

Borre, Thursday, November 09, 2023

Dear customer,

We refer to your request for information on our products, we would like to inform you that for the article(s) listed below:

reference	Description	Further description
P1000B-50	Corning® Gosselin™ Octagonal PET Bottle, 1 L, Graduated, 31 mm Tamper-evident Cap, Sterile, Assembled	12/Pack, 48/Case

**Use of Recoverable packaging**

Currently, the finished parts are manufactured with virgin materials, including caps manufacturing. No recycled materials used.

**Storage conditions**

The storage and transport condition should be at ambient temperature (15 to 30°C) in a dry environment.

These recommendations should be validated with the real environment during the different product using phases by the customer.

**VOC (variant of concern)**

There is no tallow derivative in this product. The component of this product is not manufactured from and does not come into contact with material of animal origin.

**Formaldehyde**

PET material is resistant at 20°C and 50°C facing reagent formaldehyde. The data is based on information and documentation provided by our raw material suppliers and on our own many years of technical experience.

Customers should test our products to ensure that they are suitable for their own specific requirements. The information provided is for guidance only and we cannot accept further responsibility.

**Residual Solvents and any impurities**

The raw material does not contain any substance that is listed on the current Article 59 list (so-called candidate list) of Regulation (EC) No 1907/2006 (REACH), above 0.1% (w/w). And the raw material contains less than 100 ppm of residual trace heavy metals covered under the EU Directive 94/62/EC (sum of Cd, Cr, Hg and Pb). However, we do not systematically perform specific tests to verify and quantify these substances as impurities.

**Oxygen and humidity permeability**

<https://www.corning.com/catalog/cls/documents/product-information-sheets/CLS-GL-036.pdf>

**Process for obtaining a product**

Corning PET Bottles are manufactured by injection-blow molding and the caps are injection molded. Both are made and assembled in a controlled manufacturing environment.

The product is irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.

## Migration test analysis results

- **PET material for bottle body part**

Intentionally added substances used in the Manufacture of Polyethylene Terephthalate (PET) subject to Specific Migration Limits:

CAS	Substance name	Specific Migration Limit (SML)
100-21-0	Terephthalic Acid	7,5 mg/Kg
121-91-5	Isophthalic Acid	5 mg/Kg
107-21-1	Ethylene glycol (MEG)	30 mg/Kg
111-46-6	Di-ethylene glycol (DEG)	(Incl. MEG + DEG)

Antimony trioxide which is used as a catalyst in the production of PET polymers (CAS No 0001 309-64-4) is listed as an additive and does not have a SML.

In ANNEX II Restrictions on plastic materials and articles, point (1), Table 1 of Commission Regulation (EU) No 10/2011 – PET polymers do not intentionally contain metals listed or their salts.

However, Antimony is present in the polymer at a level of < 300ppm, expressed as Antimony (Sb). Antimony (Metal) has a SML of 0,04 mg/kg food or food simulant – listed in Table 1. General list of migration limits for substances migrating from plastic materials and articles.

- **HDPE material for cap part**

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Article 6.3.a and Annex II), Mercosur (Res. 39/2019 Annexo 4.3.b and Res. 02/2012 chapter 4b) and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid; 4h/100°C; S/V-ratio 6) did not show any migration above 0,04 mg/kg (limit of detection).

Other used monomers and additives are not regulated with specific migration limits.

Substances also authorized as direct food additives ("Dual use additives") are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of the limits as set in the applicable food legislation.

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21, article 2.12 of Chinese standard GB4806.1 and Mercosur GMC Res No. 56/92 as amended by Res 20/2021, the overall migration shall not exceed 10 mg/dm<sup>2</sup> from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg).

A representative sample from this or a comparable material, tested for 2d at 20°C in iso-octane (1 mm plate / total immersion) did not exceed the limit of 10 mg/dm<sup>2</sup> for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.

Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with food stuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 10/2011; Annex 4 of Swiss Ordinance

817.023.21; Chinese standard GB31604.8-2021; Mercosur GMC Res No. 32/2010. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

However, our finished products have not been validated for food contact applications. The finished products made from food contact raw materials were not tested to ensure the compliance with Overall Migration Limit ('OML') requirements and Specific Migration Limits ('SML'), in contacting with different food-types (aqueous, fat/oil, alcoholic, etc) and various end-use conditions (temperature of use, etc).

They are designed for laboratory applications only.

Should you require any further information, please do not hesitate to contact us.

Yours sincerely,

**Sandra Bianchi**  
Quality Manager

