EU – NIAS (non-intentionally added substances) assessment:

The submitted sample was screened for NIAS in the sample mass and in 95% ethanol after migration.

The following substances was identified in the sample after migration:

Name of the Substance	PM/Ref. No.	CAS No.	SML [mg/kg]
2,4-di- <i>terc</i> -butylphenol = ARVIN 4		96-76-4	45 mg/kg
3,5-di- <i>tert</i> butyl-4-hydroxystyrene = ARVIN 5		52858-87-4	ND
7,9-di- <i>terc</i> -butyl-1-oxaspiro (4,5) deca-6,9diene-2,8-dione = ARVIN 8		82304-66-3	4,5 mg/kg

- in acc. to Annex II of Commission Reg. 10/2011/EU: metals 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: 16 cm² of product area/ 100g (ml) or more of food;
2,96 cm² 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 document was issued on the basis of the accredited Test Report Ref. No. 472114281-01 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. 3258 100 23 52 0132 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.

The certificate is issued for the customer:

Sázava, 29. 01. 2024
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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