

SECTION 1. Identification of the substance/mixture and of the company/enterprise

1.1. Product identifier

Product name : ENZYLIA Opera
Product code: refer to sales department

1.2. Relevant identified uses of the substance or mixture and uses advised against

Enzyme preparations
Sectors of use:
Manufacture of food products[SU4]
Product category:
Technological adjuvant

Not recommended uses
Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms:

GHS08

Hazard Class and Category Code(s):

Resp. Sens. 1

Hazard statement Code(s):

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

The product, if inhaled, can cause sensitization.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):

GHS08 - Danger

Hazard statement Code(s):

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Supplemental Hazard statement Code(s):

not applicable

Precautionary statements:



Prevention

- P261 - Avoid breathing vapours/spray.
- P284 - In case of inadequate ventilation wear respiratory protection.

Response

- P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or a doctor.

Contains: pectin lyases, polygalacturonase, betaglucanase (β 1-3, β 1-6)

Ingredients: maltodextrin, potassium chloride, glycerol, ammonium sulphate, pectin lyases, potassium sorbate, polygalacturonase, betaglucase (β 1-3, β 1-6), water to taste at 100.
For food, oenological use. Not intended for the final consumer. Complies with current regulations on specific matters.
Exclusively for industrial use

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent implies the obligation of the "risk assessment" by the employer according to the provisions of Legislative Decree April 9, 2008 no. 81 and subsequent amendments. If the results of the risk assessment demonstrate that, in relation to the type, quantity, methods and frequency of exposure, there is only a low risk for the safety and irrelevant for the health of the workers and that the measures referred to in paragraph 1 of Legislative Decree April 9, 2008 no. 81 are sufficient to reduce the risk, the provisions of articles 225, 226, 229, 230 of the same Legislative Decree do not apply
Do not ingest. Keep out of reach of children.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Substance	Concentration[w/w]	Classification	IUB n.	CAS	EINECS	REACH
Glycerol substance for which there are Community workplace exposure limits	>= 3 < 5%			56-81-5	200-289-5	
Pectin lyases	>= 1 < 2,5%	Resp. Sens. 1, H334	4.2.2.10	9033-35-6	232-894-5	
Polygalacturonase	>= 0,1 < 1%	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Resp. Sens. 1, H334;	3.2.1.15	9032-75-1	232-885-6	

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
		STOT SE 3, H335				
Beta-glucanase (β 1-3, β 1-6)	$\geq 0,1 < 1\%$	Resp. Sens. 1, H334	3.2.1.6	62213-14-3	263-462-4	

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation: ventilate the environment. Immediately remove the patient from the contaminated environment and keep him at rest in a well-ventilated area. In case of malaise consult a doctor.

Direct contact with the skin (of the pure product): wash thoroughly with soap and water.

Direct contact with the eyes (of the pure product): rinse immediately with running water for 10-15 minutes, keeping the eyelid open. Remove contact lenses if they are worn and can be easily removed.

Ingestion: drink water in sips. Consult a doctor if you experience symptoms.

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

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If you experience respiratory symptoms, contact a POISON CENTER or doctor.

Symptomatic treatment.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Recommended extinguishing media: water spray, CO₂, foam, chemical powders depending on the materials involved in the fire. Extinguishing media to avoid: Water jet. Use jets of water only to cool the surfaces of containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and complete protective clothing. Water spray can be used to protect people engaged in firefighting. It is also advisable to use self-contained breathing apparatus, especially if working in closed and

poorly ventilated places. Cool containers with jets of water

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke
Wear gloves and protective clothing

6.1.2 For emergency responders:

Eliminate all unguarded flames and possible sources of ignition. No smoking.
Provide a sufficient ventilation.
Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spills with earth or sand.
If the product has entered a watercourse, sewers or has contaminated soil or vegetation, notify the authorities.
Dispose of the waste material in compliance with the regulations

6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Rapidly recover the product, wear a mask and protective clothing (for specifications refer to section 8.2. SDS)
Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material or suck it.
Prevent it from entering the sewer system.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapours. Handle the product after consulting all other sections of this safety data sheet.
Do not eat or drink while working. See also the next paragraph 8.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool and dry place, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Manufacture of food products:
Store in the original sealed packaging, protected from light, in a cool, dry, odor-free place and at a temperature < 20°C.
Do not freeze. Batch number (BN) and best before (EXP): see barcode.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:
Glycerol:
Limit value - Eight hours
Australia 10 (1) mg/m³
Belgium 10 mg/m³
Canada - Ontario 10 mg/m³
Canada - Quebec 10 mg/m³
Finland 20 mg/m³
France 10 mg/m³
Germany (AGS) 200 (1) mg/m³
Germany (DFG) 200 (1) mg/m³
Ireland 10 mg/m³
New Zealand 10 (1) mg/m³
Poland 10 mg/m³
Singapore 10 mg/m³
South Africa Mining 10 ppm
South Korea 10 mg/m³
Spain 10 mg/m³
Switzerland 50 inhalable aerosols mg/m³
USA - OSHA 15 (1) mg/m³
5 (2) mg/m³
United Kingdom 10 mg/m³

