SAFETY DATA SHEET (SDS)

According to EC Directive 1907/2006 as amended by Regulation (EU) No 453/2010 & 2015/830 & 2020/878

Section 1 IDENTIFICATION OF SUBSTANCE & COMPANY

1.1 Product Identity **Viruzyme VE**
Product Form Liquid preparation
Product Code J69
UFI Reference 2A93-N0EP-X00W-JHTG

1.2 Use A Proteolytic Enzyme based Biological Cleaner for Manual & Automatic processes.
Application For Medical and Dental Equipment and Endoscope cleaning applications
For Professional and Industrial Use

1.3 Company: Amity Ltd
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Document prepared by: Amity Ltd - Technical function

1.4 Emergency Information: TEL NUMBER +44 (0) 1226 770787
Availability Mon – Thurs 9am – 5pm, Fri 9am – 3.45pm (UK time)

Section 2 HAZARD IDENTIFICATION

2.1 Classification of the product (Substance or Mixture ref Regulation (EC) 1272/2008)

Classification:
Physical Hazards Not classified
Health hazards EUH208: Contains subtilisin, May produce an allergic reaction
Environmental hazards Not classified

2.2 Label elements

Pictogram: None

Signal Word None
Hazard statements: see 2.1
GHS Precautionary Phrases
P280 Wear protective gloves and eye protection.
P303+361+352: IF ON SKIN (or hair); Remove immediately all contaminated clothing. Wash skin with soap and water.
P305+351+338: IF IN EYES; Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + 313 If skin irritation occurs, seek medical advice
P337+313: If eye irritation persists: Get medical attention
P362: Take off contaminated clothing and wash before reuse

2.3 Other Hazards

PBT: This product is not identified as a PBT/vPvB substance.
The preparation contains amylase enzyme in low concentration but may cause allergic reaction in sensitive individuals,
The product does not exhibit any endocrine disruptive properties according to Regulation (EU) 2017/2100.
Product is Non-flammable and will not support combustion.

Section 3 COMPOSITION & INFORMATION ON INGREDIENTS

General description: An aqueous blend of enzymes, non-ionic surfactants, stabiliser and preservative.

3.2 Mixtures - Hazardous Constituents

Sodium Xylene Sulphonate	EU Index No Amity Ref RMP 3602	Content 3 to 8%w/w
CAS No 1300-72-7	EINEC No 215-090-9	REACH No 01-2119513350-56
Classification (GHS, EC Reg 1272/2008) Eye Irrit 2; H319	SCL / M Factor / ATE	

Sodium etasulphate Surfac EH40	EU Index no Amity Ref RMP 3631	Content 0.5 to 3 %w/w
CAS No 126-92-1	EINEC No 204-812-8	REACH No 01-2119971586-23
Classification (GHS, EC Reg 1272/2008) Eye Irrit 2; H319 Eye Dam 1; H318	SCL / M Factor / ATE	

Subtilisin From Protease component	EU Index no 647-012-00-8 Amity Ref RMP 4807	Content <0.25 %w/w
CAS No 9014-01-1	EINEC No 232-752-2	REACH No 01-2119480434-38
Classification (GHS, EC Reg 1272/2008) Skin Irrit 2; H315 Eye Dam 1; H318 Resp Sens 1: H334 STOT SE 3; H335	SCL / M Factor / ATE	

Amylase enzyme	EU Index No 647-015-00-4 Amity Ref RMP 4800	Content <0.03 %w/w
CAS No 9000-90-2	EINEC No 232-565-6	REACH No 01-211-9938627-26
Classification (GHS, EC Reg 1272/2008) Resp Sens 1; H334	SCL / M-Factor /ATE	

For full text of H statements given in this Section refer Section 16.

3.3 Other Components

Components not listed at section 3.2 are either non-hazardous or present at levels below that requiring detailed disclosure.
Common sense precautions should be observed
Product contains enzymes that may cause respiratory and dermal allergic reaction on repeated or prolonged contact in sensitive individuals.

