

“ For Hygiene ”
BIORAD®

**necm
kimya**

ENZYM



BIORAD® ENZYM 5 ENZYMS

Enzymatic Cleaner for Medical Instruments and Devices

- ❖ Advanced Proteolytic Action - Increased protein enzyme activity
- ❖ Proprietary blend of enzymes designed to remove all bio-burden - blood, carbohydrates, protein, polysaccharides, fats, oils, uric acid and other nitrogenous compounds
- ❖ Inhibits rust
- ❖ Biologically active additives speed the process of liquefaction and solubilization
- ❖ Safe for use on all surgical instruments and scopes/will not harm any metalsplastic, rubber or corrugated tubing
- ❖ Low-Sudsing, neutral pH, non-abrasive, free rinsing and 100% biodegradable

PRODUCT SPECIFICATIONS

BIORAD® ENZYM is a unique formulation of , amylase, lipase, protease, cellulase, mannanase enzymes and rust inhibitors to remove all bioburden and protect the instrument.

Penetration into hard-to-reach places with surgical instruments and scopes also provides a faster, more comprehensive result. It is used in the enzymatic cleaning of medical and surgical instruments and heat-resistant and heatsensitive materials. Cleans the organic dirt on the instruments. It prevents corrosion. It does not contain aldehyde, phenol and phosphate.

FIELD OF USE

Recommended for reprocessing of all instruments - from the most difficult to clean to the most delicate BIORAD® ENZYM now has biological additives that speed the process of liquefaction and solubilization, facilitating enzymatic action and contributing to the product's superior effectiveness. It is suitable for use for cleaning and disinfection of endoscopes, anesthetic apparatus, dental instruments, heatresistant and heat-sensitive materials, instrument disinfection tubs, manual, ultrasonic washing machines and automatic washing machines including treated medical and surgical instruments and MIC surgical instruments as well as all the tools made of ceramic, porcelain and glass. It is recommended to use as excipient in the cleaning and disinfection of Wolf, Storz, Fujinon, Pentax, Olympus branded endoscopes.

Manufacturer: **Necm Kimya**
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APPLICATION METHOD

Manual Cleaning:

1. Dilute BIORAD® ENZYM with between 0.4% and 3%, depending on the contamination level on the medical instruments/devices.
2. Submerge instruments and scopes to be cleaned. For scopes: suction or flush through channels before soaking.
3. Soak for as little as two (2) minutes to remove all organic soils (heavy soils may require longer time).
4. Rinse thoroughly with tap, distilled or sterile water

Automatic Cleaning Devices

Specifically Designed for use in all Automatic Washers, Washer Sterilizers, Cart Washers and Tunnel Washers.

Automatic Washers, Ultrasonics and Washer Sterilizers Following manufacturer's recommendations:

1. Pour directly into detergent reservoir full strength or
2. Dilute BIORAD® ENZYM with between 0.4% and 3%, depending on the contamination level on the medical instruments/devices.

ACTIVITY / TESTING METHODS / ACTION TIME

Biorad Enzyme contains a combination of 5 enzymes as well as a moderate level disinfectant active substance. Thus, while performing the preliminary cleaning of dirty medical instruments/devices, it simultaneously acts on bacteria and fungi, reducing the microbial load on the instruments.

| Bactericide | | Time |
|--|----------|-------|
| E. hirae, S. Aureus, E. Coli, P.aureginosa | EN 13727 | 5 min |
| Fungicide | | |
| C. albicans, A. brasiliensis | EN 13624 | 5 min |

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PHYSICAL AND CHEMICAL DATA

- pH: 6,5 – 7,5
- Density at 20 °C : 0.917 – 0.923

CHEMICAL COMPOSITION reported per 100 g of product

- Amylase 0.33%
- Lipase 0.33%
- Protease 0.33%
- Cellulase, 0.33%
- Mannanase 0.33%
- Benzalconium chloride 1.2 %

SHELF LIFE : 2 years

PERIOD OF ACTIVITY AFTER OPENING THE COVER: 75 days

PACKAGING METHODS:

- 1000 ml
- 5000 ml

CONDITIONS OF STORAGE AND DELIVERY OF PRODUCTS

- For the storage and preservation of products, the ambient temperature must be between 0 and 50 °C, and the humidity must be between 10% and 80% rH.
- It is sufficient to store the products above ground so that they are not exposed to direct sunlight and to prevent contact with water.
- A maximum of 7 (seven) boxes can be placed on top of each other both during storage and during loading, in order to preserve and not damage the packaging of the products.

GENERAL WARNINGS

- It is not classified as toxic, corrosive, mutagenic, irritating to the skin and does not cause respiratory tract sensitivity.
- In case of direct contact with the eyes, rinse immediately with plenty of water.
- It should not be used for cleaning hands, face and food.
- It should not be kept out of the reach of children.

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SAFETY MEASURES IN THE PROCESS OF USE, TRANSPORT AND STORAGE

- **application of safety measures:** avoid excessive spreading. Good ventilation of the work area. It does not require special protective measures for the personnel who ensure the cleaning procedure.
- **transport:** in closed vehicles; does not require protective measures for the personnel providing the transport;
- **storage:** in closed original packaging, in a cool and well-ventilated place, away from heat and sunlight.

CLASSIFIED IN ACCORDANCE WITH REGULATION (EC) NO. 1272/2008 (CLP)

See the safety data sheet and label for labeling information according to Regulation (EC) No. 1272/2008 (CLP).

INFORMATION REGARDING THE ENVIRONMENT

According to the safety data sheet, the substances contained in the product comply with the biodegradability criterion established by Regulation (EC) No. 648/2004 on detergents.

Necm Kimya manufactures its products according to advanced, safe and environmentally friendly processes, economically and in compliance with high quality standards (EN ISO 9001, EN ISO 13485).

CERTIFICATION

Product Class and Conformity Assessment Method:

2017/745 Medical Device Regulation Classification Rules 16, Class IIB;

Rule 16 - Specifically disinfecting, cleaning, rinsing, hydrating or sterilising devices

General explanation of the rule This rule is intended to cover various products used specifically with contact lenses such as solutions intended for storing contact lenses and solutions used to support contact lenses placed on the ocular surface. The rule also covers substances and equipment specifically intended for the disinfection or sterilisation of devices intended by the manufacturer to be sterilised or disinfected prior to use, as referred to in MDR Article 2(1). This rule does not apply to physical means for the cleaning of medical devices, such as ultrasound and brushes for general use. Such products will only be medical devices if they are specifically intended for the cleaning, disinfection or sterilisation of medical devices. Devices specifically intended for physical cleaning of contact lenses are covered by this rule.

This rule does not apply to products that clean medical devices by physical action, other than contact lenses. Since our product is used for the purpose of Disinfection of invasive Medical Devices, it is designated as class Iib in accordance with this rule.