Limit value - Short-term
Germany (AGS) 400 (1)(2) mg/m³
Germany (DFG) 400 (1)(2) mg/m³
Switzerland 100 inhalable aerosols mg/m³

Remarks
Australia (1) This value refers to inhalable dust containing no asbestos and < 1% crystalline silica.
Germany (AGS) (1) Inhalable fraction (2) Average value 15 minutes
Germany (DFG) (1) Inhalable fraction (2) Average value 15 minutes
New Zealand (1) The value for inhalable dusts containing no asbestos and less than 1% free silica.
USA - OSHA (1) Inhalable fraction (2) Breathable fraction

- Substance: Glycerol

DNEL

Systemic effects Long term Workers inhalation = 56 (mg/m³)

PNEC

Sweet water = 0,885 (mg/l)

sediment Sweet water = 3,3 (mg/kg/sediment)

Sea water = 0,088 (mg/l)

sediment Sea water = 0,33 (mg/kg/sediment)

ground = 0,141 (mg/kg ground)

- Substance: pectin lyases

PNEC

Sweet water = 0,052 (mg/l)

Sea water = 0,00052 (mg/l)

STP = 65 (mg/l)

ground = 0,001 (mg/kg ground)

- Substance: polygalacturonase

PNEC

Sweet water = 0,0237 (mg/l)

Sea water = 0,0237 (mg/l)

STP = 65 (mg/l)

ground = 0,00376 (mg/kg ground)

- Substance: Beta-glucanase (β 1-3,
 β 1-6)

PNEC

Sweet water = 0,0052 (mg/l)

Sea water = 0,00052 (mg/l)

STP = 65 (mg/l)

ground = 0,001 (mg/kg ground)

8.2. Exposure controls

Appropriate engineering controls:

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)



8.2.2 Individual protection measures:

(a) Eye / face protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations.

(b) Skin protection

(i) Hand protection

Not needed for normal use, unless otherwise provided by the employer and / or by assessments of environmental hygiene investigations.

(ii) Other

Wear normal work clothing.

(c) Respiratory protection
Use adequate protective respiratory equipment (EN 14387:2008)

(d) Thermal hazards
No hazard to report

Environmental exposure controls:
Use according to good working practices and avoid to disperse the product into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Physical state	Viscous liquid	
Colour	brune to brown	
Odour	not determined as considered not relevant for the characterization of the product	
Odour threshold	not determined as considered not relevant for the characterization of the product	
Melting point/freezing point	not determined as considered not relevant for the characterization of the product	
Boiling point or initial boiling point and boiling range	not determined as considered not relevant for the characterization of the product	
Flammability	not determined as considered not relevant for the characterization of the product	
Lower and upper explosion limit	not determined as considered not relevant for the characterization of the product	
Flash point	not determined as considered not relevant for the characterization of the product	
Auto-ignition temperature	not determined as considered not relevant for the characterization of the product	
Decomposition temperature	not determined as considered not relevant for the characterization of the product	
pH	4,5 - 6,5	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	in water	
Water solubility	miscible in all proportions	
Partition coefficient n-octanol/water (log value)	not determined as considered not relevant for the characterization of the product	
Vapour pressure	not determined as considered not relevant for the characterization of the product	
Density and/or relative density	0,950 - 1,300	
Relative vapour density	not determined as considered not relevant for the characterization of the product	
Particle characteristics	not determined as considered not relevant for the characterization of the product	

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Irrilevant

9.2.2 Other safety characteristics

Irrilevant

SECTION 10. Stability and reactivity

10.1. Reactivity

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Related to contained substances:

Glycerol:

Reacts with: Strong acids. Strong foundations

Pectin lyases:

The product is non-reactive under normal conditions of use, storage and transport.

Polygalacturonase:

Non pertinent.

Beta-glucanase (β 1-3, β 1-6):

Not relevant.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

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Related to contained substances:

Glycerol:

Humidity

Pectin lyases:

None under recommended storage and handling conditions.

Polygalacturonase:

None.

