

# PRODUCT QUALITY DECLARATION FOR SALVALAT

## Non-medicinal product not falling under the category of phytotherapeutic products

I, the undersigned Cantarelli Bruno, Tax Code CNTBRN55T13B034E, holding a degree in Biotechnology and acting as the legal representative of CNT LAB S.r.l., Headquarters and operational site located in 43036 Fidenza, Province of Parma, Italy, Tax Code and VAT No. 02674260340, Phone: +39 3772676345,

Being fully aware of the criminal sanctions outlined in Article 76 of Presidential Decree No. 445/2000 for false statements and declarations, hereby DECLARE under my responsibility that:

- The product Salvalat** is processed and bottled in accordance with the regulatory system for medical devices at the production site of Everton S.r.l., which operates one of the most modern production and commercial facilities in Europe. The site complies with the strictest current environmental and safety regulations, ensuring the highest level of safety for customers and personnel. The internal chemical laboratory is dedicated to the research and development of innovative eco-friendly products and conducts quality control activities.
- Everton Certifications**  
Located at Via Azzano, 37064 Povegliano Veronese (VR), Italy, Everton S.r.l. holds a certified Quality System pursuant to the standards UNI EN ISO 9001:2000 and ISO 13485-2018 for medical devices.  

- Salvalat** is not registered as a medical device or medicinal product, as it does not fall under these categories. It is a wash intended for internal cleaning of the udders of dairy cows, which does not require the status of a medicinal product or phytotherapeutic agent.
- Quality control** of the raw materials used has been conducted by our laboratory, confirming the selection of materials that are non-toxic and non-harmful to the health of animals and humans. Suppliers have been carefully selected and verified with the utmost professionalism by our chemists and biologists.
- Salvalat** is not included in the status list of veterinary medicinal products requiring a veterinary prescription (**as per Regulation (EU) 2019/6 Article 34**), specifically excluding:
  - Veterinary medicinal products containing narcotics or psychotropic substances.
  - Veterinary medicinal products for animals intended for food production.
  - Antimicrobial veterinary medicinal products.
  - Veterinary medicinal products for the treatment of pathological processes requiring prior precise diagnosis or whose use may interfere with subsequent diagnostic or therapeutic interventions.
  - Veterinary medicinal products used for animal euthanasia.
  - Veterinary medicinal products containing an active substance authorized in the Union for less than five years.
  - Immunological veterinary medicinal products.
  - Veterinary medicinal products containing active substances with hormonal, thyrostatic, or beta-agonist effects.
  - The status modification is excluded for medicinal products indicated in points (a), (c), (e), and (h).

**Date:** January 9, 2023.

Company Stamp and Signature of the Legal Representative



# SAFETY DECLARATION FOR SALVALAT

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Being fully aware of the criminal sanctions outlined in Article 76 of Presidential Decree No. 445/2000 for false statements and declarations, hereby DECLARE under my responsibility that:

1. **Salvalat** can be used in cases where antibiotics or allopathic veterinary medicines have been unable to resolve the animals' discomfort.
2. **Salvalat** has been tested, examined, and verified over the past 10 years with the assistance of numerous veterinarians who have confirmed its safety during its usage period as part of the Mastercow project trials.
3. **Salvalat** (renamed from the Mastercow project, which won two Seals of Excellence from the European Union through Horizon 2020) exclusively uses materials that ensure maximum safety during use:
  - a. **Spray can:** Controlled and verified by Everton as the third-party bottler for Salvalat.
  - b. **Salvalat mixture:** Inspected by Everton's regulatory team.
  - c. **Plastic catheter with reducer and three-hole exit tip:** Manufactured by a pharmaceutical company and sterilized after packaging.
  - d. **Salvalat components:** Carefully selected by our chemists and biologists, including:
    - i. **Propylene glycol:** Serves as a humectant for the biofilm.
    - ii. **Butylene glycol:** Used as a solvent.
    - iii. **Vegetable glycerin:** Denatures biological compounds.
    - iv. **Distilled water:** Used as a solvent.
    - v. **Distilled water with trace silver ions** (0.008% in clusters, no nanoparticles): Enhances slipperiness, facilitating better diffusion and adherence to the biofilm on the dermis.
    - vi. **Glycolic cucumber extract:** Mineralizing, purifying, and refreshing for the dermis, optimizing animal well-being.
    - vii. **Polysorbate 20:** Creates light foam upon exiting the catheter for better diffusion.
    - viii. **Polyvinylpyrrolidone (PVP):** An antistatic and emulsion-stabilizing material that forms a "soft film" in combination with the mixture, which settles on the biofilm.
    - ix. **Nitrous oxide (N<sub>2</sub>O):** Used in the mixture for product expulsion.

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## DECLARATION OF EFFICACY FOR SALVALAT

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Being fully aware of the criminal sanctions outlined in Article 76 of Presidential Decree No. 445/2000 for false statements and declarations, hereby DECLARE under my responsibility that:

1. **Salvalat** has been used for udder washing in dairy cows to reduce the biofilm that forms over time inside the cistern. Washing has effectively resulted in a significant reduction of biofilm, as demonstrated by tests conducted during the "Mastercow" project. These tests were performed on cattle with mastitis and metritis, showing excellent efficacy in alleviating the animals' discomfort.
2. The wash, by eroding the biofilm, can modulate the udder's response to certain inflammatory mediators and enhance local immunity.
3. Even if **Salvalat** is not administered correctly, it poses no direct or indirect risks to the treated animal(s), other animals, the person administering it, or the environment. There is no public health risk related to residues from Salvalat in milk from treated animals. Tests conducted at the Micro-B laboratory in Asola (MN) confirm the following data:
  - a. Average concentration of 0.2 ppm at the first milking;
  - b. Concentration below 0.1 ppm at the second milking.
4. The topical use of the wash on mammary epithelial cells represents a promising new frontier in safeguarding against mammary diseases.

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