Enzymatica

Coldzyme Eucalyptus Mouth Spray

SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier:
Coldzyme Eucalyptus Mouth Spray.
1.2. Relevant identified uses of the substance or mixture and uses advised against:
Mouth Spray, which forms a protective barrier on the mucous membrane in your throat. The barrier protects against common cold. The Product is a medical device.
1.3. Details of the supplier of the safety data sheet:
Enzymatica AB Tel: +46 (0) 46 286 31 00
Ideon Science Park
SE-22370 Lund
Sweden
Responsible for the safety data sheet (e-mail): info@enzymatica.se
1.4. Emergency telephone number:
NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): Dial 111
National Poisons Information Centre (Ireland): +353 (1) 809 2166 (8.00 a.m. to 10.00 p.m. 7 days a week)
Healthcare Professionals: +353 (1) 809 2566 (24-hour service)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:
None.
2.2. Label elements:
None.
2.3. Other hazards: None known
PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.
Endocrine disrupting properties: The substances are not identified as having endocrine disrupting properties in accordance with the criteria set out in Regulation 2017/2100 or Regulation 2018/605.

SECTION 3: Composition/information on ingredients

3.2. Mixtures: Aqueous solution with Glycerol.

% w/w	Substance name	CAS	EC-no.	Index-no.	REACH reg.no.	Classification
-	-	-	-	-	-	-

Contains no substances that are mandatory to declare.

SECTION 4: First-aid measures

4.1. Description of first aid measures:
Inhalation: Move the affected person to fresh air. If needed: Get medical attention.
Skin contact: Flush skin and wash thoroughly with soap and water. If irritation persist: Get medical attention.
Eye contact: Immediately flush with water or physiological saltwater, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: seek medical advice.
Ingestion: Not relevant under normal use.
4.2. Most important symptoms and effects, both acute and delayed:
May cause slight irritation of eyes, skin and airways.
4.3. Indication of any immediate medical attention and special treatment needed:
Show this safety data sheet to a physician or emergency ward.

SECTION 5: Firefighting measures

5.1. Extinguishing media:
Use water spray, carbon dioxide, dry chemical or foam.
5.2. Special hazards arising from the substance or mixture:
In case of fire, the product may form hazardous decomposition products such as oxides of carbon.
5.3. Advice for fire-fighters:
Do not inhale smoke fumes. Use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment - see section 8.
6.2. Environmental precautions:
Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations.
6.3. Methods and material for containment and cleaning up:
Wipe it up with a cloth or similar and place it in a suitable container for disposal. Further handling of spillage - see section 13.
6.4. Reference to other sections:
See above.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:
Avoid contact with eyes.
7.2. Conditions for safe storage, including any incompatibilities:
Store in original container, in a cool place at temperatures between 0-25°C.
7.3. Specific end use(s):
See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:
Occupational exposure limits: None (EH40/ed.2020)
DNEL/PNEC: No CSR.
8.2. Exposure controls:
Appropriate engineering controls: None particular.
Personal protective equipment:

Respiratory protection:	Respiratory equipment is normally not required. In case of aerosol formation: Use an approved mask (EN149) with type P2 particle filter. The filter has a limited lifetime and must be changed. Read the manufacturer's instructions.
Skin protection:	By prolonged contact: Wear protective gloves of e.g. nitrile (EN374). There are no available data for breakthrough time, therefore it is recommended to change the glove if spilled on.
Eye protection:	Normally not required. Use safety goggles (EN166) when there is a risk of eye contact.

