

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 PCD**
Covers also VIRUZYME PCD Fragrant & Dyed version
Product Form Liquid preparation
Product Code J65
UFI Reference TBA
- 1.2 Use A Proteolytic Triple-Enzyme based Biological Cleaner & Disinfectant
Application Manual & Automatic processing of Medical and Dental Equipment and Endoscope cleaning and disinfection applications
For Professional 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** Skin Irrit 2; H315 Causes skin irritation,
Eye Dam 1; H318 Causes serious eye damage
- Environmental hazards** Aquat Acute 1; H400 Very toxic to aquatic life
Aquat Chronic 1; H410 Very toxic to aquatic life with long lasting effects

2.2 Label elements

Pictogram:



Signal Word DANGER

Hazard statements: see 2.1

GHS Precautionary Phrases

- P273 Avoid release to the environment
- 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

2.3 Other Hazards

PBT: This product is not identified as a PBT/vPvB substance.

EUH208: Contains subtilisin, Lipase and 1,2-benzisothiazolin-3-one. May produce an allergic reaction
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, biocide, stabiliser and preservative.

3.2 Mixtures - Hazardous Constituents

| | | |
|--|--|---------------------------|
| Reaction products of C12-18-(even numbered)- alkylamines and acrylic acid and sodium hydroxide | EU Index No Amity Ref ----- | Content 5 to 10 %w/w |
| CAS No ----- | EINEC No 939-647-7 | REACH No 01-2119980672-29 |
| Classification (GHS, EC Reg 1272/2008) Skin Irrit 2; H315 Eye Dam 1; H318 | SCL / M Factor / ATE At conc below 30% Eye Dam reduces to Eye irritation. | |

| | | |
|--|-----------------------------------|---------------------------|
| C9-11, Alcohol ethoxylated, 9MEO | EU Index no Amity Ref RMP 3102 | Content 1 to 5 %w/w |
| CAS No 68439-46-3 | EINEC No ----- | REACH No polymer - exempt |
| Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302 Eye Dam 1; H318 | SCL / M Factor / ATE | |

| | | |
|--|------------------------------------|---------------------------|
| N-N-Didecyl—N-methyl- poly(oxyethyl) - ammonium propionate (DMPAP) | EU Index No: Amity Ref RMP 5060 | Content 1 to 5 %w/w |
| CAS No 94667-33-1 | EINEC No 619-057-3 | REACH No 01-2119950327-36 |
| Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302 Skin Corr 1B; H314 Aquat Acute 1; H400 Aquat Chronic 1; H410 | SCL / M Factor / ATE | |

| | | |
|---|--|---------------------------|
| Bis (3-aminopropyl) dodecylamine (N-(3-Aminopropyl)-N-dodecyl propane-1,3-diamine) | EU Index No Not available Amity Ref RMP 5055 | Content 1 to 5%w/w |
| CAS No 2372-82-9 | EINEC No 219-145-8 | REACH No 01-2119980592-29 |
| Classification (GHS, EC Reg 1272/2008) Acute Tox 3; H301 Skin Corr 1A; H314 STOT RE2; H373 Aquat Acute 1; H400 Aquat Chronic 1; H410 | SCL / M Factor / ATE M Factor- acute = 10 M Factor chronic = 1 | |

| | | |
|--|-----------------------------------|---------------------------|
| Ethane-1,2-diol | EU Index No Amity Ref RMP 5060 | Content 0.1 to 1 %w/w |
| CAS No 107-21-1 | EINEC No 203-473-3 | REACH No 01-2119456816-28 |
| Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302 STOT RE 2; H373 | 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 | |

| | | |
|---|-----------------------------------|----------------------------|
| Lipase enzyme | EU Index No Amity Ref RMP 4804 | Content <0.03 %w/w |
| CAS No 9001-62-1 | EINEC No 232-619-9 | REACH No 01-211-9972939-13 |
| Classification (GHS, EC Reg 1272/2008) Resp Sens 1; H334 | SCL / M-Factor /ATE | |

| | | |
|--|--|---------------------------|
| 1,2-benzisothiazol-3-one (Nipacide BIT-20) | EU Index No 613-088-00-6 Amity Ref RMP 5804 | Content <0.03 %w/w |
| CAS No 2634-33-5 | EINEC No 220-120-9 | REACH No 01-2120761540-60 |
| Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302 Skin Irrit 2; H315 Eye Dam 1; H318 Skin Sens 1; H317 Aquat Acute 1; H400 | SCL / M-Factor /ATE At C < 0.05 Skin Sens 1 disappears. | |

