



Enzymatic Pretreatment

Safety Data Sheet

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier used on the label : **Enzymatic Pretreatment**

Other means of identification : Enzymatic Pretreatment Foam Spray Multi-Enzyme, Instrument Pretreatment Foam Spray for Surgical Grade Instruments/reusable items, scopes, and devices, Enzymatic Pretreatment
: 2110032-12, 2111002, 1008877, 106-8088

Recommended use of the chemical and restrictions on use:

Product for hospital and professional use only for the cleaning of surgical instruments. Not for home use.

Name, address, and telephone number of the chemical manufacturer:

BELIMED INC.
1535 Hobby Street, Suite 103
N. Charleston, SC 29405 USA
Telephone Number for Information : 1-800-451-4118

Emergency telephone number

CHEMTREC : 1-800-424-9300 (24/7, US and Canada)

SECTION 2: HAZARD IDENTIFICATION

Classification of the substance or mixture

Hazard Class	Hazard Category
SKIN IRRITATION	: 2
EYE IRRITATION	: 2B

Signal word, hazard statement(s), symbol(s) and precautionary statement(s)

Signal word : WARNING

Hazard Statement(s) : Causes skin irritation
Causes serious eye irritation.



Precautionary Statements

: **Prevention**
Wash thoroughly after handling.
Wear eye and face protection.
Wear protective gloves.
Use personal protective equipment as required.

: **Response**
IF ON SKIN: Wash with plenty of soap and water.
IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to remove. Continue rinsing.
If eye irritation persists: Get medical attention.
If skin irritation occurs: Get medical attention.
Take off contaminated clothing and wash it before reuse.

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Storage	: Store in accordance with local regulations.
Disposal	: Dispose of contents/container to an approved waste disposal facility.
Hazards not otherwise classified	: Not available.
Percentage of ingredient(s) with unknown toxicity	: None known.

Classification complies with OSHA Hazard Communication Standard (29 CFR 1910.1200) and is consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

See Section 11 for additional toxicological information.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

The following chemicals are classified as health hazards in accordance with 29 CFR 1910.1200

Chemical Name	CAS Number (Unique Identifier)	Concentration	Classification §1910.1200
Subtilisin free Enzyme Blend	Proprietary	0.5 – 1.5 %	Eye irritation 2A, H319 Skin irritation 2, H315 Respiratory Sensitizer 1B, H334
Ethoxylated Alcohol	68439-51-0	0.5 – 2.5 %	Eye irritation 2A, H319 Skin irritation 2, H315 Acute hazards to the aquatic environment 1, H400 Chronic hazards to the aquatic environment 3, H412
Sodium Xylene Sulfonate	1300-72-7	1 – 5 %	Eye irritation 2A, H319 Skin irritation 2, H315 Chronic hazards to the aquatic environment 3, H412
Cocamidopropyl Betaine	61789-40-0	4.0 - 8.0	Eye Dem. 2A, H318 Aquatic Chronic, H412

SECTION 4: FIRST AID MEASURES

Description of necessary measures

Inhalation: Remove from exposure area to fresh air. Seek medical attention immediately.

Skin contact: Immediately wash skin with soap and water for at least 20 minutes while removing contaminated clothing. Seek medical attention if irritation persists.

Eye contact: Immediately flush with cool water for at least 20 minutes. Seek medical attention if irritation persists.

Ingestion: Do NOT induce vomiting. Dilute by rinsing the mouth and giving cool water to drink. Never give anything by mouth to an unconscious person. Contact physician or local poison control center.

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Most important symptoms and effects, both acute and delayed

Inhalation: May cause allergic respiratory reaction.

Skin contact: Health injuries are not known or expected.

Eye contact: Health injuries are not known or expected.

Ingestion: Ingestion may cause irritation of mouth, throat, and digestive tract, diarrhea, and vomiting.

Indication of any immediate medical attention and special treatment needed

After inhalation: Remove from exposure area to fresh air.