Ingredients according to EC Directive 648/2004 Annex VII on Detergents

5% to 15% : hydrotrope, glycol solvents
Less than 5% : non-ionic surfactant, alkalinity builder,
Contains enzyme at <0.03%

Section 4 FIRST AID

4.1 Description of First Aid measures:

General: If you feel unwell seek medical advice (show this information or the container label where possible). Do not give anything by mouth to unconscious person.
Eyes: Rinse immediately with water. Continue for 15 minutes. Seek medical advice if irritation develops.
Skin: Wash thoroughly with soap and water. Remove any contaminated clothing and launder before reuse.
Ingestion: Rinse out mouth and drink milk or water. Do not induce vomiting
Inhalation: If spray or mist is inhaled, remove to fresh air, rest and keep warm. Seek medical advice if feeling unwell. If symptoms of irritation or sensitization occur (shortness of breath, wheezing or laboured coughing) seek medical attention.

4.2 Most Important Symptoms:

Effects due to overexposure, particularly with neat fluid:
Contact with eyes: Causes irritation, redness and watering.
Contact with skin: Prolonged contact causes dryness and irritation due to loss of natural skin oils. Eventually could cause dermatitis especially on sensitive skins.
Ingested Non-toxic but may cause soreness to mouth and throat.
Inhaled: Inhalation of mist or spray may cause irritation of mouth, nose and throat and may induce sensitization and cause allergic reaction in sensitive individuals.

4.3 Indication of any immediate medical attention and special treatment needed

Note to physician: Treat by observation and supportive measures as indicated by the patient's condition.
No specific antidote.

Section 5 FIRE FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing Media: Not applicable – Non-flammable and will not support combustion
Media to be avoided: None

5.2 Special Hazards present in the mixture

Special Hazards No unusual fire or explosive hazards
Hazardous combustion products: During a fire, smoke may contain the original material in addition to unidentified toxic and/or irritating compounds. Hazardous combustion products may include and are not limited to: Oxides of carbon

5.3 Advice for fire fighters

Protective actions during firefighting: Isolate fire area and deny unnecessary entry. In the event of an adjacent fire, cool containers with water spray. Prevent water used for extinguishing from entering drainage systems or soils
Special protective equipment: Wear protective clothing and self-contained breathing equipment.

Section 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal protection, protective equipment and emergency procedures

Personal protection: Avoid prolonged contact with the liquid. Protective clothing should be worn when dealing with any spillage.

6.2 Environmental precautions:

Do not allow to enter drains or the aquatic environment. or watercourses. If contamination of drainage systems or water courses is unavoidable, immediately inform appropriate authorities.

6.3 Methods and material containment and cleaning up

Clean up: Contain and absorb with inert material such as earth, sand or non-organic absorbent granules. Remove contaminated material to plastic containers and thence to a safe location for subsequent disposal.
Final traces or small spillages may be flushed away to foul sewer with plenty of water.

6.4 Reference to other sections

For personal protection see Section 8
For waste disposal see Section 13

Section 7 HANDLING & STORAGE

7.1 Precautions for safe handling

Usage precautions: Avoid spillage, prolonged contact with skin and protect eyes. Avoid inhalation of mists or spray. Wear protective clothing for prolonged exposure to neat or dilute fluid.
Advice on general hygiene: When using do not eat drink or smoke. Wash hands after use.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Do not store containers in open sunshine and keep away from heat. Store in a cool well-ventilated place at a temperature between 5°C and 25°C. Keep container upright and closed when not in use.
Keep away from incompatible materials (see Section 10).

Section 8 EXPOSURE CONTROL & PERSONAL PROTECTION

8.1 Workplace exposure guidelines:

STATE	Component	LTE (8h TWA)	STE (15 Minute TWA)	Comment
UK HSE EH40	2-(2-butoxyethoxy)ethanol	67.5 mg/m^3	101.2 mg/m^3	

Note1: Contains enzymes that may cause respiratory and dermal allergic reaction on repeated or prolonged contact in sensitive individuals.
Enzymatic components present at below declarable limit in concentrate solution that reduces to <0.002% in working solution

DNEL for workers

Component	Exposure	Short term – local effects	Short term – systemic effects	Long term – local effects	Long term – systemic effects
Sodium xylene sulphonate	Inhalation	Low hazard	No hazard	Low hazard	26.9 mg/m^3
	Dermal	No hazard	No hazard	0.096 mg/cm^2	136 mg/m^3
Sodium etasulphate	Inhalation	No data	No data	No data	285 mg/m^3
	Dermal	Medium hazard	No hazard	Medium hazard	4060 mg/kg bw/day

