DURAN GROUP
magic of precision

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Date: 28.08.17
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To whom it may concern,

Duran Order code	***Description***	***Retrace Code***
218061409	DURAN® laboratory bottle with GL 25 DIN thread **25** mL, Amber glass	Not stated
218061709	DURAN® laboratory bottle with GL 32 DIN thread **50** mL, Amber glass	Not stated
218062405	DURAN® laboratory bottle with GL 45 DIN thread **100** mL, Amber glass	Not stated
218063607	DURAN® laboratory bottle with GL 45 DIN thread **250** mL, Amber glass	Not stated
218064406	DURAN® laboratory bottle with GL 45 DIN thread **500** mL, Amber glass	Not stated
218065402	DURAN® laboratory bottle with GL 45 DIN thread **1,000** mL, Amber glass	Not stated
218066304	DURAN® laboratory bottle with GL 45 DIN thread **2,000** mL, Amber glass	Not stated
218067309	DURAN® laboratory bottle with GL 45 DIN thread **5,000** mL, Amber glass	Not stated
218068605	DURAN® laboratory bottle with GL 45 DIN thread **10,000** mL, Amber glass	Not stated
218068802	DURAN® laboratory bottle with GL 45 DIN thread **15,000** mL, Amber glass	Not stated
218069104	DURAN® laboratory bottle with GL 45 DIN thread **20,000** mL, Amber glass	Not stated

The following five declarations apply to all the laboratory bottles manufactured by the DURAN group from ambered DURAN® borosilicate type 3.3 glass. These products are manufactured in accordance with the relevant DURAN Group Specifications, and under a certified DIN EN ISO 9001:2008 Quality Assurance System.

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. Amber colouring of DURAN® glass

The amber colour is applied after the hollowware moulding. The process creates layer of ambered glass on the outside surface of the bottle. The inner surface of the DURAN glass product is unchanged and remains a clear borosilicate 3.3, type 1 glass.
The external amber colouring meets the requirements of USP <671> and Eur. Ph. 3.2.1. for protection against UV light.**BSE/TSE statement for all products manufactured from ambered 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 ambered 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
- 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).

4. Phthalates and Bisphenol A (CAS Number 80-05-7) statement

We certify that during the manufacturing of the above products, we do not use or intentionally incorporate into it, Bisphenol A, plasticisers such as Adipates, ESBO, or Phthalates. The phthalates listed in Directive 2005/84/EC (Annex I of Directive 76/769/EEC) (EU) No 10/2011, or the EPA Phthalates Action plan are not added in the manufacture of or the formulation of this product.

Please do not hesitate to contact me if you require any further information.

Yours sincerely,



i.V. Alistair Rees
Product Manager Labware