



Food Contact statement

Certificate Reference: A-032 V10

Paris, July 29th, 2024

Dear Client,

SGD PHARMA bare glass bottles are entirely made of a single substance: glass. Glass is listed as a substance by ECHA (European Chemicals Agency) CAS No 65997-17-3 and EC No. 266-046-0.

Additionally:

- The internal surface of the bottle may be treated, depending on the customer requirement, with a silicone oil Silbione Emulsion 70001 SP
- The external surface of the bottle may be treated, depending on the customer requirement, with:
 - An organic treatment: Simulsol M 52 PH or Miracoat RP-40;
 - A tin hot treatment: Imacoat HE100 or Certincoat TC100 or Miracoat MBTC-100;
 - A thermosealing agent (applied on the bottle neck rim): Tecseal E-712

SGD Pharma has surveyed its suppliers. Suppliers have certified that their products comply with European regulation EC 1935/2004 or EC 10/2011.

SGD Pharma also performed analysis on its glass vials, which are compliant to the following regulations and standards as per SGD Pharma R&D Reports n°2713 and 2465 (July 5th, 2024):

- Regulation 1935/2004/EC and its amendments
- Directive 84/500 and its amendments
- DGCCRF Memorandum n°2014-108 dated 5 June 2014
- NF EN 1388-1 (1996)

Finally, SGD Pharma hereby certifies that:

- the glass of the below mentioned articles is in compliance with Regulation 1935/2004 of October 27th, 2004 on materials intended to come into contact with food. For articles not being intended for food contact, the requirements linked to the labelling (article 15) are not implemented.

- the management system of the quality of these five factories allows the traceability of products by Manufacturing Process Order from the information printed on the pallet label, in compliance with Regulation 2023/2006/CE of December 22th, 2006.

This declaration is based on the statements provided by our qualified suppliers and analysis performed on our glass vials, and is given to the best of our present knowledge and belief for the following products:

Type I, II and III Clear and Amber molded bare glass, heat sealed glass and siliconized glass (when siliconization or heat sealing is a customer requirement), tubular vials, ampoules

These products are produced in the following manufacturing sites:

Sucy-en-Brie (France), Saint-Quentin-Lamotte (France), Kipfenberg (Germany), Vemula (India), Zhanjiang (China)

Best regards,

Nathalie MARQUES

Quality System and Regulatory Affairs Group Manager
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SGD S.A.

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