DWK Life Sciences GmbH

Hattenbergstraße 10
D-55122 Mainz
Germany

Phone +49 (0)6131-1445 4131
Fax +49 (0)6131-1445 4016
www.DWK-LifeSciences.com

Date: 21.01.2021

To whom it may concern,

DWK Order code	***Description***	***Dimensional Technical Drawing Reference numbers***	***Retrace Code***
1178392	DURAN® laboratory bottle with GLS 80® thread 500 mL, clear glass body only	500ml Bottle body: 0739601-GZA-06275-E GLS 80 Thread / neck: 0733800-GZA-GLS80-A	Not stated

We hereby confirm that the article listed above is made from DURAN® borosilicate 3.3 glass, and that it have been produced in accordance with the Quality Assurance System DIN EN ISO 9001:2015.

1. DURAN® glass compliance with pharmacopoeia and ISO standards:
DURAN® is a borosilicate glass type 3.3 as specified by the international standard ISO 3585. DURAN® is notable for very high thermal shock resistance and has the following chemical properties:

- Acid resistance Class I (to ISO 1776)
- Hydrolytic resistance Class I (to ISO 719/720)
- Alkali resistance Class 2 (to ISO 695)

Due to its high hydrolytic resistance (Hydrolytic resistance Class I) DURAN® glass is classified as a "Type I neutral glass" as defined by the following pharmacopoeias.

USP <660> Containers – Glass
EP (3.2.1) Glass Containers for Pharmaceutical Use
JP <7.01> Test for Glass Containers for Injection

2. BSE/TSE statement for all products manufactured from DURAN® glass

- Glass consists of purely raw materials without any biological origin. Not are any materials of animal origin used during the manufacturing process.
- The manufacturing of our glass involves melting temperatures of minimum 1500 °C for several hours where all the ingredients are melted together. After forming the glass each item is tempered in an oven at more than 400 °C and slowly cooled.
- Manipulated products are heated up for further processing to their melting temperature at about 1250 °C, after further processing each item is tempered and cooled as described.

Because of the high temperatures involved in the manufacturing process we can act on the assumption that all biological substances are destroyed during production and no BSE/TSE causal organisms are contained in the finished goods.

We therefore state that DURAN® glass and our product are to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

3. Declaration of DURAN® glass compliance with Food Contact and Additive Regulations

DURAN® glass is compliant with the requirements of the following guidelines, laws and regulations:

- ISO 7086-1 + -2 – Glass Hollowware in contact with food – Release of Lead and Cadmium
- ISO 6486-1 + 2 – Ceramic ware, glass-ceramic ware and glass dinnerware in contact with food – Release of lead and cadmium
- DIN EN 1388-1 Silicate Surfaces – Determination of Release of Lead and Cadmium
- (EU) 2004/1935 – Materials and Articles in Contact with Foodstuff
- (EC) 2006/2023 – Manufacturing Practice for Materials and Articles in Contact with Foodstuff
- (EU) 2005/31 – Method for the Analysis of Ceramic Articles in Contact with Foodstuff
- 94/62/EU (Verpack V) – Packaging and Packaging Waste
- LFGB – Requirements regarding leaching of lead and cadmium
- FDA CPG 7117.06 – Ceramic Food Bearing Surfaces – Cadmium
- FDA CPG 7117.07 – Ceramic Food Bearing Surfaces – Lead

DURAN® glass is therefore fit for use in combination with foodstuff according to the standards and regulations listed above. This fact does not absolve the manufacturer of foodstuff using our articles and placing a food product on the market from thorough testing of his combination of filled-in goods and our glass for compliance with foodstuff according to the German LFGB and/or potentially additional applicable laws, guidelines and regulations (national and/or international).

Yours sincerely,

i.V. Alistair Rees
Product Manager Labware