

**TECHNICAL DATA SHEET**

Effective date: 01.2020  
Rev.0

**Royalblue glass bottle 30 ml**

**Glass analysis / Certificate of conformity**

The cobalt blue glass was analysed according to DIN ISO 719 and corresponds to the hydrolytic class III whereby maximum 0.85 ml HCL/g (0.01 Mol/l) is used.

We herewith assert and confirm in compliance with the provisions of the EC regulation 1935/2004 that our glass containers do not emit any substances in volumes that are qualified:

- To endanger human health or
- To cause an indefensible modification of the composition of the foodstuffs filled in them or to cause an impairment of the organoleptic characteristics of the foodstuff.

Glass analysis of our cobalt blue glass (type III):

SiO <sub>2</sub>	71.20 %
Al <sub>2</sub> O <sub>3</sub>	1.70 %
Fe <sub>2</sub> O <sub>3</sub>	0.03 %
TiO <sub>2</sub>	0.02 %
K <sub>2</sub> O	1.58 %
Na <sub>2</sub> O	12.70 %
CaO	8.99 %
MgO	3.40 %
BaO	0.03 %
SO <sub>3</sub>	0.20 %
CoO	0.05 %
Others	0.10 %

100.00 %

We hereby assert and confirm that no health-hazardous substances or smell-, taste- or visually affecting substances within the meaning of the legal regulations cited of the Foodstuffs-, Consumer Goods and Feeding Stuff Law (LFGB) in the revised form dated 26 April 2006 (BGBl. 2006 Part 1 No. 20 p. 945) do migrate from the glass containers produced by us into the products filled in them.

- § 30 LFGB; interdiction for the sake of the protection of health
- § 31 paragraph 1 LFGB; migration of substances into foodstuffs

**1. Food law related clearance certificate**

Legal basis, regulations and directives:

- *Foods, Consumer Goods and Feedstuffs Code (LFGB), in the version on 03 June 2013 (GB/. I p. 1426), last amended by the Article 2(33) and Article 4(20) of the Ordinance of te 7 August 2013 (BGB/. I p. 3154.*
- § 30 LFGB; forbiddance for health protection
- § 31(1) LFGB; migration of substances into food

The food and feedingstuff law has been newly regulated fundamentally in September 2005. Based on the law concerning the realignment of the food and feeding stuff law, the Food, Consumer Goods and Feeding Stuff Law (Lebensmittel- und Futtermittelgesetzbuch, LFGB) has been enacted with effect as of 7th September 2005.

We hereby assure and confirm that no substances, which can be health-hazardous or affect the filling by taste, smell or visually do migrate from the glass containers made by us within the meaning of the legal regulations mentioned above.

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Legal basis, regulations and directives:

- *Regulation (EC No 852/2004 on the hygiene of foodstuffs; dated 29 April 2004,*
- *Federal Regulation concerning Food Hygiene (LMHV), dated 8th August 2007, (BGB/. I p. 1816, 1817), last amended by the Article 1 of the Orance of 14 July 2010 (BGB/. I*
- *Foods, Consumer Goods and Feedstuffs Code (LFGB), in the version promulgated on 03 June 2013 (BGB/. / p. 1426)*

The HACCP concept (Hazard Analysis and Critical Control Points = system for risk analyses and supervision of critical points) required by the Regulation (EC) No 852/2004 on the hygiene of foodstuffs has become a constituent of the operational quality assurance implemented within the food industry. In view of the fact, that containers made of glass assume a certain importance with regard to the safeguarding of the production of foodstuffs, the container shall not interact as an origin of health risk. The glass container rather represents protection for the food contained within in.

As an important supplier of high-quality glass containers for the food industry, it was our important task to implement a HACCP system in our production process, that has been developed by the container glass industry in compliance with the directives, enactments and ordinances specified herein before.

**3. Good Manufacturing Practice (GMP-Regulation)**

Legal basis, regulations, directives and standard:

- *Regulation (EC) No 2023/2006 of 22<sup>nd</sup> December 2006 on good manufacturing practice for materials and articles intended to come into contact with food*
- *DIN EN ISO 15378:2012-02; Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2008, with reference to Good Manufacturing Practice (GMP) (ISO 15378:2011);*

We hereby assert and confirm that the products made by us are compliant with the above mentioned GMP-Regulation on good manufacturing practice for materials and articles intended to come into contact with food. We refer especially to article 5 (quality assurance system), article 6 (quality control system) and article 7 (documentation).

