

PPWR Compliance Information (Packaging Ordinance)

Series Alphacap APG

Version 26_344_EN

Date 20.08.2026

Compliance Information pursuant to Regulation (EU) 2025/40 (PPWR)

(1) Identification of the Packaging Unit

This declaration applies to the article numbers listed below, including all colour variants and all article numbers derived therefrom %ARTIKELLIST%

(2) Responsible Economic Operators

- Producer: Cabagaglio Packaging SRL, Via dell'Industria 17, 23844 Sirone (LC), Italy
- Distributor: PHACOTEC Produkt-Service GmbH, Heebarg 14, 22391 Hamburg, Germany

(3) Responsibility

The producer (2) bears sole responsibility for the issuance of this Declaration of Compliance. The distributor acts exclusively as an economic operator within the supply chain.

(4) Subject of the Declaration

Product series Alphacap APG made of Metall, intended for use as primary packaging (single-use) for medicinal products, food supplements, pharmaceutical and related products.

The material composition and intended use are generally identical throughout the product series, irrespective of nominal or filling volume. The technical documentation in accordance with Article 39 PPWR is maintained by the producer and shall be made available to the competent market surveillance authorities upon request.

(5) Product and Legal Compliance

The producer (2) confirms that the product referred to in section (4) complies with the applicable requirements of Regulation (EU) 2025/40. This includes, in particular, compliance with the following provisions:

- Article 5 (Substance Restrictions): The packaging is manufactured in such a way that the presence and concentration of substances of concern in the packaging materials and packaging components are minimised. The tinplate closures are coated with BPA-NIA and PFAS-NIA polyester lacquers. According to the producer's declaration, Bisphenol A is not intentionally added to the product. Compliance with the PPWR requirements concerning total fluorine, inorganic fluorine, organic fluorine and PFAS, excluding polymeric PFAS, was assessed on the basis of test reports 26RP02672, 26RP05194, 26RP05195, 26RP05196, 26RP05197 and 26RP05198 issued by a laboratory accredited in accordance with UNI CEI EN ISO/IEC 17025. For the liners used in the G and GS versions, a total fluorine content exceeding 50 mg/kg was identified. Subsequent analyses for inorganic fluorine, organic fluorine and PFAS, excluding polymeric PFAS, nevertheless comply with the applicable requirements according to the producer's declaration. The producer therefore considers the relevant components compliant and suitable for placing on the market. Based on the available manufacturer documentation, the packaging also complies with the concentration limits for lead, cadmium, mercury and hexavalent chromium under the applicable Union requirements and Regulation (EU) 2025/40. According to the available manufacturer and upstream-supplier documentation, the materials used comply with Regulation (EC) No. 1907/2006 (REACH). Under the available REACH/SVHC declaration, none of the substances covered by that declaration is present in a concentration exceeding 0.1% by weight (w/w). The continued validity of this statement depends on the most recent manufacturer and upstream-supplier documentation. This declaration does not make a general claim regarding the absence of all other bisphenols or bisphenol derivatives unless expressly supported by a corresponding manufacturer declaration.
- Article 6 (Recyclability): According to the producer's assessment, the listed closures meet Recyclability Grade A under Annex II, Table 3 of Regulation (EU) 2025/40. This corresponds to recyclability of at least 95% of the total packaging weight. The closures and their accessory components have been designed in accordance with Design for Recycling principles. According to the producer, the components are either readily separable or fully compatible with established steel and/or aluminium recovery streams. The classification remains subject to future delegated acts, harmonised standards, common specifications and binding assessment methodologies adopted by the European Commission.
- Article 7 (Recycled Content): To the best of the producer's current knowledge and based on information provided by its suppliers, the plastic components of the listed packaging do not contain post-consumer recycled material. Where the plastic

component represents less than 5% of the total weight of the packaging unit, the minimum recycled-content requirement does not apply pursuant to Article 7(5)(b) of Regulation (EU) 2025/40. Where the plastic component represents 5% or more of the total packaging weight, the applicable future recycled-content requirements will be implemented in accordance with the statutory transitional periods and the implementing and calculation rules yet to be adopted. Any general statement concerning recycled aluminium content made for other products applies to the listed tinplate closures only where expressly confirmed by the producer on a product-specific basis.

- Article 10 (Minimisation of Weight and Volume): According to the producer, the material types, material thicknesses and functional components have been selected so as to ensure closure integrity, protection against metal oxidation, the required sealing performance and proper preservation of the packaged product while using the least possible amount of material. The liners and seals have likewise been designed with regard to their intended function so that only the amount of material necessary for that function is used.
- Article 12 (Labelling): The supplied closures are packaging components. Where the harmonised labelling requirements under Article 12 of Regulation (EU) 2025/40 apply to the finished sales packaging, they shall be implemented by the responsible economic operator placing the complete packaging on the market. The producer provides the product-specific information required to determine the material composition and to enable correct labelling as part of its technical documentation. The harmonised labelling requirements will be implemented within the applicable time limits laid down in Article 12. Pending implementing acts, harmonised pictograms, technical specifications and transitional provisions remain unaffected.