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

15% to 30% : glycol,

5 to 15% : amphoteric surfactant, Non-ionic surfactants,

bactericides (Bis (3-aminopropyl) dodecylamine and DMPAP),

Contains Enzymes (Protease, Amylase and Lipase), Preservative (benzisothiazolone), Dyes

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 and nitrogen

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

subsequent disposal.
Final traces or small spillages



containers and thence to a safe location for
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 |



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 | °C | Not established |
| BOILING POINT/RANGE | °C | 100 |
| KINEMATIC VISCOSITY | mm ² /s | Not established |
| pH | @ 20 °C | 10.5 |
| | Neat 1 % sol'n | 10.7 |
| DENSITY | g/cm ³ @ 20 °C | 1.06 |
| VAPOUR PRESSURE | | Not established |
| PARTITION COEFFICIENT | Log Pow @ 25 °C | Not established |
| FLAMMABILITY | °C Open Cup, | None |
| | Explosivity - lower limit % | Not applicable |
| | - Upper limit % | Not applicable |
| | Auto ignition Temp, °C | Not established |
| THERMAL DECOMPOSITION | °C | No decomposition up to 50 |

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 °C | 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:

| | | |
|--|-----------------------|----------------|
| N,N'-didecyl-N-methyl-poly(oxyethyl)-Ammonium Propionate | LD50 (Rat, Oral) | >1150 mg/kg |
| Alcohol Ethoxylate C9-11 | LD50 (Rat, Dermal) | >2000 mg/kg |
| | LD50 (Rat, Oral) | 200-2000 mg/kg |
| Bis (3-aminopropyl) dodecylamine | LD50 (Rat, Oral) | 261 mg/kg |
| | LD50 (Rat, Dermal) | >600 mg/kg |
| 1,2-ethanediol | LD50 (Rat, Oral) | 4700 mg/kg |
| | LD50 (Rabbit, Dermal) | >10.000 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**

| | | |
|--|----------------------------|--------------|
| N,N'-didecyl-N-methyl-poly(oxyethyl)-Ammonium Propionate | EC50 (Daphnia, 48h) | 0.07 mg/L |
| | LC50 (zebrafish, 96h) | 0.78 mg/L |
| Bis (3-aminopropyl) dodecylamine | EC50 (Daphnia, 48h) | 0.073 mg/L |
| | LC50 (Rainbow trout, 96h) | 0.68 mg/L |
| 1,2-ethanediol | EC50 (Daphnia magna, 24 h) | >70,000 mg/L |
| | LC50 (Golden Orfe, 48 h) | >10,000 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 plants.

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

General: The product when supplied in containers 5 Litres or less is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID). Refer:

Road transport notes: ADR/IMDG – Special provision 375

Air transport notes: ACAO/IATA -- Special provision A197

For containers larger than 5L the following applies:

- 14.1 UN No: 3082
- 14.2 Proper Shipping Name: Environmentally hazardous substance, Liquid, nos
- 14.3 Hazard Classification: Class 9 (ADR, RID, IATA)
- 14.4 Packaging Group: III
- 14.5 Environmental Hazard: Yes
- Marine Pollutant: No
- 14.6 Special Provisions: Not established
- 14.7 Marine Transport in Bulk according to IMO Instruments: Not transported in bulk

Label for Conveyance:



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:

| | |
|------|---|
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H320 | Causes eye irritation |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |
| H373 | May cause damage to organs through prolonged or repeated exposure |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |
| 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

ATE Acute Toxicity Estimate

M-Factor Multiplication Factor

SCL Specific Concentration Limit

DNEL Derived No-Effects Level

PNEC Predicted No-Effects Concentration
STP Sewage Treatment Plant
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