Beta-glucanase (β 1-3, β 1-6):

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

10.5. Incompatible materials

No one in particular

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

(a) acute toxicity:

Glycerol: Ingestion - LD50 rat (mg / kg / 24h bw): not available

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): not available

Inhalation - LD50 rat (mg / l / 4h): not available

Pectin lyases: Ingestion - LD50 rat (mg / kg / 24h bw): not available

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): not available

Inhalation - LD50 rat (mg / l / 4h): not available

Polygalacturonase: Ingestion - LD50 rat (mg / kg / 24h bw): nd

Skin contact - LC50 rat / rabbit (mg / kg / 24h bw): nd

Inhalation - LD50 rat (mg / l / 4h): nd

Beta-glucanase (β 1-3, β 1-6): Ingestion - LD50 rat (mg/kg/24h bw): > 2000

Skin contact - LC50 rabbit (mg/kg/24h bw): nd

Inhalation - LC50 rat (mg/l/4h): 2.42

(b) skin corrosion/irritation: Glycerol: Not classified

Pectin lyases: Not corrosive

Polygalacturonase: Unavailable

Beta-glucanase (β 1-3, β 1-6): Unavailable

Glycerol: Not classified

Pectin lyases: Not irritating

Polygalacturonase: Irritating

Beta-glucanase (β 1-3, β 1-6): Not classified

(c) serious eye damage/irritation:

Glycerol: Not classified

pectin lyases: Not corrosive
polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Unavailable
Glycerol: Not classified
Pectin lyases: Not irritating
Polygalacturonase: Irritating
Beta-glucanase (β 1-3, β 1-6): Unavailable

(d) respiratory or skin sensitisation: The product, if inhaled, can cause sensitization.
Glycerol: Not classified
Pectin lyases: Sensitizer: May cause sensitization by inhalation.
Polygalacturonase: May cause sensitization by inhalation
Beta-glucanase (β 1-3, β 1-6): Once sensitized, a severe allergic reaction can occur upon subsequent exposure to very low levels.

(e) germ cell mutagenicity:
Glycerol: Not classified
Pectin lyases: Unavailable
Polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Not classified

(f) carcinogenicity:
Glycerol: Not classified
pectin lyases: Unavailable
polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Not classified

(g) reproductive toxicity:
Glycerol: Not classified - Does not affect fertility. Non-toxic for development.
pectin lyases: Unavailable
polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Unavailable

(h) specific target organ toxicity (STOT) single exposure:
Glycerol: Not classified Ingestion may cause nausea, vomiting and avoidance.
pectin lyases: Unavailable
polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Unavailable

(i) specific target organ toxicity (STOT) repeated exposure
Glycerol: Not classified
Pectin lyases: Once sensitized, a severe allergic reaction can occur upon subsequent exposure to very low levels.
Polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): Not classified

(j) aspiration hazard:
Glycerol: Inhalation: May cause irritation to the respiratory tract and other mucous membranes.
Pectin lyases: Unavailable
Polygalacturonase: Unavailable
Beta-glucanase (β 1-3, β 1-6): May cause sensitization by inhalation

11.2. Information on other hazards

No data available.

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

SECTION 12. Ecological information

12.1. Toxicity

=====
Related to contained substances:
Glycerol:

Acute aquatic toxicity: Not classified
Chronic aquatic toxicity: Not classified
LC50-96 h - fish 54000 mg / l *Oncorhynchus mykiss*
EC50-48 h - *Daphnia* 1955 mg / l
EC50-72 h - algae 3200 mg / l *Entosiphon sulcatum*
Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

pectin lyases:
Acute toxicity - fish LC50 (mg / l / 96h): not available
Acute toxicity - crustaceans EC50 (mg/l/48h) [1]: 2000 mg/l
Acute toxicity - crustaceans EC50 (mg/l/48h) [2]: 212 mg/l
Acute toxicity algae ErC50 (mg / l / 72-96h): not available
Chronic toxicity - fish NOEC (mg / l): not available
Chronic toxicity - shellfish NOEC (mg / l): not available
Chronic toxicity algae NOEC (mg / l): not available
Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

polygalacturonase:
Acute toxicity - fish LC50 (mg / l / 96h): n.a.
Acute toxicity - crustaceans EC50 (mg / l / 48h): n.a.
Acute toxicity algae ErC50 (mg / l / 72-96h): n.a.
Chronic toxicity - fish NOEC (mg / l): n.a.
Chronic toxicity - crustaceans NOEC (mg / l): n.a.
Chronic toxicity algae NOEC (mg / l): n.a.
Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

Beta-glucanase (β 1-3,
 β 1-6):
Acute toxicity - fish LC50 (mg / l / 96h): nd
Acute toxicity - crustaceans EC50 (mg / l / 48h): nd
Acute toxicity to algae ErC50 (mg / l / 72-96h): nd
Chronic toxicity - fish NOEC (mg / l): nd
Chronic toxicity - crustaceans NOEC (mg / l): nd
Chronic toxicity to algae NOEC (mg / l): nd
Acute toxicity M-factor = 1
Chronic toxicity M-factor = 1

Use according to good working practices and avoid to disperse the product into the environment.