After skin contact: Immediately wash skin with soap and water for at least 20 minutes while removing contaminated clothing.

After eye contact: Immediately flush with cool water for at least 20 minutes.

After ingestion: Do NOT induce vomiting. Dilute by rinsing the mouth and giving cool water to drink. Never give anything by mouth to an unconscious person

SECTION 5: FIREFIGHTING MEASURES

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Use extinguishing agent suitable for surrounding fire.

Unsuitable extinguishing media: None.

Specific hazards arising from the chemical: Not flammable or combustible.

Special protective equipment and precautions for firefighters

In case of fire, wear a full-face positive-pressure self-contained breathing apparatus and protective suit. Shut off all ignition sources and apply cooling water to sides of containers that are exposed to flames until well after fire is out. Avoid breathing vapors, keep upwind. Keep unnecessary personnel away.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures

Wear skin, eye, and respiratory protection. Stop or reduce any leaks if it is safe to do so. Spills present a slipping hazard. Keep unnecessary personnel away. Ensure clean-up is conducted by trained personnel only. Make sure area is slip-free before re-opening to traffic.

Environmental Precautions

Avoid runoff into sewers, ditches, and waterways.

Methods and materials for containment and cleaning up

Contain and absorb with sand or other absorbent material and place into containers for later disposal. Wash site of spillage thoroughly with water. In case of large spills, dike far ahead of spill to prevent further movement. Recover by pumping or by using a suitable absorbent material and place into containers for later disposal. Dispose in suitable waste container.

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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Use with adequate ventilation. Avoid breathing vapors, spray, or mist.

Conditions for safe storage, including any incompatibilities

Store away from incompatible substances and avoid extreme temperatures. Keep the containers tightly closed when not in use.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

Hazardous Component(s)	ACGIH	OSHA PEL	AIHA WEEL	OTHER
Protease Enzyme	TLV-C: 0.00006 mg/m ³ .	None	None	None

Appropriate engineering controls

Good general ventilation should be sufficient. Handle in accordance with good industrial hygiene and safety practices.

Individual protection measures

Respiratory: If respiratory protection is required, it must be based on the contamination levels found in the workplace and be jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH-MSHA) and must not exceed the working limits of the respirator.

Eye: Safety glasses are recommended but not required.

Hand/Body: Gloves are recommended but not required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Clear, Blue, Liquid
Odor	: Mild
Odor threshold	: Not available
pH	: 6.5 - 8.5 (neat)
pH	: Not available
Melting point / range	: Not available
Boiling point / range	: Not determined
Flash point	: Not determined
Evaporation rate	: Not determined
Flammable/Explosive limits - lower	: Not available
Flammable/Explosive limits - upper	: Not available
Vapor pressure	: Not determined
Vapor density	: Not determined
Solubility in water	: Completely soluble
Partition coefficient (n-octanol/water)	: Not available
Autoignition temperature	: Not available
Decomposition temperature	: Not available
Viscosity	: Not available
VOC content	: Not available
Density	: Not available
Relative Density	: Approximately 1.015 (Specific Gravity)

SECTION 10: STABILITY AND REACTIVITY

Reactivity	: None known.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: None known.
Conditions to avoid	: Avoid extremes of temperature.
Incompatible materials	: None known.
Hazardous decomposition products	: Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

Likely routes of exposure including symptoms related to characteristics

Inhalation: May cause allergic respiratory reaction.

Skin contact: Health injuries are not known or expected.

Eye contact: Health injuries are not known or expected.

Ingestion: Ingestion of large quantities may cause gastrointestinal irritation with nausea, vomiting, and diarrhea.

Physical/Chemical: No physical/chemical hazards are anticipated for this product.

Other relevant toxicity information:

The use of this product by the end-user is safe under normal and reasonable foreseen use.

