

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 **Virusolve+ EDS concentrate**
Product Form Liquid preparation
Product Code J35
UFI Reference 2Y90-G0AA-F008-EQVH
- 1.2 Use A Sporicidal High-Level Disinfectant (Cold Sterilant) Cleaner.
Application For Invasive and Non-Invasive Medical Devices, Dental & Surgical Instruments, Flexible Endoscopes and Surfaces.
For Professional Use
- 1.3 Company: Amity Ltd
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Telephone: +353 1 215 0696
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

Tox Acute 4; H302 Harmful if swallowed
Skin Corr 1A; H314 Causes severe skin burns and eye damage
STOT SE; H335 May cause respiratory irritation

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

Precautionary Phrases

P260 Do not breathe vapour, mist or spray
P273 Avoid release to the environment
P280 Wear protective gloves and eye protection
P301+330+331: IF SWALLOWED; rinse mouth. Do not induce vomiting.
P303+361+353: IF ON SKIN (or hair); Remove immediately all contaminated clothing. Rinse skin with water.
P305+352+338: IF IN EYES; Wash with plenty of water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other Hazards

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

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: A blend of low foam, non-ionic surfactants, chelating agents and biocides, with or without fragrance and/or dye.

3.2 Mixtures - Hazardous Constituents

2-Aminoethanol (Monoethanolamide)	EU Index No 603-030-00-8 Amity Ref RMP 4100	Content 5 to 10 %w/w
CAS No 141-43-5	EINEC No 205-483-3	REACH No 01-2119486455-28
Classification (GHS, EC Reg 1272/2008) Acute Tox 4; H302, H312, H332 Skin Corr 1B; H314 STOT SE 3; H335 Aquatic Chronic 3; H412	SCL / M-Factor /ATE Classification of the component when present at 5% to 10% in the preparation:	

Didecylidimethyl ammonium Chloride	EU Index No Amity Ref RMP 5052	Content 3 to 8 %w/w
CAS No 7173-51-5	EINEC No 230-525-2	REACH No 01-2119945987-15
Classification (GHS, EC Reg 1272/2008) Acute Tox 3; H301 Skin Corr 1A; H314 Aquat Acute 1; H400	SCL / M-Factor /ATE	

Propan-2-ol (iso-propyl alcohol, IPA)	EU Index no 603-117-00-0 Amity Ref RMP 5052	Content 1 to 5 %w/w
CAS No 67-63-0	EINEC No 200-661-7	REACH No 01-2119457558-25
Classification (GHS, EC Reg 1272/2008) Flam Liq 2; H225 Eye Irrit 2; H319 STOT SE 3; H336	SCL / M-Factor /ATE	

Potassium Carbonate	EU Index no ----- Amity Ref RMP 0103	Content 1 to 5 %w/w
CAS No 584-08-7	EINEC No 209-529-3	REACH No 01-2119532646-36
Classification (GHS, EC Reg 1272/2008) Skin Irrit 2; H315 Eye Irrit 2; H319 STOT SE3; H335	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	

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%: Aminoethanol, Glycol

Less than 5%: non-ionic emulsifier, alcohol, Polycarboxylate

Didecylidimethyl ammonium Chloride and Bis (3-aminopropyl) dodecylamine disinfectants, dye

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).
Eye: Irrigate with flowing water for at least 15 minutes. Seek medical attention if irritation or soreness persists.
Skin: After prolonged use, rinse affected area with water. In the unlikely event of irritation or soreness developing, seek medical advice. Launder contaminated clothing before re-use.
Ingestion: Do not induce vomiting, unless instructed to do so by medical personnel. Rinse mouth with water and drink 1 or 2 glasses of water or milk. Seek medical advice if discomfort persists.
Inhalation: Remove from exposure. Keep warm and at rest. If discomfort persists seek medical advice.

4.2 Most Important Symptoms:

- Contact with eyes:** Causes irritation, redness and non-reversible local damage if not immediately rinsed away after contact.
Contact with skin: Causes irritation and redness.
Ingested: Will irritate and cause soreness to mouth, throat and digestive system.
Inhaled: Mist or spray may cause soreness and irritation of the mucous membrane and the respiratory system.

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. Ensure adequate ventilation. Evacuate personnel (Large spillage).

6.2 Environmental precautions:

- Keep large spills out of sewers. If contamination of drainage systems or watercourses is unavoidable, immediately inform appropriate authorities. Small spills may however be safely flushed away to foul sewer with plenty of water.

