SteriTech
SPECIALIST INFECTION PROTECTION

NZYMed LOW FOAM

LOW FOAMING ENZYMATIC INSTRUMENT CLEANER

INTENDED USE

Pre-soak, manual and or ultrasonic and or automated cleaning of soiled instruments, scopes and other immersible medical devices.

ACTIVE INGREDIENTS

5.8% Enzyme blend (lipase, protease / amylase / pectinase / carbohydrase) and Surfactants

PRODUCT VARIANTS

2L Dosing Bottle, 5L Wide neck (Auto compatible), 5L Dosing Pump, 25L

PRODUCT CHARACTERISITICS

Dilution Factor: 1% (10 mL per 1L water).
Physical Form: Blue-Green liquid
Odour: Mild citrus smell (Fragranced)
pH (Concentrate): 7.0 - 8.0
pH (Diluted): 8.0 - 9.0
Incompatibilities: Do not mix with other chemicals or products.
Environmental Concerns: 100% Biodegradable

For additional information about this product, or to give product feedback to the manufacturer, please scan this QR code.

PPE REQUIREMENTS

Latex or nitrile gloves are required for prolonged contact. **Chemical safety goggles** are recommended if splashing is anticipated.

REGULATORY INFORMATION

Risk Classification: A / I
GMDN Code: 63385
GMDN Descriptor: Medical Device Cleaning Agent
SAHPRA Medical Device Reg no.: Awaiting Class A Registration Call-up.

1 Bohnevista, 25 Payne Street, Pinetown P.O. Box 1338, Kloof, 3640, South Africa.
T + 27 31 702 7656 | W www.steritech.co.za | E info@steritech.co.za

INSTRUCTIONS FOR USE

For pre-soaking and or manual cleaning: Dilute with warm water (25°C - 48°C) at a rate of 1:100 (eg 10mL product per 1L water) and decant solution into a clean, dry receptacle. Double the dilution rate if an extremely heavy bio-load is suspected. Ensure that there is enough solution in the receptacle to completely cover immersed instruments. Allow the instruments to soak for 2-5 minutes, or 10 minutes if the bio-burden has dried on the instruments prior to immersion. Ensure that the product is flushed through all channels and hinges. Remove the instruments from the solution and rinse thoroughly under running water. Pat dry the instruments prior to sterilisation. Mix only enough for immediate single use.

For automated washers with automated dosing functionality: Open lid of product and insert the withdrawal suction valve or probe of the machine into the bottle using appropriate hygienic precautions. Ensure that the valve fits correctly, and or that the bottle, once connected, is placed in a position where it cannot be knocked over. Using the washer settings, select the appropriate withdrawal rate per cycle and operational temperature. The intended use dilution of the product is 1% or 10mL per L of water used in the wash cycle. The intended operational temperature is 25°C - 48°C. Run the machine as per the manufacturer's instructions. Ensure that a rinse cycle occurs prior to proceeding to the following step in the reprocessing cycle of the institution. Product is intended to be a single-use solution – discard immediately after use.

For automated washers with manual dosing functionality: Add 10mL per L, or 1 pump with a dosing pump per 2.5 L of water to be used in the wash cycle directly into the detergent compartment of the machine. Using the washer settings, select the appropriate operational temperature. The intended operational temperature is 25°C - 48°C. Run the machine as per the manufacturer's instructions. Ensure that a rinse cycle occurs prior to proceeding to the following step in the reprocessing cycle of the institution. Product is intended to be a single-use solution – discard immediately after use.

For Ultrasonic Baths: Add 10mL per L, or 1 pump with a dosing pump per 2.5 L of water to be used and decant into the ultrasonic tank until the tank is full. Ensure that the operational temperature of the cycle is set to between 25°C - 48°C. Process the instruments following the manufacturer's instructions. Remove the instruments from the solution and rinse thoroughly under running water. Pat dry the instruments prior to sterilisation. Mix only enough for immediate single use and remove the solution from the tank immediately after use and discard.

CERTIFIED LR ISO 9001 UKAS MANAGEMENT SYSTEMS 001

OTHER INFORMATION:

CERTIFIED LR ISO 13485 UKAS MANAGEMENT SYSTEMS 001

Biodegradability	Yes
Storage Temperature	+5 degrees C to +35 degrees C
Performance indicator	Demonstrates removal of residual haemoglobin and residual protein (< 2.2 µg/cm^2 for haemoglobin and < 6.4 µg/cm^2 for protein). Evaluation parameters as per (AAMI) Technical Information Report (TIR) 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices (August 10, 2011); the FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (June, 2017); and the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities (February, 2017).