1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND THE COMPANY:

1.1. Commercial product name: Enzym Med 4
1.2. Use of the substance/preparation: Enzymatic detergent for Medical Instruments
1.3. Manufacturer: VESISMIN S.L. C/Lluçà, 28 5º – 08028 Barcelona
Telephone number: +34 934 095 301
Fax: +34 933 396 628
1.4. Emergency number: +34 934 095 301 (working hours)

2. HAZARD IDENTIFICATION

2.1. Classification of the mixture
Classification according to CE Regulation num. 1272/2008 [CLP]
H302 ACUTE TOXICITY. Category 4
H315 SKIN IRRITATION. Category 2
H319 EYE IRRITATION. Category 2
H373 STOT, RE. Category 2

Most adverse effects, physicochemical, on health and the environment
Delayed or immediate effects can be expected, after a short or long term exposure.

2.2. Label elements according to CE Directives
Hazard pictograms:

Signal word: ATTENTION
Hazard statements:
- Harmful if swallowed (H302)
- Causes skin irritation (H315)
- Causes serious eye irritation (H319)
- May cause damage to organs through prolonged or repeated exposure (H373)

Precautionary Statements
Keep out of reach of children (P102)
Wear protective gloves/protective clothing/eye protection/face protection (P280)
IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell (P301 + P312)
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338)
IF ON SKIN: Wash with plenty of water (P302+P352)
Dispose of contents/container in accordance with local/regional/national/international regulations (P501)

2.3. Other hazards
Contains Etileneglycol, Quaternary ammonium compounds, Alkyl dimethyl bencil-C12-16 chloride.

**PBT:** Not identified as substance PBT/vPvB.

### 3. COMPONENT COMPOSITION / INFORMATION

**3.2. Substance/Mixture:** Mixture
Contains protease, amylase, lipase and celulase enzimes.

**Dangerous components:**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Nº CAS/EC</th>
<th>Clasification 1272/CE*</th>
<th>Conc%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene glycol</td>
<td>107-21-1 / 203-473-3</td>
<td>Acute tox. 4: H302; STOT RE 2: H373</td>
<td>10 – 25 %</td>
</tr>
</tbody>
</table>

* Complete text of H-phrases indicated in this Section are explained in Section 16.

### 4. FIRST AID MEASURES

**4.1. Description of first aid measures**

**General notes.**
Do not leave the patient unattended. Move the victim out of the danger area. Keep the affected person warm, immobile and covered. Remove all contaminated clothing immediately. In case of doubt, or if symptoms persist, seek medical attention. If the victim is unconscious, place her in recovery position. Do not give anything by mouth.

**First aid measures:**

- **Inhalation:** If breathing is irregular or interrupted, seek medical assistance immediately, and start first aid. In case of irritation of the respiratory tract, consult a doctor. Provide fresh air
- **Eye contact:** Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate abundantly with clean, fresh water for at least 10 minutes, keeping the eyelids open.
- **Skin contact:** Wash thoroughly with soap and water.
- **Ingestion:** Wash your mouth with water (only if the person is conscious). DO NOT induce vomiting.

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

**Effects and symptoms:** No specific effects and/or symptoms are known

**4.3. Indications of any immediate medical attention and special treatment needed:** no further relevant information available.
5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media
Suitable extinguishing media: Spray water, powder-BC, carbon dioxide (CO₂).
Extinguishing media that do not have to be used for safety reasons: Jet water

5.2. Special hazards arising from the substance or mixture
Special exposure hazards arising from the substance or preparation itself:
Nitrogen oxide (NOₓ), carbon monoxide (CO), carbon dioxide (CO₂).

5.3. Advice for firefighters
No special measures required. In case of fire and / or explosion, do not breathe fumes. Coordinate fire-fighting measures. Do not allow water used in the fight against fire between watercourses. Collect contaminated water separately. Fight against fire with normal precautions from a reasonable distance.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
For personnel not involved in the emergency: move people to a safe place
For emergency personnel: Wear breathing apparatus in case of exposure to vapors / dust / spray / gases.

6.2. Environmental precautions
Environmental protection measures: Avoid contact with sewage, surface water and groundwater. Hold the wash water and dispose of it as waste.

6.3. Methods and material for containment and cleaning up
Containment measures of a spill: cover the drains
Cleaning methods: Absorb spillage with an absorbent material (eg cloth, wool). Collect the spill (sawdust, diatomaceous earth (kieselguhr), sand, universal binder.
Appropriate containment techniques: Use adsorbent materials
Other information: collect in appropriate containers for disposal. Ventilate the affected area.

6.4. Reference to other sections
Hazardous combustion products: see section 5.
Personal protective equipment: see section 8
Incompatible materials: see section 10
Considerations for disposal: see section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling
Recommendations
Measures to prevent fire as well as the generation of aerosols and powders
Use local and general ventilation. Use only in well-ventilated areas
Precautions for general occupational hygiene
Wash hands after use. Do not eat, drink or smoke in the work areas. Remove contaminated clothing and contaminated protective equipment before entering food areas. Do not store food or drink in the vicinity of the chemical. Do not place the product in containers that are normally used for food or drinks. Keep away from food, drink and animal feed.

7.2. Conditions for safe storage, including any incompatibilities
Management of associated risks
Incompatible substances or mixtures
Observe suggestions for combined storage
Effects control
Protection against external exposure, such as ice.

7.3. Specific end use(s)
See section 16.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
Occupational exposure limits

Relevant DNELs of the components of the mixture

<table>
<thead>
<tr>
<th>Substance</th>
<th>Nº CAS</th>
<th>Value</th>
<th>Limit level</th>
<th>Destination, exposure route</th>
<th>Used in</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>DNEL</td>
<td>35 mg/m³</td>
<td>Human, inhalatory</td>
<td>Worker (industry)</td>
<td>Chronic – local effects</td>
</tr>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>DNEL</td>
<td>106 mg/kg</td>
<td>Human, dermal</td>
<td>Worker (industry)</td>
<td>Chronic – systemic effects</td>
</tr>
</tbody>
</table>

Relevant PNECs of the components of the mixture

<table>
<thead>
<tr>
<th>Substance</th>
<th>Nº CAS</th>
<th>Value</th>
<th>Limit level</th>
<th>Organism</th>
<th>Environmental compartment</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>PNEC</td>
<td>10 mg/l</td>
<td>Aquatic organisms</td>
<td>Fresh water</td>
<td>Short term (sole exp.)</td>
</tr>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>PNEC</td>
<td>199.5 mg/l</td>
<td>Aquatic organisms</td>
<td>Sewage Treatment Plant (STP)</td>
<td>Short term (sole exp)</td>
</tr>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>PNEC</td>
<td>1.53 mg/kg</td>
<td>Terrestrial organisms</td>
<td>Soil</td>
<td>Short term (sole exp)</td>
</tr>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>PNEC</td>
<td>10 mg/lg</td>
<td>Aquatic organisms</td>
<td>Water</td>
<td>Intermitent release</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
Engineering controls
General ventilation
Individual protection measures (personal protective equipment)
Personal protective equipment must be used when the risks cannot be avoided or sufficiently limited by technical means or collective protection, or methods or procedures of the organization.

**Eye / face protection**
Wear eye protection / face

**Skin care**
- **Protection of hands**
  Wear suitable gloves. The chemical protection gloves are suitable, which are tested according to EN 1374. Verify the impermeability before use. In case you want to use the gloves again, clean them before removing them, and aerate them. For special purposes, it is recommended to check the chemical resistance of the protective gloves mentioned above, together with the supplier of the gloves. Recommended: protection index 6, corresponding to > 480 minutes of permeability time according to EN 374.
- **Other protection measures**
  Take recovery periods for skin regeneration. Preventive protection of the skin (creams / barrier ointments) is recommended. Wash hands after handling.

**Environmental exposure controls**
Use appropriate container to avoid environmental contamination. Keep away from drains, surface water and groundwater.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**9.1. Information on basic physical and chemical properties**
- **Aspect:** Liquid, colour clear, slightly yellow
- **Odour:** Typical
- **pH (20°C):** 5.0 – 6.0
- **Freezing point:** Not determined
- **Boiling point:** >100 °C at 1.013 hPa
- **Flash point:** Not determined
- **Flammability:** not pertinent (fluid). Not flammable
- **Danger of explosion:** Not determined
- **Vapour pressure at 25°C:** 0.123 hPa
- **Density (20°C):** 1.005 – 1.010 g/cm³
- **Water solubility:** completely miscible
- **Partition coefficient n-octanol/water (log Kow):** not available
- **Ignition temperature:** 398 °C
- **Viscosity:** Not determined
- **Explosive properties:** none
- **Oxidation properties:** none

**9.2. Other data**
Not available.

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### 10. STABILITY AND REACTIVITY

**10.1. Reactivity**
See below “conditions to avoid” and “incompatible materials”

10.2. Chemical stability
See below “conditions to avoid”

10.3. Possibility of hazardous reactions
Not known.

10.4. Conditions to avoid
Not known.

10.5. Incompatible materials
Additional information not available.

10.6. Hazardous decomposition products
No dangerous decomposition products are known. Hazardous combustion products: see section 5.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
There is no test data for the complete mixture

Classification procedure
The method of classification of the mixture is based on the ingredients of the mixture (addition formula)

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity
Harmful by ingestion

- Estimated acute toxicity (ETA)
  Oral: 1.667 mg/kg

- Acute toxicity of the components of the mixture

<table>
<thead>
<tr>
<th>Substance</th>
<th>Nº CAS</th>
<th>Exposition route</th>
<th>ETA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>Oral</td>
<td>500  mg/kg</td>
</tr>
<tr>
<td>Quaternary ammonium compound, Alkyl dimethyl benzyl-C12-16 chloride</td>
<td>68424-85-1</td>
<td>Oral</td>
<td>100  mg/kg</td>
</tr>
<tr>
<td>Quaternary ammonium compound, Alkyl dimethyl benzyl-C12-16 chloride</td>
<td>68424-85-1</td>
<td>Dérmica</td>
<td>300  mg/kg</td>
</tr>
</tbody>
</table>

Irritation / corrosion of the skin
Causes skin irritation

Serious eye damage / eye irritation
Causes serious eye irritation

Respiratory or skin sensitzation
It is not classified as respiratory or skin sensitizer

Summary of the evaluation of CMR properties
It is not classified as mutagenic of the cells, carcinogenic or as toxic for reproduction

Toxicity to specific organs (STOT)

Toxicity to specific organs - single exposure
It is not classified

Toxicity to specific organs - repeated exposure
May cause organ damage due to prolonged or repeated exposure
12. ECOLOGICAL INFORMATION

12.1. Toxicity
Not classified as dangerous for the aquatic environment.  

**Acute toxicity of the components of the mixture**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Nº CAS</th>
<th>Parámetro</th>
<th>Value</th>
<th>Species</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>LC50</td>
<td>72.860 mg/l</td>
<td>Fish</td>
<td>96 h</td>
</tr>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>EC50</td>
<td>&gt; 100 mg/l</td>
<td>Aquatic invertebrates</td>
<td>48 h</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

**Degradability of the components of the mixture**

<table>
<thead>
<tr>
<th>Substance</th>
<th>Nº CAS</th>
<th>Process</th>
<th>Degradation rate</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Etano-1,2-diol</td>
<td>107-21-1</td>
<td>Elimination DOC</td>
<td>90 – 100 %</td>
<td>10 d</td>
</tr>
</tbody>
</table>

No further relevant information available.

12.3. Bioaccumulative potential
No further relevant information available.

12.4. Mobility in soil
No further relevant information available.

12.5. Results of PBT and vPvB assessment
PBT: not applicable  
vPvB: not applicable

12.6. Other adverse effects: no further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1. Methods for waste treatment

**Relevant information waste disposal**
Avoid release to the environment. Refer to special instructions / safety data sheets.

**Treatment of packaging waste**
Completely empty containers can be recycled.

**Observations**
Consider national and regional requirements. The waste must be separated into categories that can be managed separately by local or national waste management facilities.

14. TRANSPORT INFORMATION

14.1. UN number
Not applicable

Road/Train transport (ADR/RID): not applicable
Sea transport (IMDG): not applicable
Air transport (IATA): not applicable
The substance is not dangerous for transport (European Agreement on International Transport of Dangerous Goods)

14.2. UN proper shipping name
Not applicable.

14.3. Transport hazard class(es)
Not applicable

14.4. Packaging group
Not applicable

14.5. Environmental hazards
Not applicable

14.6. Special precautions for user
Not applicable

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
The information for safety and health with respect to the label of this product is in accordance with the European Union regulation: nº 1907/2006 and 453/2010 and 830/2015.

15.2. Chemical safety assessment: not required

16. OTHER INFORMATION

Complete text of H-phrases as referred to in sections 2 and 3:
- H290: May be corrosive to metals
- H301: Toxic if swallowed
- H302: Harmful is swallowed
- H311: Toxic in contact with skin
- H314: Causes severe skin burns and eye damage
- H315: Causes skin irritation
- H318: Causes serious eye damage
- H319: Causes serious eye irritation
- H373: May cause damage to organs through prolonged or repeated exposure
- H400: Very toxic to aquatic life

Formation advice:
The product must be handled by specialized personnel, following manufacturer instructions.
Changes from last version refer to format and content of EC Regulation 453/2010.
Calculation method determination according to Regulation 1278/2008 has been used
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