12.2. Persistence and degradability

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Related to contained substances:

Glycerol:

Persistence and degradability Readily biodegradable.

COD value 1.16 g O₂ / g substance

ThOD (gO₂ / g) 1.217 g O₂ / g substance

BOD (% of ThOD) 71% DTO

Pectin lyases:

Readily biodegradable

Polygalacturonase:

Unavailable

Beta-glucanase (β1-3, β1-6):

Easily biodegradable

12.3. Bioaccumulative potential

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Related to contained substances:

Glycerol:

Log P octanol / water at 20 ° C -1.76 - 2.6

Kow log -1.76 Bioaccumulative potential

Not expected to bioaccumulate.

Pectin lyases:

not available

Polygalacturonase:

Unavailable

Beta-glucanase (β1-3, β1-6):

No bioaccumulation potential

12.4. Mobility in soil

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Related to contained substances:

Glycerol:

ground Product that penetrates easily into the ground.

Pectin lyases:

not available

Polygalacturonase:

Unavailable

Beta-glucanase (β1-3, β1-6):

Unavailable

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.
Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information

14.1. UN number or ID number

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

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

No data available.

14.7. Maritime transport in bulk according to IMO instruments

Transport in bulk is not foreseen

SECTION 15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Restrictions relating to the product or the substances contained (Annex XVII EC Reg. 1907/2006): not applicable

Substances in Candidate list (art. 59 EC Reg. 1907/2006): the product does not contain SVHC in percentage = a 0.1 %.

Regulation (EU) 1169/2011: see point 2.2

Regulation (EU) 1308/2013; see point 2.2

Regulation (EC) 1333/2008; see point 2.2

Regulation (EC) 1332/2008; see point 2.2

REGULATION (EU) No 1357/2014 - waste:HP13 - Sensitising

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information

16.1. Other information

Description of hazard statements set out in paragraph 3

H334 = May cause allergy or asthma symptoms or breathing difficulties if inhaled

H315 = Causes skin irritation.

H319 = Causes serious eye irritation.

H335 = May cause respiratory irritation.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008

[CLP]:

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled Classification procedure: Calculation method

Main normative references:

Reg. (CE) n. 1907 del 18/12/06 REACH (Registration, Evaluation and Authorisation of CHemicals) et seq.

Reg. (CE) 1272/2008 CLP (Classification Labelling and Packaging) et seq.

Directive 2012/18/EU (on the control of major-accident hazards involving dangerous substances) et seq.

Training required: This document must be submitted to the employer to determine the possible need for appropriate training for workers to ensure protection of human health and the environment.

n.a.: not applicable

n.d.: not available

ADR: Accord européen relative au transport International des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ATE: Acute Toxicity Estimat

BFC: Bioconcentration Factor

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstract Service number

CAP: Centre AntiPoison

CE/EC number EINECS (European Inventory of existing Commercial Substances) e ELINCS (European List of notified Chemical Substances)

CL50/LC50: Lethal Concentration 50

DL50/LD50: Lethal Dose 50

COD: Chemical Oxygen Demand

DNEL: Derived No Effect Level

EC50: half maximal Effective Concentration

ERC: Environment Release Classes

EU/UE: European Union

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods code

Kow: Octanol water partition coefficient

NOEC: No Observed Effect Concentration

OEL: Occupational Exposure Limit

PBT: Persistent Bioaccumulative and Toxic

PC: Product Categories

PNEC: Predicted No Effect Concentration

PROC: Process Categories

RID: Règlement concernant le transport International ferroviaire des marchandises dangereuses (Regulations concerning International rail transport of dangerous goods)

STOT: Target Organ Systemic Toxicity

STOT (RE): Repeated Exposure

STOT (SE): Single Exposure

STP: Sewage Treatment Plants

SU: Sector of Use

SVCH: Substance of Very High Concern

TLV: Threshold Limit Value

vPvB: Very Persistent Very Bioaccumulative

References and Sources:

- ECHA Registered Substances:

<https://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

- SDS raw material supplier

- GESTIS International Limit Value: <http://limitvalue.ifa.dguv.de>

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*** this tab annuls and replaces any previous edition. (IIXX)

Changes to the previous edition: Global update and label
