

Primary Packaging Glass
Gerresheimer Essen GmbH
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Confirmation

To whom it may concern

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Glass Specification

Dear Sir or Madam,

We confirm that our amber and flint glass containers Type III and II comply with the current European Pharmacopoeia (EP 3.2.1 · Glass containers for pharmaceutical use), the United States Pharmacopoeia (USP<660> · Glass containers) and the Japonica (JP).

Average composition of our amber and flint glass type III:

Flint Glass

SiO ₂	71,50 ± 1,0%
Al ₂ O ₃	2,25 ± 0,5%
Fe ₂ O ₃	< 0,1%
CaO	10,15 ± 0,5%
MgO	2,60 ± 0,5%
Na ₂ O	12,30 ± 0,5%
K ₂ O	1,10 ± 0,5%
Ti O ₂	0,03 ± 0,5%
SO ₃	0,14 ± 0,1%

Amber Glass

SiO ₂	71,30 ± 1,0%
Al ₂ O ₃	2,40 ± 0,5%
Fe ₂ O ₃	0,30 ± 0,1%
CaO	10,15 ± 0,5%
MgO	2,60 ± 0,5%
Na ₂ O	12,20 ± 0,5%
K ₂ O	0,9 ± 0,5%
Ti O ₂	0,05 ± 0,5%
SO ₃	0,03 ± 0,1%

Remark

The above-mentioned raw materials are naturally occurring substances that are subject to fluctuation. In order to compensate for these fluctuations, appropriate tolerances were specified. Our resulting basic glass corresponds to type III. These type III glass bottles do not need to be washed before filling.

Usability of the bottles:

Our bottles are designed with wall thickness and contact points for single use. If the bottles are to be used multiple times, they must be re-tested and redesigned for multiple use.

Glass-Type II

The base glass is always Type III only the inner surface is changed to Type II by an chemical process: $(\text{NH}_4)_2\text{SO}_4 \rightarrow 2\text{NH}_3 + \text{SO}_3 + \text{H}_2\text{O}$

The **type II bottles** are to be used only once according to current, valid Ph. Eur. / USP/JP and must be washed prior to filling.

Examinations regarding the contents of Heavy metals specifically Pb, Cd, Hg, and Cr +6 in our glass showed values below the limit of 100 ppm by weight. The content of arsenic is below the values of 0,1 ppm.

Therefore, and with the exception of marginal substances which do not affect human health, odour and taste and which cannot be avoided during manufacturing no other substances are released to food or its surface. This means, that we can confirm and reference to the paragraph 21 CFR 174.186.

It can be excluded that our glass contains substances like Latex, Gluten, Lactose, Bisphenol-A (BPA), Melamine, Phthalates or Nitrosamines.

We also confirm that products delivered by us, no raw materials, excipients and further materials of animal origin are used. Due to the fact that for the manufacture of these packaging material no materials are used, which might have a TSE / BSE risk, the bottles are not affected by the general text regarding vaccines, Ph. Eur. 5.2.8, "Minimizing the risk of transmitting animal spongiform encephalopathy agents via medicinal products", and by the EMEA-guideline EMEA/410/01, "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products".

Furthermore, we can confirm, that our products will be produced according:

1. EMA "Guideline on the specification limits for residues of metal catalysts or metal reagents"(EMA/CHMP/ICH/353369/2013).
2. Guideline for Elemental Impurities ICH Q3D
3. General chapter of "Metal residues" in the European Pharmacopoeia (5.20)
4. USP general chapters <232> and <233> "Elemental impurities - limits" and "Elemental impurities- Procedure"

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This confirmation base on our regular proceeds glass analyses. The specified Limits for elemental impurities are not passed.

Should you have any further questions, please do not hesitate to contact us.

Yours sincerely

Gerresheimer Essen GmbH



A handwritten signature in blue ink, appearing to be 'Th.' or similar, representing Thomas Rau.