PNEC Data							
Fresh water organisms	Freshwater sediment	Marine organisms	Marine sediment	STP	Hazard to Air	Terrestrial organisms	Hazard to predators
Component – data to be defined							

8.2 Exposure controls:

Protective equipment



Engineering controls: Good general ventilation should be sufficient for most conditions.
Eye/face protection: Use chemical goggles or face shield if splashes are a risk.
Skin protection: Use rubber gloves when handling neat product or diluted solutions. This product should be treated as a biological liquid. Always wash your hands thoroughly after use to avoid irritation.
Respiratory protection: Not normally required, but if inhalation of mist or spray is a possibility then wear a respirator fitted with a P3 filter
Hygiene measures: When using, do not eat, drink, or smoke. Wash hands after use

Section 9 PHYSICAL & CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Property		Typical Value
APPEARANCE	Physical state & colour	Clear Pale blue liquid
ODOUR		Very slight odour
MELTING/FREEZING POINT	ºC	Not established
BOILING POINT/RANGE	ºC	100
KINEMATIC VISCOSITY	mm^2/s	Not established
pH	@ 20 ºC Neat 1 % sol'n	10.5 10.6
DENSITY	g/cm^3 @ 20 ºC	1.06
VAPOUR PRESSURE		Not established
PARTITION COEFFICIENT	Log Pow @ 25 ºC	Not established
FLAMMABILITY	°C Open Cup, Explosivity - lower limit % - Upper limit % Auto ignition Temp, ºC	None Not applicable Not applicable Not established
THERMAL DECOMPOSITION	ºC	Not established

9.2 Other Information

9.2.1 Physical Hazards

Property		Typical Value
OXIDATION		Non oxidising
EVAPORATION RATE		Not established

9.2.2 Other Safety Characteristics

Property		Typical Value
SOLUBILITY/MISCIBILITY	g/L @ 20 ºC	Completely miscible

Section 10 STABILITY & REACTIVITY

10.1 Reactivity Stable
10.2 Chemical stability: Stable under recommended storage and use conditions.
10.3 Possibility of hazardous reactions: Will not occur under normal transport or storage conditions
10.4 Conditions to avoid: Avoid high temperatures, heat.
10.5 Incompatible materials: Do not mix with strong acids, oxidising agents
10.6 Hazardous decomposition products: Does not decompose under normal use conditions. Decomposition will normally only occur if product is involved in a fire

Section 11 TOXICOLOGICAL PROPERTIES

11.1 Toxicological effects:

Components:

Sodium xylene sulphonate	LD50 (Rat, Oral)	>7,200 mg/kg
	LD50 (Rat, Dermal)	>2000 mg/kg
1-hydroxy-1,1-diphosphonic acid	LD50 (Rat, Oral)	>2000 mg/kg
	LD50 (Rat, Dermal)	>7500 mg/kg

Microbial formulation: This product is formulated using a range of naturally occurring micro-organisms that are known to be non-pathogenic to animals and humans. These micro-organisms have not been engineered in any way.

Mixture: No significant health hazard when properly used for the application it was designed for.
See section 4 for exposure symptoms
Skin irritation test (rabbit): Mildly irritating
Inhalation of aerosols or mist may induce sensitization and may cause allergic reactions in sensitive individuals
Route of exposure:
Dermal and eye contact, Ingestion, or inhalation

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties
Not applicable, no endocrine disrupting agents are present in the product

11.2.2 Other hazards
No data

Section 12 ECOLOGICAL PROPERTIES

12.1 Ecotoxicity

Alkyl ethoxylate C13-15	LC50 (golden orfe, 96h)	1 to 10 mg/L
1-hydroxy-1,1-diphosphonic acid	EC50 (Daphnia magna, 48h)	878 mg/L
	LC50 (rainbow trout, 96h)	300 mg/L

12.2 Persistence and Degradability:
All surfactants, enzymes and components are readily biodegradable according to appropriate OECD criteria.
The surfactant(s) contained in this preparation comply with the biodegradability requirements as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the member states and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3 Bioaccumulative potential
The product does not contain any substances that have potential for bioaccumulation.