**4. Migration of substances into foodstuffs**

Legal basis, regulations, directives and standard:

- *Regulation (EC) No 1935/2004 of 26 October 2004 applicable for materials and goods destined to come into contact with foodstuffs*
- *Ph. Eur. Current Edition - Chapter 3.2.1 and USP 36-NF 31 - Chapter <660> Glass container for pharmaceutical use*
- *ISO 719:1985: Glass-- Hydrolytic resistance of glass grins at 98 degrees C-- Method of test and classification*
- *ISO 4802-1:2010: Glassware -- Hydrolytic resistance of the inferior surfaces of glass containers- - Par 1: Determination by titration method and classification*
- *Examination of the spectral transmittance of colored glass container according DAB, Ph. Eur. and USP*

Based on the results of the hydrolytical resistance testing of the inner surface of the glass container or glass grains against water we can confirm that our soda-lime-silica glass corresponds to the hydrolytical class Typ III. In addition we confirm that the observed spectral transmission for our amber glass containers does not exceed 10 per cent at any wave length in the range of 290 nm to 450 nm, irrespective of the type and the capacity of the glass container.

We hereby assert and confirm in compliance with the provision of Regulation (EC) 1935/2004 that under normal or reasonably foreseeable conditions of use our glass containers do not transfer their constituents to food in quantities which could:

- endanger the human health or
- cause an indefensible modification to the composition of the foodstuffs filled in or
- cause an impairment of the organoleptic characteristics of the foodstuffs.

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Legal basis, regulations and directives:

- *European Packaging Directive 94/62/EU, article 11, dated 20.12.1994 in conjunction with the EC decision 2001/171/EU dated 19.02.2001 and 2006/340/EU dated 08.05.2006 German Packaging Regulation dated 21.08.1998 (GBl. I S. 2379), article 5 (19) of the Packaging Regulation last amended on 2nd of April 2008, 2012 Ph. Eur. 2.2.23*
- *Testing for arsenic (AAS and USP <211>*

We hereby assert and confirm, that glass containers delivered by us are compliant with the specifications concerning heavy metals (lead, cadmium, mercury and chromium VI) required by the above mentioned Directive and Regulation.

**6. Traceability**

Legal basis, regulations and directives:

*EC regulation 1935/2004, article 17, dated 27th of October 2004*

Among other things, the EC regulation 1935/2004 also requires that the traceability of materials and/or objects determined that come into contact with food, must be secured in order to facilitate controls, the recall of non-conforming or faulty products and information of the consumer as well as the determination of the corresponding liabilities. The companies concerned must, in due consideration of the technological feasibility, dispose of systems and procedures that enable to find out from whom to which company the materials or objects or, if applicable, the products or substances used for their production coming under said directive and the appurtenant implementing provisions have been supplied or from which company they have been procured.

We hereby assert and confirm that we, based on the information imprinted on the pallet label, are able to meet the traceability requirements with regard to materials and or objects that are determined to come into contact with foodstuffs as specified and set out in the EC regulation 1935/2004.

**7. Declaration concerning the REACH-Regulation**

Legal basis, regulations and directives:

- *Regulation (EC No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as amended by the Commission Regulation (EC) No 987/2008 of 8<sup>th</sup> October 2008 as regards Annexes IV and V of Regulation (EG) No 1907/2006*

The products of the glass industry (e.g. container made of glass for packaging use) are articles in the meaning of the REACH-Regulation, because the function is mainly determined by form, design and surface and not by its chemical composition. Therefore no obligation exists to register these articles according to the REACH-Regulation.

On the supply chain side we have ensured that all raw materials which are being used within our manufacturing process of glass are compliant with the requirements of the REACH-Regulation, especially in case a pre-registration should be necessary.

**8. Guide for the evidence of conformity**

Legal basis, ordinances and directives:

- *EC Packaging Directive 94/62/EU dated 2d Dec.1994 in conjunction with the EG decision 001/171/EU; dated 19th Feb. 2001 and 2006/340/EU; dated 8th May' 2006*
- *European Standard Series DIN EN 13427 f Version 2004-10*

We hereby assert and confirm that, on the basis of the directives specified herein before, the packaging requirements, conformity obligations and procedures mentioned in the guide for the evidence of the conformity have been and are all followed and adhered to during the production and the control of our products.

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**9. Principles of Ethical Sourcing**

We are committed to legal compliance wherever we conduct business. We expect our suppliers to comply with all applicable laws of their country, including laws relating to employment, discrimination, environment and health and safety. Suppliers who knowingly violate laws will not be our business partners. We, furthermore, expect that our suppliers comply with a certain standard of internationally accepted rules of behavior in respect of the above issues.

**TECHNICAL DRAWINGS**

**RoyalBlue glass bottle 30 ml DIN 18, 45 g, brimful volume 34 +-1ml**

