



SAFETY DATA SHEET

Pentazyme

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name Pentazyme

Product No. CSC011

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Multi-Enzymatic Cleaner for surgical instruments.

1.3. Details of the supplier of the safety data sheet

Supplier Case Medical Inc.
19 Empire Blvd.
South Hackensack
NJ 07606
USA
Tel: 201-313-1999
Fax: 201-373-9090
Contact Person SDS Contact: DCM Compliance, info@dcmcompliance.com

1.4. Emergency telephone number

201-313-1999

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

| | |
|-------------------------------|---------------------|
| Physical and Chemical Hazards | Not classified. |
| Human health | Skin Sens. 1 - H317 |
| Environment | Not classified. |

Classification (1999/45/EEC)

R43.

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

2.2. Label elements

Contains 1,2-BENZISOTHIAZOL-3(2H)-ONE
SUBTILISIN

Label In Accordance With (EC) No. 1272/2008



Signal Word Danger

Hazard Statements

H317

May cause an allergic skin reaction.

Precautionary Statements

P280

Wear protective gloves/protective clothing/eye protection/face protection.

Supplementary Precautionary Statements

P272

Contaminated work clothing should not be allowed out of the workplace.

P261

Avoid breathing vapour/spray.

P321

Specific treatment (see medical advice on this label).

P302+352

IF ON SKIN: Wash with plenty of soap and water.

2.3. Other hazards

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

| | | |
|--|---|----------------|
| 1,2-BENZISOTHIAZOL-3(2H)-ONE | | < 1% |
| CAS-No.: 2634-33-5 | EC No.: 220-120-9 | |
| Classification (EC 1272/2008) Acute Tox. 4 - H302 Skin Irrit. 2 - H315 Eye Dam. 1 - H318 Skin Sens. 1 - H317 Aquatic Acute 1 - H400 | Classification (67/548/EEC) Xn;R22 R43 Xi;R38,R41 N;R50 | |
| AMYLASE, alpha | | < 1% |
| CAS-No.: 9000-90-2 | EC No.: 232-565-6 | |
| Classification (EC 1272/2008) Resp. Sens. 1 - H334 | Classification (67/548/EEC) R42 | |
| Poly(oxy-1,2-ethanediyl), a-(2-ethylhexyl)-w-hydroxy- | | 1-10% |
| CAS-No.: 26468-86-0 | EC No.: | |
| Classification (EC 1272/2008) Eye Dam. 1 - H318 | Classification (67/548/EEC) Xi;R41. | |
| PROPYLENE GLYCOL | | 1-10% |
| CAS-No.: 57-55-6 | EC No.: 200-338-0 | |
| Classification (EC 1272/2008) Not classified. | Classification (67/548/EEC) Not classified. | |

| | | |
|--|---|----------------|
| SODIUM HYDROXIDE | | < 1% |
| CAS-No.: 1310-73-2 | EC No.: 215-185-5 | |
| Classification (EC 1272/2008) Skin Corr. 1A - H314 | Classification (67/548/EEC) C;R35. | |
| SODIUM XYLENE SULPHONATE 40% | | 1-10% |
| CAS-No.: 1300-72-7 | EC No.: 215-090-9 | |
| Classification (EC 1272/2008) Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 STOT SE 3 - H335 | Classification (67/548/EEC) Xi;R36/37/38. | |
| SUBTILISIN | | < 1% |
| CAS-No.: 9014-01-1 | EC No.: 232-752-2 | |
| Classification (EC 1272/2008) Skin Irrit. 2 - H315 Eye Dam. 1 - H318 Resp. Sens. 1 - H334 STOT SE 3 - H335 | Classification (67/548/EEC) R42 Xi;R37/38,R41 | |

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Move the exposed person to fresh air at once. Rinse nose and mouth with water. Get medical attention if any discomfort continues.

Ingestion

Remove victim immediately from source of exposure. Rinse mouth thoroughly. Drink plenty of water. Get medical attention.

Skin contact

Remove affected person from source of contamination. Remove contaminated clothing. Wash the skin immediately with soap and water. Get medical attention if irritation persists after washing.

Eye contact

Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

Skin contact

May cause sensitisation by skin contact.

4.3. Indication of any immediate medical attention and special treatment needed

Treat Symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media

This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials. Use: Water spray. Dry chemicals. Foam.

5.2. Special hazards arising from the substance or mixture

Unusual Fire & Explosion Hazards

No unusual fire or explosion hazards noted.

5.3. Advice for firefighters

Protective equipment for fire-fighters

Self contained breathing apparatus and full protective clothing must be worn in case of fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures6.2. Environmental precautions

Not relevant considering the small amounts used.

6.3. Methods and material for containment and cleaning up

Wear necessary protective equipment. Absorb in vermiculite, dry sand or earth and place into containers. Do not contaminate water sources or sewer. Flush with plenty of water to clean spillage area.

