

Apeldoorn, 03-08-2026

To whom it may concern,

Etigam considers its sterilization indicators to be specialised functional process aids intended to demonstrate a significant colour change when exposed to a sterilization process. Based on their intended purpose, design and function, Etigam does not currently classify these indicators as packaging or packaging components within the meaning of Regulation (EU) 2025/40 on Packaging and Packaging Waste (PPWR).

Etigam acknowledges that in certain applications sterilization indicators may remain attached to, affixed to, or otherwise accompany the packaging of the final product after processing and throughout subsequent distribution or use. As a result, some economic operators may consider the presence of such indicators when assessing the compliance of their packaging systems under the PPWR.

To support customers in their own regulatory assessments and compliance activities, Etigam voluntarily provides relevant compliance information regarding its sterilization indicators. The purpose of this letter is to support the conformity assessment procedure that may be carried out by the manufacturer of the finished packaging, as defined in Article 3(1)(13) of Regulation (EU) 2025/40, when placing packaging on the EU market.

The provision of such information is solely intended to support customers in their independent evaluation of their obligations under applicable legislation. The provision of this information shall not be interpreted as an acknowledgement or declaration by Etigam that the sterilization indicators themselves constitute packaging or packaging components within the scope of the PPWR.

As of the date of this letter, the information below is applicable to all Etigam sterilization indicators and is provided solely to support customer conformity assessments where considered relevant.

Article 5(1) – Substances of Concern (SoC) – All intended uses.

Etigam is committed to minimising the presence of substances of concern in its products. To the best of our knowledge, our sterilization indicators comply with:

- Regulation (EC) No. 1907/2006 (REACH), including screening against the Candidate List of Substances of Very High Concern (SVHC), Annex XIV and Annex XVII.
- Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs).

Article 5(4) – Heavy Metals – All intended uses.

Etigam has performed analytical testing for the cumulative concentration of lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr(VI)) in representative sterilization indicator products.

Based on the available test results, the combined concentration of these four heavy metals is below the limit value of **100 ppm (mg/kg)** specified under applicable European packaging legislation and referenced by the PPWR.

Article 5(5) – PFAS – Food contact intended use only

Etigam sterilization indicators are not intended for direct food contact applications.

Therefore, the PFAS restrictions applicable to food-contact packaging are not considered relevant for the intended use of these products.

Article 6 - Recyclable packaging

Etigam sterilization indicators consist predominantly of paper-based label materials incorporating an adhesive layer and printed and/or coated functional chemistry. The paper substrate typically represents approximately 80% to 95% of the total product weight.

The functional indicator chemistry and related product formulation are proprietary and confidential. Accordingly, Etigam does not disclose detailed compositional information.

Customers remain responsible for assessing the recyclability and regulatory compliance of their finished packaging systems. Etigam makes no independent claim regarding the recyclability classification of the finished packaging into which the indicator may be incorporated.

Article 7 – Minimum recycled content in plastic packaging.

Etigam sterilization indicators are not plastic packaging products.

Based on the nature and intended use of the products, Etigam has not identified obligations under Article 7 as being applicable to the sterilization indicators themselves.

Article 8 – Biobased feedstock in plastic packaging

Etigam has not identified obligations under Article 8 as being applicable to the sterilization indicators themselves.

Article 9 – Compostable packaging

Etigam sterilization indicators are not designed, marketed or supplied as compostable packaging.

Article 10 – Packaging minimisation

Etigam sterilization indicators are designed solely to fulfil their intended process indication function using the minimum practical size and material required to ensure visibility, performance and regulatory compliance.

Article 11 – Reusable packaging

Etigam sterilization indicators are intended for single-use applications and are not designed to be reusable.

Each customer remains responsible for determining the regulatory status of the indicator within its specific application and for assessing any obligations arising from the placement of packaging or packaged products on the market. Etigam makes no representation regarding the customer's own compliance obligations under the PPWR or any other applicable legislation.

Etigam reserves the right to review and amend its assessment should future legislation, guidance documents, harmonised standards, regulatory interpretations or decisions of competent authorities provide additional clarification regarding the classification of sterilization indicators under the PPWR.

Disclaimer

This letter is provided for informational purposes only and does not constitute legal advice, a Declaration of Conformity, or a determination of regulatory status under Regulation (EU) 2025/40 (PPWR).

On behalf of Etigam,
Sincerely,

G. Bogaard
Manager QA and R&D

ETIGAM bv
Prinsenweide 30, 7317 BB Apeldoorn
The Netherlands
Tel. +31 55 521 17 21
Fax. +31 55 522 39 31
BTW/VAT NL801117537B01
www.etigam.nl - info@etigam.nl

