

Reference: Regulation (EC) 1907/2006 453/2010	MATERIAL SAFETY DATA SHEET (MSDS) Product: Enzym Med 4	Version 10 Date last revision: 13.02.18 SHEET 1 of 9
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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

Product classification: Medical Device type I.

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

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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 enzymes.

Dangerous components:

Ingredients	Nº CAS/EC	Clasification 1272/CE*	Conc%
Ethylene glycol	107-21-1 / 203-473-3	Acute tox. 4: H302; STOT RE 2: H373	10 – 25 %
Alkyldimethylbenzyl ammonium chloride	68424-85-1 / 270-325-2	Met. Corr. 1: H290 Acute tox. 3: H301 Acute tox. 3: H311 Skin Corr. 1C: H314 Eye Dam. 1: H318 Aquatic acute 1: H400	1 – 5 %

* 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.

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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 (NO_x), 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

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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

Substance	N° CAS	Value	Limit level	Destintion, exposure rute	Used in	Exposure time
Etano-1,2-diol	107-21-1	DNEL	35 mg/m ³	Human, inhalatory	Worker (industry)	Chronic – local effects
Etano-1,2-diol	107-21-1	DNEL	106 mg/kg	Human, dermal	Worker (industry)	Chronic – systemic effects

Relevant PNECs of the components of the mixture

Substance	N° CAS	Value	Limit level	Organism	Environmental compartment	Exposure time
Etano-1,2-diol	107-21-1	PNEC	10 mg/l	Aquatic organisms	Fresh water	Short term (sole exp.)
Etano-1,2-diol	107-21-1	PNEC	199.5 mg/l	Aquatic organisms	Sewage Treatment Plant (STP)	Short term (sole exp)
Etano-1,2-diol	107-21-1	PNEC	1.53 mg/k	Terrestrial organisms	Soil	Short term (sole exp)
Etano-1,2-diol	107-21-1	PNEC	10 mg/lg	Aquatic organisms	Water	Intermitent release

8.2. Exposure controls

Engineering controls

General ventilation

Individual protection measures (personal protective equipment)

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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.

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.

10. STABILITY AND REACTIVITY

10.1. Reactivity

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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**

Substance	Nº CAS	Exposition rute	ETA
Etano-1,2-diol	107-21-1	Oral	500 mg/kg
Quaternary ammonium compound, Alkyl dimethyl benzyl-C12-16 chloride	68424-85-1	Oral	100 mg/kg
Quaternary ammonium compound, Alkyl dimethyl benzyl-C12-16 chloride	68424-85-1	Dérmica	300 mg/kg

Irritation / corrosion of the skin

Causes skin irritation

Serious eye damage / eye irritation

Causes serious eye irritation

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

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Aspiration hazard

It is not classified

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Not classified as dangerous for the aquatic environment.

Acute toxicity of the components of the mixture

Substance	N° Cas	Parametre	Value	Species	Exposure time
Etano-1,2-diol	107-21-1	LC50	72.860 mg/l	Fish	96 h
Etano-1,2-diol	107-21-1	EC50	> 100 mg/l	Aquatic invertebrates	48 h

12.2 Persistence and degradability

Degradability of the components of the mixture

Substance	N° CAS	Process	Degradation rate	Time
Etano-1,2-diol	107-21-1	Elimination DOC	90 – 100 %	10 d

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

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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: n° 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 if 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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for the classification of the mixture.

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