1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND THE COMPANY:

1.1. Commercial product name: Enzym Med Wipes
1.2. Use of the substance/preparation: Wipes with enzymatic detergent for Medical Instruments

Product classification: Medical Device type I.

1.3. Manufacturer: VESISMIN S.L. C/Lluçà, 28 5ª – 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]
Non classified

2.2. Label elements according to CE Directives

Does not require

2.3. Other hazards

Any additional information

PBT: Not identified as substance PBT/vPvB.

3. COMPONENT COMPOSITION / INFORMATION

3.2. Substance/Mixture: Mixture

Contains protease, amylase, lipase and celulase enzymes.

Dangerous components:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Nº CAS/EC</th>
<th>Classification 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>1 – 2.5 %</td>
</tr>
<tr>
<td>Alkyldimethylbenzyl ammonium chloride</td>
<td>68424-85-1 / 270-325-2</td>
<td>Met. Corr. 1: H290  Acute tox. 3: H301  Acute tox. 3: H311  Skin Corr. 1C: H314  Eye Dam. 1: H318  Aquatic acute 1: H400</td>
<td>0.1 – 0.5 %</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

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
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties
Aspect: Liquid, colour clear, slightly yellow
Odour: Typical

Other physicochemical parameters
pH: not determined
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: not determined
Density (20°C): 1.000 – 1.10 g/cm³
Water solubility: not determined
Partition coefficient n-octanol/water (log Kow): not available
Ignition temperature: not determined
Viscosity: Not determined
Explosive properties: none
Oxidation properties: none

9.2. Other data
Not available.

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
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
Not classified for acute toxicity

Irritation / corrosion of the skin
Not classified as corrosive/irritating to the skin

Serious eye damage / eye irritation
Not classified as causing serious eye damage or irritating to the skin

Respiratory or skin sensitization
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

Aspiration hazard
It is not classified

12. ECOLOGICAL INFORMATION

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

Biodegradation
Relevant substance of the mixture are readily biodegradable

12.2 Persistence and degradability
No information available

12.3 Bioaccumulative potential
No information available

12.4 Mobility in soil
No information available

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

Other information: Text indicated show the changes from the last revision.

Abbreviations and acronyms:
- CMR: Carcinogenic, Mutagenic or Toxic to the Reproduction
- MARPOL: International agreement to prevent contamination by boats (abbreviation from “Marine Pollutant”)
- vPvB: Very persistent and very bioaccumulating
- PBT: Persistant, Bioacumulable and Toxic

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 for the classification of the mixture.

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