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, Use only in accordance with label instructions in well ventilated areas.
 Do not return unused material to original container.
 Avoid inhalation of mists or spray. Avoid prolonged contact with skin & eyes . Wear protective clothing.
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 35°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-Aminoethanol	1ppm (2.5 mg/m ³)	3ppm (7.6 mg/m ³)	Contains Skin notation to warn of danger of skin adsorption Component present at <5% in concentrate and < 0.3 in the working solution
UK HSE EH40	Propan-2-ol	400 ppm (999 mg/m ³)	500 ppm (1250 mg/m ³)	

DNEL for workers

Component	Exposure	Short term – local effects	Short term – systemic effects	Long term – local effects	Long term – systemic effects
2-aminoethanol	Inhalation	Low hazard	Low hazard	0.51 mg/m ³	1 mg/m ³
	Dermal	Low hazard	Low hazard	Medium hazard	3 mg/kg bw/day
Propan-2-ol	Inhalation	No data	No data	No data	500 mg/m ³
	Dermal	No data	No data	No data	888 mg/kg bw/day
Didecylmethyl ammonium Chloride (DDAC)	Inhalation	Medium hazard	Medium hazard	No hazard	No hazard
	Dermal	Medium hazard	Medium hazard	No hazard	No hazard
Bis (3-aminopropyl) dodecylamine	Inhalation	No hazard	No hazard	No hazard	0.79 mg/m ³
	Dermal	Medium hazard	No hazard	Medium hazard	8.96 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. Provision of appropriate exhaust ventilation is required when spray or mist is present.

Eye/face protection:

Use chemical goggles or face shield if splashes are a risk.

Skin protection:

Use suitable protective clothing, gloves/coveralls, for periods of prolonged contact. PVC, Butyl or nitrile rubber gloves are suitable. Use aprons if splash protection is required during prolonged exposure

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, blue coloured liquid
ODOUR		Low odour
MELTING/FREEZING POINT	°C	Not established
BOILING POINT/RANGE	°C	100
KINEMATIC VISCOSITY	mm ² /s	Not established
pH	@ 20 °C	12.6
	Neat 1% sol'n	10.8
DENSITY	g/cm ³ @ 20 °C	1.05
VAPOUR PRESSURE		Not established
PARTITION COEFFICIENT	Log Pow (octanol/water) @ 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:

2- Aminoethanol	LD50 (Rat, Oral)	1720 mg/Kg
	LD50 (Rabbit, Dermal)	>1200 mg/Kg
	LD50 (Rat, IVN)	225 mg/Kg
Didecylmethyl ammonium chloride	LD50 (Rat, IPR)	45 mg/Kg
	LD50 (Mouse, Oral)	268 mg/Kg
Potassium Carbonate	LD50 (Mouse, Oral)	>2500 mg/Kg
Bis (3-aminopropyl) dodecylamine	LD50 (Rat, Oral)	261 mg/Kg
	LD50 (Rat, Dermal)	>600 mg/Kg

Mixture: No significant health hazard when properly used for the application it was designed for.

See section 4 for exposure symptoms

Not known to be a skin or respiratory sensitizer.

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**

2- Aminoethanol	EC50 (Daphnia, 48h)	65 mg/L
Didecylmethyl ammonium chloride	No data	
Propan-2-ol	EC50 (Daphnia magna, 24h)	>5000 mg/L
Bis (3-aminopropyl) dodecylamine	EC50 (Daphnia, 48h)	0.073 mg/L
	LC50 (Rainbow trout, 96h)	0.68 mg/L

12.2 Persistence and Degradability:

Chelating agents are fully biodegradable according to appropriate OECD criteria. Main concern is the high alkalinity of the product should it enter surface drains or rivers, etc.

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

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

- 14.1 UN No: 1760
 14.2 Proper Shipping Name: Corrosive liquid n.o.s (contains Didecylmethyl ammonium Chloride)
 14.3 Hazard Classification: 8 (ADR, RID, IMDG, ICAO, IATA)
 14.4 Packaging Group: III
 14.5 Environmental Hazard: Yes
 Marine Pollutant: Yes
 14.6 Special Provisions: 274 (ADR) , 223, 274 (IMDG), A3 (ICAO, IATA)

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
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H320	Causes eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H373	May cause damage to organs through prolonged or repeated exposure

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