

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:

MORTARS WITH A POUR-OUT LIP AND PESTLE, INSIDE GLAZED

<u>Cat. No. & Description</u>	<u>Product IDN</u>	<u>Mortar [mm]</u>			<u>Pestle [mm]</u>
		d_1 [mm]	d_2 [mm]	h [mm]	L [mm]
2231 clear & inside glazed	1632538150080	80	50	60	110
	1632538150100	100	60	75	130
	1632538150120	120	70	90	150
	1632538150150	150	85	110	180
	1632538150200	200	120	135	230

Scheme of the glass item



Material specification:		
Mortar	clear, glazed	Borosilicate glass SIMAX®
Pestle	clear, glazed	Borosilicate glass SIMAX®
Purpose of use	Laboratory glassware Ideal for preparing compounds, mixing and grinding powders	

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

Glass containers for pharmaceutical use:

- Eur. Ph. 10th – 3.2.1 Glass Type I.

Technical standards for products:

- **Commission Regulation (EU) No. 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food
- **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
- **Regulation of Czech Health Ministry Decree No. 38/2001 Coll.**, on hygienic demands for products 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

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. 1907/2006 of the European Parliament and of the Council of 18 December - [EU REACH Regulation](#)**
Products do not contain any substance from the REACH Candidate list of Substances of Very High Concern (SVHC).

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)
- **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, 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

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

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%

Additional information:

The producer confirms hereby that the characteristics, measures and accuracy of the products listed above are in full conformity with the provisions of the standard.

The producer also 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, 26. 04. 2021
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

KAVALIERGLASS, a.s.
Křížová 1018/6, 150 00 Praha 5
office: Sklářská 359, 285 06 Sázava
Czech Republic
IČ: 474 68 815
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