Enzymatic Detergent Ultrasonic Cleaning Concentrate

Safety Data Sheet

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier used on the label : **Enzymatic Detergent Ultrasonic Cleaning Concentrate, pH Neutral**

Other means of identification : Multi-Enzyme Detergent for Ultrasonic Cleaning of Surgical Instruments
: 2130001, 2130002, 2130005, 2130015, 106-8036, 106-8038, 106-8039, 106-8040

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 hands 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.

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	1 – 10 %	Eye irritation 2A, H319 Skin irritation 2, H315 Respiratory Sensitizer 1B, H334 EU CMR- Annex I
Polyoxalene	9003-11-6	1 – 10 %	Eye irritation 2A, H319 Skin irritation 2, H315 Chronic hazards to the aquatic environment 3, H412
Dipropylene Glycol Monomethyl Ether	34590-94-8	1 – 10 %	Eye Irritant 2A, H319 STOT – SE 3, H335
Sodium Lauryl Sulfate / Sodium Xylene Sulfonate	151-21-3 / 1300-72-7	1 – 10 %	Eye irritation 2A, H319 Skin irritation 2, H315 Chronic hazards to the aquatic environment 3, H412
Sodium Tetraborate Pentahydrate	12179-04-3	0.1 - 3%	Eye irritation 2A, H319 Skin irritation 2, H315 STOT – SE 3, H335 STOT - RE 2, H373 Reproductive toxicity 1B, H360 EU CMR- Annex I

SECTION 4: FIRST AID MEASURES

Description of necessary measures

Inhalation: Remove from exposure area to fresh air. Contact physician or local poison control center.

Skin contact: Rinse affected area with soap and water until no evidence of product remains.
Get medical attention if irritation persists.

Eye contact: Rinse eyes immediately with plenty of water until no evidence of product remains.
Get medical attention if pain or irritation persists.

Ingestion: Do NOT induce vomiting. Dilution by rinsing the mouth and giving water to drink is generally recommended.

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Never give anything by mouth to an unconscious person. Contact physician or local poison control center.

Most important symptoms and effects, both acute and delayed

Inhalation: Breathing high vapor concentrations may produce anesthetic effects, nausea, dizziness, and headache.

Skin contact: Temporary irritation of the skin.

Eye contact: Mild-to-moderate irritation of the eyes (redness, watering eyes).

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: Rinse affected area with large amounts of mild soap and water until no evidence of product remains.

After eye contact: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.

After ingestion: Dilution by rinsing the mouth and giving water to drink is generally recommended.

SECTION 5: FIREFIGHTING MEASURES

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media: Dry chemical, carbon dioxide, water spray, or regular foam

Unsuitable extinguishing media: None

Specific hazards arising from the chemical: Oxides of carbon and oxides of nitrogen

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 storm 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
Do not get in eyes, on skin, on clothing. Use with adequate ventilation. Avoid generating aerosols and mists. Keep the containers closed when not in use.

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/m3.	None	None	None
Sodium Borate (Borate compounds, inorganic)	STEL: 6 mg/m^3 (inhalable fraction); TWA: 2 mg/m^3 (inhalable fraction)	TWA: 10 mg/m3	None	None
Confidential Component	TLV: 100 ppm STEL: 150 ppm (skin)	TWA: 100 ppm; 600 mg/m3	None	None
Glycerin	None	5 mg/m3 PEL Respirable fraction. 15 mg/m3 PEL Total dust.	None	None

Appropriate engineering controls
Provide local exhaust or general dilution ventilation to keep potential exposure to airborne contaminants below the permissible exposure limits where mists or vapors may be generated.

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: Splash-proof safety glasses are required to prevent eye contact where splashing of product may occur.

Hand/Body: Chemical-resistant gloves are required where repeated or prolonged skin contact may occur. Protective clothing is required where repeated or prolonged skin contact may occur.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Clear, Blue, Liquid
Odor	:	Mild odor
Odor threshold	:	No data available
pH	:	8.0 - 9.0 (neat)
pH	:	6.0 - 8.0 (1% solution)
Melting point / range	:	No data available
Boiling point / range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammable/Explosive limits - lower	:	No data available
Flammable/Explosive limits - upper	:	No data available
Vapor pressure	:	No data available
Vapor density	:	No data available
Solubility in water	:	Completely soluble
Partition coefficient (n-octanol/water)	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	No data available
VOC content	:	No data available
Density	:	No data available
Relative Density	:	Approximately 1.030 (Specific Gravity)

SECTION 10: STABILITY AND REACTIVITY

Reactivity : This product could react with strong acids.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Hazardous polymerization does not occur under normal temperatures and pressures.

