

Form: TDS-001 Root Reference: X-4178

Effective date: 06.2020

Rev.0

Laura glass bottle, 50 ml

REGULATORY COMPLIANCE CERTIFICATE

General Material Specification For Clear Glass Containers

Parameter	Specification
Material	Soda-Lime Glass
Water resistance tested at 98°C according to DIN ISO719	HGB 3 with a typical consumption of 0,5 ml hydrochlorhidric acid per 1 gram glass grit
Acid resistance tested according to DIN 12116	class 1
Alkali resistance tested according to DIN 52322 ISO 695	Class A2 with typical mass lost 85 mg/dm2
Arsenic	≤0,1 ppm
Heavy metals (Pb, Cd, Hg, Cr VI)	≤100 ppm
Storage	dry, clean area
Shelf life	min. 60 months from date of production

DECLARATION OF ACCORDANCE

We declare that the delivered bottles of glass fulfils the requirements of packaging material for food industry.

- 1. We are certifying herewith that the product is made of Soda-Lime-Silicate Glass 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 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.
- 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 LFBG; 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.



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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.

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

The glass actually produced corresponds to a conventional soda-lime glass and is tested according to DIN ISO 719.

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. Absence of substances

It not use or intentionally incorporate into its polymers any of the following chemicals. Although it is not foreseeable their presence in the final product, specific analyses to assure the absence of most of these chemicals have not been performed. This is a non-exhaustive list of substances.

Acrylamide

Alkylphenol ethoxylates (APEO)

Aromatic amines

Arsenic and arsenic compounds

Asbestos

Azoic colorants

Benzene

Benzophenone, hydroxybenzophenone and 4-methylbenzophenone

Biocides

Bisphenol A (BPA) and Bisphenol F (BPF)

Boron and boron compounds

Butylated hydroxytoluene (BHT) / Butylated hydroxyanisole (BHA)

Cadmium and cadmium compounds

CFC (chlorofluorocarbons) y HCFC (hydrochlorofluorocarbons)

CMR substances class 1A and 1B (Carcinogens, Mutagens and Reprotoxics) according with Regulation CLP (1272/2008)

Diethylhexyl adipate (DEHA)

Dimethyl fumarate (DMF)

Dioxines

Epichlorhydrin

N-Ethyl o-Toluensulfonamide and N-Ethyl p-Toluensulfonamide (NETSA)

Flame retardants: organic brominated compounds (pentabromodiphenyl ether, octabromodiphenyl ether...), antimony compounds, chlorinated paraffins, triaryl phosphates...

Formaldehyde



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Formamide

Halogens and halogenated compounds

Hexavalent Chromium and hexavalent chromium compounds

Isopropylthioxantone (ITX)

Latex

Lead and lead compounds

Lindane

Melamine

Mercury and mercury compounds

Nitrosamines

Nyckel and nyckel compounds

Nonylphenol, nonylphenol ethoxylate and cement

Organostannic / Organotin compounds

PBT Substances (Persistent, Bioaccumulating and Toxics) and vPvB (very persistents and very bioaccumulating

Pentachlorophenol and its salts and esters

Phenol

Perfluorooctane sulfonates (PFOS)

Polycyclic aromatic hydrocarbons (PHA): anthracene, fluoranthene, naphthalene, pyrene, benzoanthracene, benzofluoranthene

Solvents: dichlorometane, dimethylacetamide, dimethylformamide, 2-ethoxy ethanol, nitrobenzene, trichloroethylene trichlorobenzene, hexachlorobenzene...

Stvrene

Toluene

Triclosan

Vinyl chloride monomer (VCM) and its polymers (PVC...)

6. 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.

7. 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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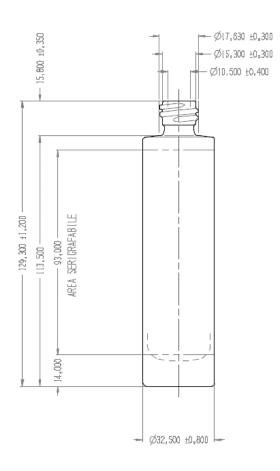
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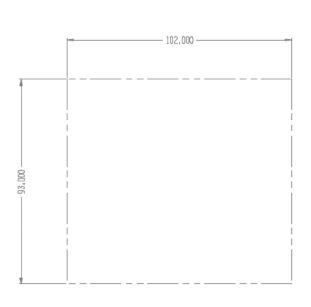
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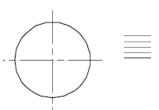
TECHNICAL DRAWINGS

Weight: 99 gr

Nominal volume: 50 ml Brimful volume: 55,9 ml +-3







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.