Numerical measures of toxicity, including delayed and immediate effect

This table shown below addresses the following toxicological endpoints, if applicable:

- Acute toxicity
- Skin corrosion/irritation
- Serious eye damage/irritation
- Respiratory or skin sensitization
- Carcinogenicity
- Reproductive toxicity
- Specific target organ toxicity (single exposure)
- Aspiration hazard

Hazardous Component(s)	LD50s and LC50s	Immediate and Delayed Health Effects
Sodium Xylene Sulfonate	None	Irritant
Ethoxylated Alcohol	None	Irritant
Subtilisin Free Enzyme Blend	None	Respiratory sensitizer

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Carcinogenicity information

Hazardous Component(s)	NTP Carcinogen	IARC Carcinogen	OSHA Carcinogen
Not known	Not known	Not known	Not known

Carcinogenicity : None of the ingredients in this product are listed as carcinogens by the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), or the Occupational Safety and Health Administration (OSHA).

Mutagenicity : None of the ingredients in this product are known to cause mutagenicity.

Reproductive Toxicity : Not available.

SECTION 12: ECOLOGICAL INFORMATION

Aquatic Toxicity:

The following toxicity information is available for the hazardous ingredient(s) when used as a technical grade. The product is anticipated to be safe for the environment at concentrations predicted in settings under normal use conditions.

Toxicity to fish:

The product is not anticipated to be toxic to fish. The following data is for the product tested in accordance with EPA-821-R-02-012 (Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms).

Hazardous substance	Parameter	Value	Exposure Time	Species
Product	LC50	750 mg/L	96 hrs.	Pimephales promelas

Toxicity to aquatic invertebrates:

The product end-use dilutions are not anticipated to be toxic to aquatic invertebrates.

Toxicity to algae:

The product is not anticipated to be toxic to algae.

Persistence and degradability:

The majority of the components of his product are anticipated to be biodegradable.

Bioaccumulation Potential:

The bioaccumulation potential of this product has not been determined.

Mobility:

The mobility of this product (in soil and in water) has not been determined.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Number and Description : Not applicable

Disposal Considerations : Not regulated

Disposal of products : This product is not a RCRA hazardous waste and can be disposed of in accordance with federal, state, and local regulations.

Disposal of packages : Do not reuse container. Rinse it with water and place it in trash.

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SECTION 14: TRANSPORT INFORMATION

The information in this section is for reference only and should not take the place of a shipping paper (bill of lading) specific to an order. Please note that the proper shipping classification may vary by packaging, properties, and mode of transportation.

Land Transport (DOT) : Not dangerous goods
Sea Transport (IMDG/IMO) : Not dangerous goods
Air transport (IATA) : Not dangerous goods

SECTION 15: REGULATORY INFORMATION

Occupational Safety and Health Act:

Hazard Communication Rule, 29 CFR 1910.1200: The Occupational Safety and Health Administration (OSHA) require Safety Data Sheets (SDSs) to provide information about any hazard that may be associated with the product and make this information available in the workplace. Since the use pattern and exposure in the workplace are generally not consistent with those experienced by consumers, this SDS may contain health hazard information not relevant to consumer use.

United States Regulatory Information

TSCA 8 (b) Inventory Status

All components of this product are either listed on or exempt from the U.S. Toxic Substances Control Act (TSCA) chemical substance inventory.

TSCA 12 (b) Export Notification : All components are listed.
CERCLA/SARA Section 302 EHS : None
CERCLA/SARA Section 311/312 : Acute health hazard
CERCLA/SARA Section 313 : Does not contain any components with reportable quantities.
California Proposition 65 : This product does not contain substances listed under California Proposition 65.

SECTION 16: ADDITIONAL INFORMATION

NFPA health hazard: 1
NFPA fire hazard: 0
NFPA reactivity: 0
Additional information: None

DISCLAIMER: The information provided on this sheet is not to be considered as warranty or quality specification. The information is given to provide general knowledge as to health and safety based on our understanding of safe handling, storage, transportation, disposal, and release. The information relates to the specific material designated and may not be valid for such material used in combination with any other materials or any process unless specified in the text.

This safety data sheet contains changes from the previous version in sections: title, section 1

Prepared by: Belimed Inc.

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