

EU DECLARATION NO:

PPWR-DoC-LBL-01

Date

06.08.2026

Product Identification

Unique identification of the packaging

Printed Self-Adhesive Plastic Roll Label (Material Code: PP 05 / Polypropylene Opaque) (Printed, varnished/cellophane opaque polypropylene pressure-sensitive roll labels custom manufactured for 350ml, 1L and 50ml plastic bottle/spray packaging)

Manufacturer name and address

ACTO GmbH

Sole responsibility statement

Schulstr. 8, 31613 Wietzen, Germany
This declaration of conformity is issued under the sole responsibility of the manufacturer. (ACTO GmbH).

Object of the Declaration

Description of packaging

Pressure-sensitive self-adhesive primary product labels applied to plastic bottle/spray containers exclusively for Hydroclean Solution (350ml), Preventia Surgical Irrigation (350ml & 1L), Tiritas Spray (50ml), Dermaplast Spray (50ml), and Cosmos Spray (50ml).

Primary pressure-sensitive label component custom manufactured for the specified ACTO GmbH product line, composed of Opaque Polypropylene (PP 05) face stock, permanent acrylic adhesive layer, protective varnish/cellophane coating, and printing inks, fully compatible with the recycling stream of the primary bottle.

Relevant Union Legislation

Reference to Regulation (EU) 2025/40 and applicable articles

Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5
• Article 7(5)(b) [EXEMPTION]: Mandatory Recycled Content (%PCR) Exemption for plastic label components weighing less than 5% of the total packaging unit weight.
• Article 12(11) [EXEMPTION]: Labelling Requirement Exception for medical device/health packaging due to space limitations or safety constraints.

Harmonized Standards

Harmonised standards applied

- EN 13428:2004: Prevention by source reduction
- EN 13430:2004: Requirements for packaging recoverable by material recycling

References to common specifications used

- EN 13431:2004: Requirements for packaging recoverable in the form of energy recovery (19,000 kJ/kg calorific gain)
- REACH Regulation (EC) No 1907/2006: SVHC Candidate List Chemical Safety Standard
- Avery Dennison Statement (01/2026): Heavy Metals <100 (ppm) Compliance Certificate
- Avery Dennison REACH Statement (03/2026): SVHC Candidate List 0.1\% (w/w) Declaration
- UPM Raflatac PPWR Statement (06/2026): EN 13430 and PPWR Article 5-7 Compliance Statement
- Egeli Basım PPWR Questionnaire (10.06.2026): Self-Adhesive Roll Label Supplier Compliance Statement

Additional Information

Place and Date of Issue

Wietzen, Germany — 06.08.2026

Name, Function (Signature)

Dr. Hasan Cicek

Quality Assurance & Regulatory Affairs Manager

Authorised to sign this EU Declaration of Conformity
for and on behalf of ACTO GmbH.

Signature: _____

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