6.4. Reference to other sections

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid spilling, skin and eye contact.

7.2. Conditions for safe storage, including any incompatibilities

If pH exposure is below 2.5 or above 9.5 products efficacy may be lost. If temperature exceeds 77°F (25°C) product efficacy may be lost. Follow GMP. Keep containers closed when not in use. Wash thoroughly after handling.

7.3. Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

| Name | STD | TWA - 8 Hrs | | STEL - 15 Min | | Notes |
|------------------|-----|-------------|-----------------------|---------------|-------------------|-------|
| PROPYLENE GLYCOL | | 150 ppm | 470 mg/m ³ | | | |
| SODIUM HYDROXIDE | WEL | | | | mg/m ³ | |

WEL = Workplace Exposure Limit.

Ingredient Comments

Ireland, Occupational Exposure Limits 2010

8.2. Exposure controls

Protective equipment



Engineering measures

No particular ventilation requirements.

Respiratory equipment

No specific recommendation made, but respiratory protection must be used if the general level exceeds the recommended occupational exposure limit.

Hand protection

Use suitable protective gloves if risk of skin contact. Protective gloves complying with EN 374.

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Eye protection

If risk of splashing, wear safety goggles or face shield. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Other Protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures

DO NOT SMOKE IN WORK AREA! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly if skin becomes wet or contaminated. Promptly remove any clothing that becomes contaminated. When using do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|---|-------------------|
| Appearance | Liquid |
| Colour | Amber. |
| Odour | Characteristic. |
| Solubility | Soluble in water. |
| Initial boiling point and boiling range | >100°C |
| pH-Value, Conc. Solution | 7±0.5 |

9.2. Other information

Not known.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards associated with this product.

10.2. Chemical stability

Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerisation

Will not polymerise.

10.4. Conditions to avoid

Avoid contact with acids.

10.5. Incompatible materials

Materials To Avoid

Strong acid s/oxidizers. Do not mix with chlorinated detergents (bleach).

10.6. Hazardous decomposition products

Burning may produce oxides of carbon and other substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General information

Contact with eyes may causes irritation. Prolonged or repeated contact with skin may cause irritation or skin sensitization. May be harmful if swallowed

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

Not regarded as dangerous for the environment.

12.1. Toxicity

12.2. Persistence and degradability

Degradability

There are no data on the degradability of this product.

12.3. Bioaccumulative potential

Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil

Mobility:

The product is soluble in water.

12.5. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

SECTION 14: TRANSPORT INFORMATION

General

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

ADR/RID/ADN Class

Not classified for transportation.

Transport Labels

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant
No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Environmental Listing

Rivers (Prevention of Pollution) Act 1961. Control of Pollution (Special Waste Regulations) Act 1980.

Statutory Instruments

The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (S.I 2009 No. 716). Control of Substances Hazardous to Health.

Approved Code Of Practice

Classification and Labelling of Substances and Preparations Dangerous for Supply.

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Guidance Notes

Workplace Exposure Limits EH40. Introduction to Local Exhaust Ventilation HS(G)37. CHIP for everyone HSG(108).

EU Legislation

The UN Globally Harmonised System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 453/2010 of 20th May 2010 amending regulation (EC) No 1907/2006

15.2. Chemical Safety Assessment

SECTION 16: OTHER INFORMATION

Revision Date JAN 12/2017

Revision G

Risk Phrases In Full

| | |
|-----------|---|
| R35 | Causes severe burns. |
| R20/21/22 | Harmful by inhalation, in contact with skin and if swallowed. |
| R22 | Harmful if swallowed. |
| R36/38 | Irritating to eyes and skin. |
| R36/37/38 | Irritating to eyes, respiratory system and skin. |
| R37/38 | Irritating to respiratory system and skin. |
| R38 | Irritating to skin. |
| R42 | May cause sensitisation by inhalation. |
| R43 | May cause sensitisation by skin contact. |
| NC | Not classified. |
| R41 | Risk of serious damage to eyes. |
| R50 | Very toxic to aquatic organisms. |

Hazard Statements In Full

| | |
|------|--|
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H332 | Harmful if inhaled. Harmful if |
| H302 | swallowed. Harmful in |
| H312 | contact with skin. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H317 | May cause an allergic skin reaction. |
| H335 | May cause respiratory irritation. |
| H400 | Very toxic to aquatic life. |

HIMS Rating

| | | |
|---------------------|---|---|
| Health | 1 | 0- least 1- slight 2- moderate 3- high 4- extreme |
| Flammability | 0 | |
| Reactivity | 0 | |
| Personal Protection | B | |

Note:

The chemical components in the formulation, while having different risk classifications, provide a safe threshold when this product is used as directed and diluted according to manufacturer's instructions.

Disclaimer

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.