

TECHNICAL DATA SHEET

Effective date: 01.2020
Rev.0

Amber bottle DIN18, 10 ml

GENERAL MATERIAL SPECIFICATION FOR AMBER GLASS CONTAINERS

Parameter	Standard / Norm	Specification
Material	---	Soda-Lime-Silicate Glass
Hydrolytic resistance of glass grains	Pharm.Eur. 3.2.1, USP <660>	≤0,85ml 0,02N HCl/g
	ISO 719	0,20 – 0,85ml 0,01N HCl/g
Hydrolytic Resistance of inner surface	Pharm. Eur. 3.2.1, USP <660>, ISO 4802-1	usage of 0,01N HCL/100ml must comply with specification of the container size
Light transmission (290-450nm)	Pharm. Eur. 3.2.1, USP <660>	≤10%
Arsenic	Pharm. Eur. 3.2.1, USP <660>	≤0,1 ppm
Heavy metals (Pb, Cd, Hg, Cr VI)	EU-Dir. 94/62, CONEG	≤100 ppm
Storage	---	dry
Shelf life	---	min. 60 months from date of production

DECLARATION OF ACCORDANCE

We declare that the delivered bottles (glass for health services and pharmaceutical purposes) fulfils the requirements of packaging material for pharmaceutical and food industry.

1. We are certifying herewith that the product is made of Soda-Lime-Silicate Glass, hydrolytic resistance class 3 according to the European pharmacopoeia and USP, current editions.
2. We are also certifying that all the materials used during the production are free of the hazardous substances for the human health. The glass meets the national and international regulations for the pharmaceutical, cosmetic, food and beverage use such as Directives 94/ 62/ EC and 1935/2004/ EC.
3. The bottle is produced in accordance to the following standards:
European Pharmacopoeia 8, current version; DIN 51032:1986; ISO 7086-2:2000.

1. Food law related clearance certificate

Legal bases, enactments, regulations and directives:
- Directives 94/ 62/ EC and 1935/ 2004/ EC.

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- e.g.: German Food, Consumer Goods and Feeding Stuff Law (LFGB), 22nd of August 2011 (BGBl. 2013 part I no. 27), last revision from 03rd of June 2013, last time changed by article 2G from 05.12.2014 (1975).

- §30 LFGB; forbiddance for health protection
- §31; clause 1 LFGB; migration of substances into food

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

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. 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 not 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

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.

6. Declaration concerning the REACH –Regulation

Legal bases, enactments, regulations and directives:

- Regulation (EC) No 1907/ 2006 of the European Parliament and the Council dated 18th of Dec. 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

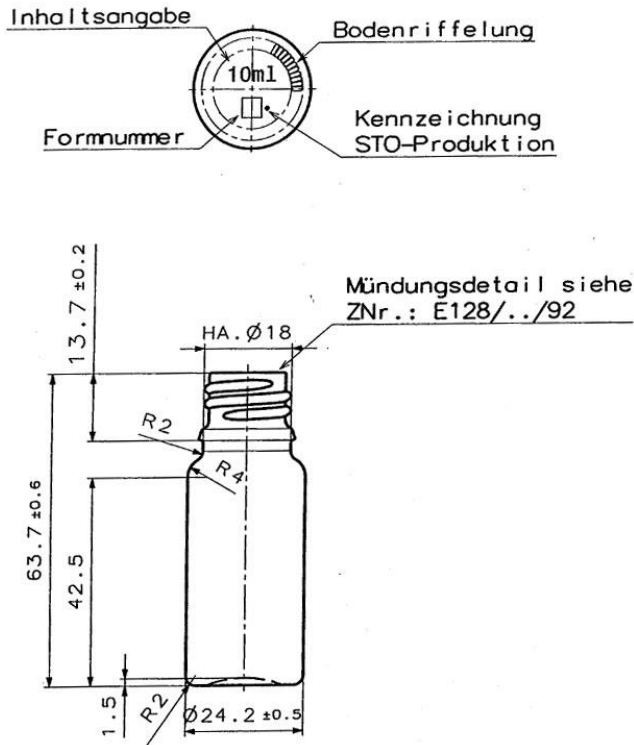
The products of the glass industry (e.g. containers made of glass for packaging use) are not articles in the meaning of the REACH-Regulation, because the function is mainly determined by form, design and surface and not by its chemical composition. Therefore, no obligation exists to register these articles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

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TECHNICAL DRAWINGS



Volume	12 ± 1,2 ml
Weight	Approx. 30 g

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications.