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

1.1. Product identifier

Product name: Pentazyme
Product No.: CSCxxx

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

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

Signal Word: Warning

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

If skin irritation or rash occurs: Get medical advice/attention.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2. Mixtures

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1,2-BENZISOTHIAZOL-3(2H)-ONE</strong></td>
<td>&lt; 1%</td>
</tr>
<tr>
<td>CAS-No.: 2634-33-5</td>
<td>EC No.: 220-120-9</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th><strong>2-BUTOXYETHANOL</strong></th>
<th>&lt; 1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-No.: 111-76-2</td>
<td>EC No.: 203-905-0</td>
</tr>
</tbody>
</table>

**Classification (EC 1272/2008)**
- Acute Tox. 4 - H302
- Acute Tox. 4 - H312
- Acute Tox. 4 - H332
- Skin Irrit. 2 - H315
- Eye Irrit. 2 - H319

**Classification (67/548/EEC)**
- Xn;R20/21/22
- Xi;R36/38

<table>
<thead>
<tr>
<th><strong>AMYLASE, alpha</strong></th>
<th>&lt; 1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-No.: 9000-90-2</td>
<td>EC No.: 232-565-6</td>
</tr>
</tbody>
</table>

**Classification (EC 1272/2008)**
- Resp. Sens. 1 - H334

**Classification (67/548/EEC)**
- R42

<table>
<thead>
<tr>
<th><strong>Poly(oxy-1,2-ethanediyl), a-(2-ethylhexyl)-w-hydroxy-)</strong></th>
<th>1-10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-No.: 26468-86-0</td>
<td>EC No.:</td>
</tr>
</tbody>
</table>

**Classification (EC 1272/2008)**
- Eye Dam. 1 - H318

**Classification (67/548/EEC)**
- Xi;R41.

<table>
<thead>
<tr>
<th><strong>PROPYLENE GLYCOL</strong></th>
<th>1-10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-No.: 57-55-6</td>
<td>EC No.: 200-338-0</td>
</tr>
</tbody>
</table>

**Classification (EC 1272/2008)**
- Not classified.

**Classification (67/548/EEC)**
- Not classified.
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 procedures

6.2. 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

<table>
<thead>
<tr>
<th>Name</th>
<th>STD</th>
<th>TWA - 8 Hrs</th>
<th>STEL - 15 Min</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-BUTOXYETHANOL</td>
<td>WEL</td>
<td>25 ppm(Sk)</td>
<td>50 ppm(Sk)</td>
<td></td>
</tr>
<tr>
<td>PROPYLENE GLYCOL</td>
<td></td>
<td>150 ppm</td>
<td>470 mg/m3</td>
<td></td>
</tr>
<tr>
<td>SODIUM HYDROXIDE</td>
<td>WEL</td>
<td></td>
<td></td>
<td>mg/m3</td>
</tr>
</tbody>
</table>

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.
Pentazyme

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Amber</td>
</tr>
<tr>
<td>Odour</td>
<td>Characteristic</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water.</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>&gt;100ºC</td>
</tr>
<tr>
<td>pH-Value, Conc. Solution</td>
<td>7±0.5</td>
</tr>
</tbody>
</table>

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


Statutory Instruments


Approved Code Of Practice

Classification and Labelling of Substances and Preparations Dangerous for Supply.
Pentazyme

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 Apr’ 19, 2012
Revision D
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 swallowed. Harmful in 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

<table>
<thead>
<tr>
<th>Health</th>
<th>1</th>
<th>0- least</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>0</td>
<td>1- slight</td>
</tr>
<tr>
<td>Reactivity</td>
<td>0</td>
<td>2- moderate</td>
</tr>
<tr>
<td>Personal Protection</td>
<td>B</td>
<td>3- high</td>
</tr>
<tr>
<td>Protection</td>
<td></td>
<td>4- extreme</td>
</tr>
</tbody>
</table>

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