12.4 Mobility in Soil
Product is miscible in water. Spills may penetrate soil and contaminate groundwater

12.5 PBT & vPvB Assessment
Does not contain any PBT or vPvB substances

12.6 Endocrine disrupting properties
Does not contain any endocrine disrupting agents

12.7 Other adverse effects
None known, has no long-term detrimental effect on the environment.
Substantially removed by water treatment plant

Section 13 DISPOSAL INFORMATION

General: Do not discharge into surface drains, on the ground or into any body of water.
Disposal Methods: All disposal methods must be in compliance with local laws and regulations. (Regulations may vary in different locations.)

For unused and uncontaminated product, the preferred disposal options include sending to a licensed, permitted recycler or reclaimer. Incineration or other thermal destruction device should be used to dispose of unwanted/contaminated product. Disposal of small quantities of dilute solutions via foul sewer is acceptable.

Packaging containers are recyclable. Rinse out well with water and send for recycling or dispose of in accordance with local authority requirements.

Section 14 TRANSPORT INFORMATION

14.1 UN No:
14.2 Proper Shipping Name:
14.3 Hazard Classification: Not Classified and non-hazardous for transport
14.4 Packaging Group:
14.5 Environmental Hazard:
Marine Pollutant:
14.6 Special Provisions: Not applicable

14.7 Marine Transport in Bulk according to IMO Instruments: Not established

Label for Conveyance: None

Section 15 REGULATORY INFORMATION

15.1 Safety, health and environment regulations/legislation specific for the substance/mixture

This Safety Data Sheet is provided in compliance with the European REACH Directive (1907/2006/EC) and is in agreement with the GHS (Globally Harmonised System) for the classification and labelling of Dangerous Chemicals. This safety data sheet is distributed solely for the purpose of the Health and Safety at Work Act 1974; included under this heading is article 10 of Directive 88/379/EEC.

All components that make up this product are registered, or are not required to be listed, with:
EUROPEAN INVENTORY OF NEW AND EXISTANT CHEMICAL SUBSTANCES (EINECS), and
TOXIC SUBSTANCES CONTROL ACT (TSCA).
REACH – Regulation 1907/2006/EC, The raw materials used within this preparation have been pre-registered in accordance with the requirements of REACH

Regulatory References:
Regulation (EC) 1272/2008 on Classification, Labelling and Packaging (CLP)
UN Globally Harmonised System (GHS) for Classification & Labelling ST-SG-AC10-30
UK - Occupational Exposure Limits Guidance Note EH40
EU Occupational Exposure Limits – Directives 2000/39/EC, 2006/15/EC and 2009/161/EU
Detergents – Regulation (EC) 648/2004
Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties.
Personal Protective Equipment – Directive 89/686/EEC
Waste – Directive 2008/98/EC

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for the product by the supplier

Section 16 OTHER INFORMATION

The data contained in this data sheet is based on Amity's present knowledge of the health and safety properties of the product and is believed to be accurate and given in good faith.
The physical and chemical properties are typical values only and do not constitute the specification of the product, which will be agreed separately.
The data given here only applies when product is used for proper application(s). The product is not sold as suitable for applications other than those identified at section 1, usage as such may cause risks not mentioned in this sheet.
It is for the customer to satisfy itself on the suitability of the product for its own particular purpose. Amity gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded, except to the extent that law prevents such exclusion.

Hazard Phrases used in Sections 3 and not stated at Section 2:

H302 Harmful if swallowed
H315 Causes skin irritation
H318 Causes serious eye damage
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 May cause respiratory irritation
H412 Harmful to aquatic life with long lasting effects

The following definitions of terms and abbreviations that may be used within this document are:
NTP: National Toxicology Programme (US);
IARC: International Agency for Research on Cancer;
EINECS: European Inventory of New and Existent Chemical Substances;

OSHA: Occupational Safety & Health Administration (US);
OECD: Organisation for Economic Co-operation and Development;
ACGIH: American Conference of Governmental Industrial Hygienists;
CAS: Chemical Abstracts Number;
STOT SE Specific Target Organ Toxicity – Single Exposure
STOT RE Specific Target Organ Toxicity – Repeated Exposure
PBT: Persistent, Bio-accumulative, and Toxic
vPvB: Very persistent and very bio-accumulative
OES: Occupational Exposure Standard.
TLV: Threshold Limit Value.
TWA: Time Weighted Average.
LTEL: Long Term Exposure Limit
STEL: Short Term Exposure Limit.
HSE: Health & Safety Executive (UK)
LEV: Local Exhaust Ventilation