Conditions to avoid : Avoid extremes of temperature.

Incompatible materials : Strong oxidizers, acids.

Hazardous decomposition products : Thermal decomposition products may include oxides of carbon.

SECTION 11: TOXICOLOGICAL INFORMATION

Likely routes of exposure including symptoms related to characteristics

Inhalation: Breathing high vapor concentrations may produce anesthetic effects, nausea, dizziness, and headache.

Skin contact: Repeated or prolonged excessive exposure may cause irritation or dermatitis.

Eye contact: This product may cause irritation with stinging and redness.

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.

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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
Confidential Component	None	Irritant
Sodium Lauryl Sulfate	None	Irritant
Sodium Xylene Sulfonate	None	None
Subtilisin Free Enzyme Blend	None	Respiratory sensitizer
Sodium Tetraborate Pentahydrate (Boric Acid)	Oral LD50 (RAT) = 2.660 mg/kg Dermal LD50 (RABBIT) = > 2.000 mg/kg Inhalation LC50 (RAT, 4 h) = > 0,002 mg/l	Behavioral, Central nervous system, Developmental, Gastrointestinal, Irritant, Kidney, Liver, Reproductive, Skin, less weight gain and food intake.

Carcinogenicity information

Hazardous Component(s)	NTP Carcinogen	IARC Carcinogen	OSHA Carcinogen
Confidential Component	No	No	No
Sodium Lauryl Sulfate	No	No	No
Sodium Xylene Sulfonate	No	No	No
Subtilisin Free Enzyme Blend	No	No	No
Sodium Tetraborate Pentahydrate	No	No	No

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 : Sodium borate and boric acid interfere with sperm production, damage the testes, and interfere with male fertility when given to animals by mouth at high doses. Boric acid produces developmental effects, including reduced body weight, malformations and death, in the offspring of pregnant animals given boric acid by mouth.

SECTION 12: ECOLOGICAL INFORMATION

Aquatic Toxicity:
The following toxicity information is available for the hazardous ingredient(s) when used as technical grade.
The product is anticipated to be safe for the environment at concentrations predicted in settings under normal-use conditions. One component, sodium tetraborate pentahydrate, is considered harmful to the aquatic environment when used in high concentrations.

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 this 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 this container. Rinse it with water and place it in trash.

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-hazardous
Sea Transport (IMDG/IMO) : Not-hazardous
Air transport (IATA) : Not-hazardous

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

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consistent with those experienced by consumers, this SDS may contain health hazard information not relevant to consumer use.

United States Regulatory Information

TSCA 12 (b) Export Notification : Not available
CERCLA/SARA Section 302 EHS : The following components are subject to reporting levels established by SARA Title III, Section 302: Formaldehyde (CAS# 50-00-0).
CERCLA/SARA Section 311/312 : Not available
CERCLA/SARA Section 313 : None above reporting de minimis
California Proposition 65 : This product does not contain substances listed under California Proposition 65.

California Cleaning Product Act to Know Act of 2017 (SB 258) : This product is labeled in compliance with CA SB258.

Chemical Name	CAS Registry Number	Functional Purpose	List(s)
Water	7732-18-5	Diluent	Not Applicable
Polypropylene polyethylene block copolymer	Withheld	Cleaning Agent	Not Applicable
Enzyme Blend (subtilisin free protease, lipase, amylase)	Proprietary	Cleaning Agent	Not Applicable
Glycerin	56-81-5	Stabilizer	Not Applicable
Dipropylene Glycol Monomethyl Ether	34590-94-8	Stabilizer	Not Applicable
Sodium Xylene Sulfonate	1300-72-7	Cleaning Agent	Not Applicable
Tetrasodium Iminodisuccinate	144538-83-0	Chelating Agent	Not Applicable
Sodium Tetraborate Pentahydrate	12179-04-3	Stabilizer	1
Sodium Lauryl Sulfate	151-21-3	Cleaning Agent	Not Applicable
DMDM Hydantoin	6440-58-0	Biocide	Not Applicable
Antifoam	Withheld	Stabilizer	Not Applicable
Benzotriazole	Withheld	Corrosion Inhibitor	Not Applicable
Colorant	Not Available	Dye	Not Applicable

*refer to www.belimed.com/en-us/solutions/consumables-protect for electronic links to designated lists

The ingredients of this product are reported on the following inventories:

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.

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.

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Prepared by: Belimed Inc.

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