Environmental exposure controls: None particular.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Physical state:	Liquid in a pump spray
Colour:	Clear
Odour:	Eucalyptus
Melting point/freezing point (°C):	Not determined
Boiling point or initial boiling point and boiling range (°C):	Not determined
Flammability (solid, gas):	Not relevant
Lower and upper explosion limit (vol-%):	Not relevant
Flash point (°C):	Not determined
Auto-ignition temperature (°C):	Not determined
Decomposition temperature (°C):	Not determined
pH:	6,5 - 9
Kinematic viscosity:	Not determined
Solubility:	Fully miscible with water
Partition coefficient n-octanol/water (log value):	Not determined
Vapour pressure:	Not determined
Density and/or relative density:	Not determined
Relative vapour density:	Not determined
Particle characteristics:	Not determined
9.2. Other information:	None relevant

SECTION 10: Stability and reactivity

10.1. Reactivity:
No available information.
10.2. Chemical stability:
Stabile at recommended storage conditions – see section 7.
10.3. Possibility of hazardous reactions:
No available information
10.4. Conditions to avoid:
Avoid heating, frost and direct sunlight.
10.5. Incompatible materials:
No available information.
10.6. Hazardous decomposition products:
Fire causes formation of dangerous decomposition products: Carbon-oxides.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:
Acute toxicity: Based on available data, the classification criteria are not met.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/irritation: Based on available data, the classification criteria are not met.
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.
STOT-single exposure: Based on available data, the classification criteria are not met.
STOT-repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

Hazard class	**Data** (Glycerol)	**Test**	**Data source**
Acute toxicity: Inhalation Dermal Oral	 No data LD_{50} (rabbit) >10.000 mg/kg LD_{50} (rat) >12.600 mg/kg	 - No info. No info.	 - Supplier Supplier
Corrosion/irritation:	No skin or eye irritation, rabbit	No info.	ECHA
Sensitization:	Not a skin sensitizer	No info.	ECHA
CMR:	No CMR effects	No info.	ECHA

Information on likely routes of exposure: Skin, lungs and gastrointestinal tract.
Symptoms:
Inhalation: No irritation at normal use
Skin: No irritation at normal use.
Eyes: May cause slight irritation with redness and pain.
Ingestion: May cause slight irritation to the gastrointestinal tract by the ingestion of large amounts.
Chronic effects: None known.
11.2. Information on other hazards:
None known.

SECTION 12: Ecological information

12.1. Toxicity:
No relevant data
12.2. Persistence and degradability:
Glycerol is easily biodegradable.
12.3. Bioaccumulative potential:
The product is not expected to bioaccumulate.
12.4. Mobility in soil:
No relevant data available.

SECTION 12: Ecological information (cont.)

12.5. Results of PBT and vPvB assessment:
The substance is not considered PBT/vPvB according to criteria in Annex XIII.
12.6. Endocrine disrupting properties:
None known.
12.7. Other adverse effects:
None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods:
To municipal collection point or waste disposal facility.
EWC-kod:
18 01 07 (Product itself)
15 02 03 (absorbents, wiping cloths, etc.)

SECTION 14: Transport information

Not dangerous goods for transport (ADR-RID-IMDG-IATA)
14.1. UN number or ID number: None
14.2. UN proper shipping name: None.
14.3. Transport hazard class(es): None.
14.4. Packing group: None
14.5. Environmental hazards: None.
14.6. Special precautions for user: None.
14.7. Maritime transport in bulk according to IMO instruments: Not relevant.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
The preparation is covered by Regulation (EU) 2017/745, concerning medical devices and must fulfil the requirement set forth in this Regulation.
15.2. Chemical safety assessment:
No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 2 and 3:
None.
Abbreviations:
CMR = Carcinogenicy, Mutagenicity and Reproduction toxicity.
CSR = Chemical Safety Report
DNEL = Derived No-Effect Level
LD_{50} = Lethal Dose 50 %
PBT = Persistent, Bioaccumulative, Toxic
PNEC = Predicted No-Effect Concentration
vPvB = very Persistent, very Bioaccumulative
Literature:
ECHA = REACH registration dossier from the ECHA homepage.
Training advice:
The mixture may be used only by persons who are well instructed in the work and who has knowledge of the contents in this SDS.
Prepared based on the information available to Altox A/S as of December 2022.
Changes since the previous edition:
Not relevant.

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