

PPWR Compliance Information (Packaging Ordinance)

Series Standard Bech

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 following article numbers, including all colour variants and all article numbers derived therefrom 213383 213487 213488 213502 213508 213509 213510 213511 213512 213533 213534 213535 213536 214848 214849

(2) Responsible company

- Manufacturer: Bech Packaging Spolka Z, Kolejowa 56 , 64-300 Nowy Tomysl (PL)
- Distributor: PHACOTEC Produkt-Service GmbH, Heegbarg 14, 22391 Hamburg (DE)

(3) Responsibility and role within the supply chain

The manufacturer's (2) responsibility for ensuring that the packaging or packaging component they manufacture complies with the applicable requirements of Regulation (EU) 2025/40 remains unaffected. The distributor (2) acts, with regard to the products in question, as an economic operator within the supply chain, in particular as a distributor or, where relevant in the specific case, as an importer. The distributor (2) shall make available to its customers the product and conformity-related information provided by the manufacturer (2) or by upstream economic operators, and shall fulfil the obligations associated with its respective role in accordance with Regulation (EU) 2025/40. The disclosure, compilation or processing of this information by the distributor (2) does not result in the assumption of the manufacturer's responsibility and does not replace the conformity assessment to be carried out or the EU declaration of conformity to be issued by the respective responsible manufacturer, insofar as these are required under Regulation (EU) 2025/40. Where the supplied packaging or packaging component forms part of a subsequent or final packaging, the conformity of this final packaging must be assessed by the economic operator responsible for it under Regulation (EU) 2025/40, taking into account its final configuration and intended use.

(4) Subject of the declaration

Product line Standard Bech made of PE, intended for use as primary packaging (single-use) for medicinal products, food supplements, pharmaceutical and related products.

The material used and the intended use are, in principle, identical within the product series, regardless of the nominal or filling volume. The technical documentation in accordance with Article 39 of the PPWR is maintained by the manufacturer and made available to the competent market surveillance authorities upon request.

The technical documentation in accordance with Article 39 of the PPWR is maintained by the manufacturer, who continuously monitors compliance with the requirements of Regulation (EU) 2025/40. The documentation will be made available to the competent market surveillance authorities upon request.

(5) Product and regulatory compliance

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

- Article 5 (Minimisation of Weight and Volume): The packaging has been designed in accordance with its intended function in such a way that its weight and volume are limited to the minimum necessary to ensure product protection, product safety, stability and usability.
- Article 6 (Recyclability): The packaging consists of PE monomaterial and is suitable for material recycling within existing plastic recycling systems. The recyclability of the relevant product range has been confirmed by the manufacturer. The classification remains subject to future delegated acts and harmonised assessment methodologies adopted by the European Commission.
- Article 7 (Recycled Content): The packaging contains no post-consumer recycled (PCR) material. This statement is based on the product-specific declaration issued by the manufacturer. The requirements applicable to this packaging under Article 7 are fulfilled in accordance with the relevant transitional provisions and implementing measures.

- Article 9 (Substance Restrictions): To the best of the producer's knowledge, no intentionally added per- and polyfluoroalkyl substances (PFAS) are used in the manufacture of the packaging. The packaging complies with the concentration limits for lead, cadmium, mercury and hexavalent chromium laid down in Regulation (EU) 2025/40. To the best of the producer's current knowledge, the raw materials and additives used do not contain intentionally added Bisphenol A (BPA), other bisphenols or bisphenol derivatives within the meaning of Regulation (EU) 2024/3190. Furthermore, the raw materials used comply with the requirements of Regulation (EC) No. 1907/2006 (REACH). Based on the information available to the producer, the product does not contain substances included in the current Candidate List of Substances of Very High Concern (SVHC) pursuant to Article 59 of REACH in concentrations exceeding 0.1% by weight (w/w). In addition, the raw materials used comply with the applicable food-contact and pharmaceutical requirements.
- Article 12 (Labelling): The supplied packaging components are provided unprinted. Where labelling requirements pursuant to Article 12 of Regulation (EU) 2025/40 apply to the finished sales packaging, these shall be implemented by the responsible economic operator placing the finished packaging on the market. To the best of the manufacturer's knowledge, no additional product-specific marking obligations apply to the supplied packaging components. Transitional provisions and future implementing acts of the European Commission 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 (EU) No. 10/2011
- Regulation (EC) No. 2023/2006

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 for food contact materials relating to product series Standard Bech.

(7) Declaration

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