Thomas Rau
Senior Quality Manager Essen

A handwritten signature in blue ink, appearing to be 'UW' or similar, representing Ulrike Werner.

Ulrike Werner
Quality Management



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November 14, 2025

Statement on Regulation (EU) 2025/40 (PPWR)

Concerning: Obligations and requirements under the regulation

Dear valued customer,

We appreciate the importance of regulatory compliance and the shared commitment of all actors in the packaging value chain to support the objectives of the Packaging and Packaging Waste Regulation (EU) 2025/40 ("**PPWR**"). In response to your recent inquiry, we would like to take this opportunity to clarify the respective roles and responsibilities of packaging suppliers under the PPWR, particularly concerning conformity assessments and declarations of conformity.

As a supplier of primary packaging components for pharmaceutical, food & beverage, and cosmetics applications on a B2B basis, we are, in most cases, not the legal manufacturer of the packaging. The roles of supplier and manufacturer are defined under Article 3(16) and Article 3(13) of the regulation, respectively.

Accordingly, we are unable to issue a Declaration of Conformity (DoC) under the PPWR for finished packaging. That said, we remain fully committed to providing our customers with the necessary technical information and documentation¹ in accordance with Article 16(1) of the regulation, to enable them to prepare their own DoCs.

It shall also be noted that the PPWR applies as of 12 August 2026.² Until then, the Packaging and Packaging Waste Directive 94/62/EC, along with its associated obligations,

¹ Articles 15(1), 38 and 39 in conjunction with Annexes VII and VIII to the PPWR

² Some obligations under the PPWR will be phased in gradually, with specific application dates. Certain provisions, for instance, will only take effect in 2030.

will remain in force.³ Hence, requests to us for any relevant technical information should be considered in the context of this timeline.

Our readiness roadmap is aligned with the regulatory timeline

We are monitoring regulatory guidance and engaging with industry associations, customers, and suppliers to interpret PPWR requirements for glass packaging. Certain implementation measures, delegated acts, harmonized standards and guidance from EU institutions remain pending. Gerresheimer Moulded Glass is actively preparing to meet both the technical requirements for our packaging and the documentation requirements for traceability and conformity, in order to ensure our readiness.

For all packaging components we supply and that our customers place on the EU market, Gerresheimer Moulded Glass will make available the required technical information in due time and will retain the corresponding supporting technical files for the legally required period.

Concerning topics like the use of recyclate or design for recycling we emphasize that these topics also require the input and communication of requirements from our customers and are not our responsibility alone.

Compliance with heavy metals and PFAS limits

As of now we confirm that the glass containers we supply are compliant with article 5 "Requirements for substances in packaging" of the regulation regarding the concentration of heavy metals (lead, cadmium, mercury and chromium VI) and PFAS.

Please note that glass packaging benefits from a long-standing derogation, as established in Commission Decision 2001/171/EC,⁴ which allows glass packaging to exceed the 100 mg/kg threshold provided it complies with the specific conditions set out in Articles 4 and 5 of that Decision.

Recyclability of amber glass

We confirm that our amber glass is regarded as recyclable material content.

We would like to point out that our amber glass has a specified transmission of less than 10 % in the wavelength range of 290 – 450 nm in accordance with Pharmacopeia requirements (EP 3.2.1). For longer wavelengths up to 780 nm, the transmission is significantly higher and thus fulfilling the criteria for recyclability including the German "Minimum standards for assessing the recyclability of packaging designs".

Yours sincerely

Gerresheimer Moulded Glass GmbH



Dr. Thomas Höver
Manager Global Regulatory Affairs



Felicitas Wagner
Technical Sustainability Manager

³ Article 70 of the PPWR provides for a transitional regime for certain provisions of the Packaging and Packaging Waste Directive.

⁴ Commission Decision of 19 February 2001 establishing the conditions for a derogation for glass packaging in relation to the heavy metal concentration levels established in Directive 94/62/EC on packaging and packaging waste