(6) Information on Standards / Specifications

The producer (2) confirms compliance with the food-contact requirements applicable to the packaging concerned, in particular:

- Regulation (EC) No. 1935/2004
- Regulation (EC) No. 2023/2006
- Regulation (EU) No. 10/2011, insofar as applicable to coatings, sealing materials or plastic components

Further details regarding food-contact materials, conditions of use, migration requirements and, where applicable, substances subject to specific migration limits are set out in the separate Declaration of Compliance relating to product series Alphacap APG.

(7) Declaration

The distributor (2) confirms that the above information has been prepared to the best of its knowledge on the basis of the information, specifications, supplier declarations and technical documentation made available by the producer (2).

This document was created digitally based on information provided by the responsible company (1) and is valid without a signature.

This document is provided for information purposes only. Only the current original manufacturer documentation and declarations of compliance issued by the respective manufacturer shall be considered binding. In the event of discrepancies, the manufacturer documentation shall prevail.

Supplementary Notes and Explanations regarding Regulation (EU) 2025/40

[1] General

The present PPWR compliance assessment is based on manufacturer information, raw material specifications, supplier declarations, test reports and other technical documentation available at the time of document preparation.

Unless expressly stated otherwise, the information has not been independently verified by the distributor.

[2] Technical Documentation

The technical documentation required under Article 39 of Regulation (EU) 2025/40 is maintained by the respective producer or manufacturer.

Access to complete technical documentation may be restricted due to trade secrets and confidential business information.

[3] Product Families and Material Groups

Manufacturer declarations, technical assessments and compliance evaluations are generally based on material families, product groups, formulations, material/colour combinations or worst-case evaluations.

Accordingly, such documentation generally applies to all covered article variants, provided that material composition, manufacturing process and intended use remain identical.

[4] Recyclability [Article 6]

The recyclability assessment is based on the legal requirements, manufacturer information and recognised evaluation methods available at the time of document preparation.

Should the European Commission publish binding harmonised assessment methodologies or delegated acts in the future, reassessment may become necessary.

[5] Recycled Content [Article 7]

Statements regarding recycled content are based on manufacturer information and available raw material documentation.

Unless expressly stated otherwise, no independent material analyses have been performed to determine recycled content.

[6] PFAS

Statements regarding PFAS are based on manufacturer and supplier declarations as well as available raw material specifications.

Analytical testing for individual PFAS substances, Total Fluorine (TF), Total Organic Fluorine (TOF) or comparable screening methods is only available where such testing has been expressly performed by the respective manufacturer or an accredited laboratory.

[7] Bisphenols

Statements regarding Bisphenol A (BPA), other bisphenols and bisphenol derivatives are based on manufacturer and supplier declarations as well as available raw material information.

Unless otherwise documented, no independent analytical testing for BPA, BPF, BPS or other bisphenol compounds has been performed.

[8] REACH and SVHC

The assessment regarding Regulation (EC) No. 1907/2006 (REACH) and the Candidate List of Substances of Very High Concern (SVHC) is based on the manufacturer information available at the time of document preparation.

Updates to the Candidate List may require an update of the underlying manufacturer declarations.

[9] Heavy Metals

Statements regarding lead, cadmium, mercury and hexavalent chromium are generally based on raw material approvals, supplier declarations, material specifications or manufacturer test reports.

Product-specific laboratory analyses are generally not available for each individual article number.

[10] Substance Testing and Product Families

Analytical testing regarding PFAS, heavy metals, migration limits or other substance restrictions is generally performed by manufacturers on material, formulation, colour or product-family level.

Separate testing for each individual article number, colour variant or production batch is generally not performed unless expressly agreed otherwise.

[11] Labelling [Article 12]

Where transitional provisions, guidance documents, implementing acts or technical specifications issued by the European Commission are still pending for specific packaging categories, implementation will take place once such requirements enter into force.

[12] Basis of Documentation

The present assessment has been prepared on the basis of manufacturer information available at the time of issue.

Updated manufacturer documentation or changes in legal requirements may require revision of the assessment.

[13] Disclaimer

This annex is provided for information purposes only.

Only the current declarations, technical documentation and compliance evidence issued by the respective producer or manufacturer shall be considered binding.

In the event of discrepancies, the original manufacturer documentation shall prevail.