



KAVALIER

DECLARATION OF COMPLIANCE

399/25

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

Object of the declaration: **LABORATORY, TECHNICAL GLASS**

Material: **Borosilicate glass SIMAX®, glass with high thermal and chemical resistance**

Country of origin: **Czech Republic**

Purpose of use: **Application in technical, pharmaceutical, laboratory or food industry**

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
 - Chemical durability (art. 4.1, 4.2, 4.3, 4.4)
 - Physical properties (art. 5.1, 5.2, 5.3, 5.4, 5.5, 5.6)
- Glass containers for pharmaceutical use
 - Eur. Ph 10th Edition - 3.2.1 Glass Type I.
 - USP <660> Glass Type I.

FOOD CONTACT:

- General Product Safety Regulation 2023/988 (GPSR) of 13 December 2024 Ensuring product safety in the EU
- Commission Regulation (EU) No. 2023/2006

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

- 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

- 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 7086-1:2019 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

- ISO 719:2020 Glass - Hydrolytic resistance of glass grains at 98 °C

Method of test and classification

- ASTM E438 Standard Specification for Glasses in Laboratory Apparatus

Classification, chemical requirements of the glass

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

- **Regulation (EC) No. 987/2008 of 8 October 2008 amending Regulation (EC) No. 1907/2006** – REACH as regards Annexes IV and V – glass was exempted from the obligation to register.
The object of declaration does not contain any substances from the REACH – Candidate list of SVHC.
- **Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December - [EU REACH Regulation](#)**
Products do not release Substances of Very High Concern (SVHCs) above their respective threshold values listed in SVHC-Candidate List, published by European Chemicals Agency (ECHA) as a part of REACH regulation with latest date of inclusion: June 25th 2025 as part of their formulation
- **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.**
- **Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).**
- **Chemical characteristics (acc. to Regulation No 1907/2006/EC):**

Composition:	CAS No.	EINECS No.	Component:	Concentration /Percent:
	65997-17-3	266-046-0	Glass, oxide, chemicals	100%

- **Chemical characteristics of borosilicate glass (approximate values)** ASTM E438

Component	Content (percentage by weight)
SiO ₂	80,3%
B ₂ O ₃	13,0%
Al ₂ O ₃	2,4%
Na ₂ O + K ₂ O	4,3%

- **Chemical stability:** Stable
- **Phthalate/DEHP Statement:** Not Applicable
- **BSE/TSE Declaration:** Glass is free from BSE and TSE.
Glass is manufactured by using raw material of non-animal origin, does not contain meat product and does not come in contact with meat products.
- **BpA** No Bisphenol A in the product and the production.

TECHNICAL REQUIREMENTS ACCORDING TO PURPOSE OF USE

Characteristics of Borosilicate glass SIMAX®

- **Acid resistance** Class I. ISO 1776
- **Hydrolytic resistance** Class I. HGB1 to ISO 719;
HGA1 to ISO 720
- **Alkali resistance** Class II. ISO 695
- **Coefficient of mean linear thermal expansion α : $3,3 \times 10^{-6} \text{ K}^{-1}$** ISO 7991; (20/300 °C)
- **Glass containers for pharmaceutical use**
 - Eur. Ph 10th Edition - 3.2.1 Glass Type I.
 - USP <660> Glass Type I.
 - 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	mg As/g	max 0,1	< 0,001

Additional information:

These products are made of borosilicate glass, which does not harm the human health. Its characteristics are constantly tested and comply fully with the standard ISO 3585 Borosilicate glass 3.3 –Properties.

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 for 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, 02. 07. 2025
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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