



SAFETY DATA SHEET (SDS)

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

1. IDENTIFICATION OF SUBSTANCE & COMPANY IDENTIFICATION:

- 1.1 Product **Viruzyme**
Product Code J60
- 1.2 Use A Protolytic Double-Enzyme based Biological Cleaner for Medical Equipment and Endoscope cleaning applications
- 1.3 Company: Amity Ltd
Address: Libra House, West Street,
Worsbrough Dale,
BARNSELY, S YORKS, S70 5PG
UNITED KINGDOM
Telephone: 01226 770787
Fax: 01226 291936
E-mail: sales@amityinternational.com
Web site: www.amityinternational.com
www.virusolve.com
- 1.4 Emergency Information: TEL NUMBER +44 (0) 1226 770787 (Mon – Thurs 9am – 5pm
Fri 9am – 3.45pm UK time)

2. HAZARDS IDENTIFICATION.

2.1 Classification of the product (Substance or Mixture)

Classification:

- Physical Hazards None
- Health hazards Eye Dam 1; H318 Causes serious eye damage
- Environmental hazards H412 Harmful to aquatic life with long lasting effects

2.2 Label elements

Pictogram:



Signal Word DANGER

Hazard statements: see 2.1

GHS Precautionary Phrases

- P264 Wash thoroughly after handling
- P270: Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/eye protection.
- P337+313: If eye irritation persists: Get medical attention.
- P305+351+338: IF IN EYES; Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P362: Take off contaminated clothing and wash before reuse

2.3 Other Hazards

EUH208; Contains subtilisin, amylase, alpha-, May produce an allergic reaction.
PBT: This product is not identified as a PBT/vPvB substance.

EMERGENCY OVERVIEW:

Pale brown slightly hazy liquid, slight odour, Non-flammable and will not support combustion.

3. COMPOSITION AND INFORMATION ON INGREDIENTS.

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

3.2 Mixtures - Hazardous Constituents

Ethoxylated 2-ethylhexanol (Berol LFG61)	EU Index no Amity Ref RMP 3050	Content 10 to 20 %w/w
CAS No 26468-86-0 / 1559-35-9	EINEC No 607-943-2 / 216-323-7	REACH No 01-2120765339-43
Classification (GHS, EC Reg 1272/2008) Eye Dam 1; H318	Classification (67/548/EEC or 1999/45/EC) Xn, R41	

Sodium Xylene Sulphonate	EU Index no Amity Ref RMP 3602	Content 1 to 5 %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	Classification (67/548/EEC or 1999/45/EC) Xi, R36	

Amylase enzyme	EU Index no 647-015-00-4 Amity Ref RMP 4800	Content 0.01 to 0.05 %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	Classification (67/548/EEC or 1999/45/EC)	

1,2,3-benzotriazole	EU Index no ---- Amity Ref RMP 6100	Content <0.02 %w/w
CAS No 95-14-7	EINEC No 202-394-1	REACH No 01-2119979079-20
Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302 Eye Irrit 2; H319 Aquat Chronic 3; H412	Classification (67/548/EEC or 1999/45/EC) T R22 Xi / R36 N R52/53	

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

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

5% to 15% : non-ionic surfactants,

Less than 5% : Hydrotrope surfactant,

Amylase and protease enzymes, Fragrance, Preservative (benzisothiazolinone), dye

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.

5. FIRE FIGHTING MEASURES.**5.1 Extinguishing Media**

Suitable Extinguishing Media: Not applicable

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 and nitrogen

5.3 Advice for fire fighters

Protective actions during fire fighting: 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.

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

7. HANDLING AND 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.

8. EXPOSURE CONTROL/PERSONAL PROTECTION.**8.1 Workplace exposure guidelines:**

STATE	Component	LTE (8h TWA)	STE (15 Minute TWA)	Comment
UK HSE EH40	None specified			

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 To be advised

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

9. PHYSICAL AND CHEMICAL PROPERTIES.**9.1 Information on basic physical and chemical properties**

Property		Typical Value
APPEARANCE		Pale red liquid
ODOUR		Slight odour
pH	@ 20 °C Neat	9.5
DENSITY	g/cm ³ @ 20 °C	1.05
SOLUBILITY	g/L @ 20 °C	Completely miscible
PARTITION COEFFICIENT		Not established
FLAMMABILITY	°C Open Cup, Explosivity - lower limit % - Upper limit % Auto ignition Temp, °C	None Not applicable Not applicable Not established
THERMAL DECOMPOSITION	°C	Not established

9.2 Other Information

No data

10. STABILITY AND REACTIVITY**10.1 Reactivity** Stable**10.2 Chemical stability:** Stable under recommended storage and use conditions.**10.3 Possibility of hazardous reactions:** none known**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.**11. TOXICOLOGICAL INFORMATION:****11.1 Toxicological effects:**

Components:

mixture	LD50 (Rat, Oral)	>2000 mg/Kg
Sodium xylene sulphonate	LD50 (Rat, Oral)	>7,200 mg/kg
	LD50 (Rat, Dermal)	>2000 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

12. ECOLOGICAL INFORMATION.**12.1 Ecotoxicity**

Alcohol ethoxylate	EC 50 (daphnia magna, 48h)	6.5 mg/L
	LC50 (fish, 96h)	13 mg/L

12.2 Mobility

Miscible in water. No information on soil mobility.

12.3 Degradation and Persistence:

All surfactants, enzymes and components are fully 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.

12.4 Bioaccumulative potential

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

12.5 PBT & vPvB Assessment

Does not contain any PBT or vPvB substances

12.6 Other adverse effects

Substantially removed by water treatment plants.

13. DISPOSAL CONSIDERATIONS.

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.

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:

Label for Conveyance: None

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.

UN Globally Harmonised System for Classification & Labelling GHS ST-SG-AC10-30

UK - Occupational Exposure Limits Guidance Note EH40

EU Detergents Directive 648/2004

15.2 Chemical Safety Assessment

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

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

H319 Causes serious eye irritation

Risk Phrases used in Section 3

R22 Harmful if swallowed

R36 Irritating to eyes

R41 Risk of serious damage to eyes

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

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;

OTHER INFORMATION. (Continued)

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

It is the responsibility of the user to ensure safe working conditions. The health hazards and general information contained within this material safety data sheet are given as a guide to the precautions required to maintain a safe working environment.