

Certificate of Conformity



Article no.	Retrace Code/Batch/Lot no.	Date of Manufacture
292401305	210249F	2021-07-06

Article description

Screw-caps, GL 25, PBT, red, with PTFE protected seal, for DURAN® laboratory glass bottles with DIN thread

Component	Drawing Number	Manufacturing Location
Red PBT GL 25 cap body	0667901-GZA-0GL25-B	Approved DWK Life Sciences GmbH supplier, Hesse, Germany
PTFE coated silicone GL 25 cap liner	292481312-E	Approved DWK Life Sciences GmbH supplier, Lower Saxony Germany

The articles listed under "article number" are hereby confirmed to have been produced using a quality system conforming to ISO 9001 and comply with the DWK Life Sciences quality standards.

Regulatory compliance (PBT)

The red PBT with 30% glass fiber resin used to manufacture the screw cap listed above conforms to the following standards:

- Commission Regulation (EU) No.10/2011 and its subsequent amendment, as all raw materials (monomers/additives) are listed in Annex 1 of (EU) No.10/2011
- FDA CFR 21 Part 177.1660 with the usage conditions A to H+J for all food contact of Poly (tetramethylene terephthalate)
- FDA CFR 21 Part 178.3297 (Colorants for Polymers)
- EU Resolution of the Council of Europe AP (89) 1 (Colorant in Plastics)
- BfR Recommendation IX (Colorant)

Regulatory compliance (PTFE-coated silicone cap liner)

The PTFE-coated vinyl-methyl-silicone (VMQ) cap liner conforms to the following standards:

Raw material Silicone (VMQ)

- FDA CFR 21 Part 177.2600
- BfR Recommendation XV
- Ph. Eur. chapter 3.1.9

Raw material Polytetrafluoroethylene (PTFE)

- Commission Regulation (EU) No. 10/2011
- FDA CFR 21 Part 177.1550
- BfR Recommendation LI; 2.1.1.1.
- USP <88> Class VI

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Statement on BSE/TSE

We confirm that the raw material used in the manufacture of the referenced product is not of animal origin. Accordingly, transmission of animal spongiform encephalopathy agents via the mentioned components is extremely improbable. We therefore state that these materials and the product is to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

Statement regarding natural rubber latex

We confirm that during the manufacturing of the product listed above, we do not use or intentionally incorporate into it, natural rubber latex or derivatives of latex.

Statement regarding DEHP

We confirm that during the manufacturing of the above product, we do not use or intentionally incorporate into it any of the following chemicals:

- Bis(2-ethylhexyl) phthalate (DEHP)

Statement regarding Bisphenol A (BPA)

The product is not BPA free, BPA comes with glass fiber added. However, its concentration is lower than 0.01 ppm.

Recommended Shelf-life

We suggest a 5-year shelf life from the date of manufacture if stored under the recommended storage conditions.

Recommended storage conditions for DURAN Labware Products:

- Storage in a dry place (less than 40% relative humidity) with a Controlled Room Temperature (20-25 °C) as defined in USP <659>
- Excursions during storage in warehouses and during shipping are allowed.
- Avoid exposing plastic components to sunlight and other sources of ultra-violet light (UV).

Certified by: 
Mariska Jefferson
Quality Manager

Date: 2022-01-19