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Skleněná lahvička

We herewith confirm that our amber and flint glass containers Type III and II comply with the current European Pharmacopoeia (EP) and United States Pharmacopoeia (USP).

Average composition of our amber and flint glass type III:

Flint Glass

SiO ₂	71,5 ± 0,3 %
Al ₂ O ₃	1,7 ± 0,15 %
Fe ₂ O ₃	< 0,035 %
CaO	9,80 ± 0,2 %
MgO	3,10 ± 0,30 %
Na ₂ O	12,30 ± 0,50 %
K ₂ O	1,20 ± 0,2 %
Ti O ₂	0,02 ± 0,01 %
SO ₃	0,15 ± 0,04 %
B ₂ O ₃	0,2 ± 0,05 %

Amber Glass

SiO ₂	71,3 ± 0,3 %
Al ₂ O ₃	2,3 ± 0,2 %
Fe ₂ O ₃	0,3 ± 0,05 %
CaO	9,90 ± 0,30 %
MgO	2,6 ± 0,15 %
Na ₂ O	12,20 ± 0,20 %
K ₂ O	0,54 ± 0,09 %
Ti O ₂	0,035 ± 0,02 %
SO ₃	0,04 ± 0,01 %
B ₂ O ₃	0,28 ± 0,04 %
Li ₂ O	0,36 ± 0,04 %

Remark: The base glass is always Type III only the inner surface is changed to Type II by an chemical process: $(\text{NH}_4)_2\text{SO}_4 \rightarrow 2\text{NH}_3 + \text{SO}_3 + \text{H}_2\text{O}$

The **type II bottles** are to be used only once according to current, valid Ph.Eur. / USP and have to be washed prior to filling.

Examinations regarding the contents of Heavy metals specifically Pb, Cd, Hg, and Cr ⁺⁶ in our glass showed values below the limit of 100 ppm by weight. The content of arsenic is below the values of 5 ppm.

Therefore, and with the exception of marginal substances which do not affect human health, odour and taste and which cannot be avoided during manufacturing no other substances are released to food or its surface. It can be excluded that our glass contains substances like latex, gluten or lactose.

We also confirm that products delivered by us, no raw materials, excipients and further materials of animal origin are used. Due to the fact that for the manufacture of these packaging material no materials are used, which might have a TSE / BSE risk, the bottles are not affected by the general text regarding vaccines, Ph.Eur.5.2.8,"Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products", and by the EMEA-guideline EMEA/410/01,"Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products".

☐ **Food law related clearance certificate**

Legal bases, enactments, regulations and directives:

- ☐ Food, Consumer Goods and Feeding Stuff Law (LFGB), 22nd of Aug. 2011 (BGBl. I No. 47, from 08th of Sep. 2011 S. 1770)
- ☐ § 30 LFGB; forbiddance for health protection
- ☐ § 31; clause 1 LFGB; migration of substances into food

The food and feeding stuff 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 assert 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.

2. HACCP declaration

Legal bases, enactments, regulations and directives:

- ☐ Regulation (EC) No 852/2004 on the Hygiene of Foodstuff; dated 28th of April 2004,
- ☐ Food Hygiene Ordinance (LMHV), dated 8th of August 2007, (BGBl. I No. 39, S. 1816, 1817)
- ☐ Food, Consumer Goods and Feeding Stuff Law (LFGB), 22nd of Aug. 2011 (BGBl. I No. 47, from 08th of Sep. 2011 S. 1770)

The HACCP concept (**H**azard **A**nalysis and **C**ritical **C**ontrol **P**oints = system for risk analyses and supervision of critical points) required by the Regulation (EC) No 852/2004 on the Hygiene of Foodstuff 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 hereinbefore.

3. Good Manufacturing Practice (GMP-Regulation)

Legal bases, enactments, regulations and directives:

- ☐ Regulation (EC) No. 2023/2006; dated 22nd of Dec. 2006 on good manufacturing practice for materials and articles intended to come into contact with food

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 bases, enactments, regulations and directives:

- ☐ DIN ISO 719, state 1989-12; water resistance of finely crushed glass at 98° C, test processes and classification
- ☐ EC directive 1935/2004; dated 27th of October 2004

The glass actually produced corresponds to a conventional soda-lime glass and is tested according to DIN ISO 719, which means that the glass containers produced do, on account of a consumption of no more than 0.85 ml hydrochloric acid (0.01 Mol/l) per gram of crushed glass, correspond to the 3rd hydrolytic class.

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

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

5. Heavy metal thresholds for container made of glass

Legal bases, enactments, 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, last amended on 2nd of April 2008 by the 5th Regulation to amend the Packaging Regulation

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 bases, enactments, 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 callback of non-conforming or faulty products, the information of the consumer and 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 bases, enactments, regulations and directives:

- *Regulation (EC) Nr 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 October 2008 as regards Annexes IV and V of Regulation (EC) Nr 1907/2006*

The products of the glass industry (e.c. 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 bases, enactments, ordinances and directives:

- *EC Packaging Directive 94/62/EU dated 20th of Dec. 1994 in conjunction with the EC decision 001/171/EU; dated 19th of Feb. 2001 and 2006/340/EU; dated 8th of May 2006*
- *European standard series DIN EN 13427 ff, state 2004-10*

We hereby assert and confirm that, on the basis of the directives specified hereinbefore, 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.