

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

1.1. Product identifier

Product name : ENDOZYM Glucacel UHT

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

AEB France Sarl

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Produced by

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1.4. Emergency telephone number

AEB SpA

Centralino/Switchboard: +39.030.2307.1 - (h 8.30-12.00 13.30-18.00 GMT +1; Lingua/Language: Italiano, English)

AEB USA
Switchboard: +1 2096258139 (GMT -8; Language: English)

AEB AFRICA (PTY) LTD
Switchboard: +27 215512700 (GMT +1; Language: English, Afrikaans)

AEB OCEANIA PTY LTD
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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.

2.2. 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

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:

Beta-glucanase, Xlinalase



Ingredients: glycerol, beta-glucanase, maltodextrin, potassium sorbate, sodium benzoate, xylanase, sodium chloride, cellulase, water q.s. to 100.

Food use. Not intended for the final consumer. In accordance with current regulations on the specific matter.

Only 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

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Glycerol substance for which there are Community workplace exposure limits	>= 25 < 50%			56-81-5	200-289-5	
Beta-glucanase	>= 3 < 5%	Resp. Sens. 1, H334	3.2.1.6	62213-14-3	263-462-4	
Xylanase	>= 0,1 < 1%	Resp. Sens. 1, H334	3.2.1.8	9025-57-4	232-800-2	

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation:

Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product):

Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion:

Not dangerous. In case of malaise consult a doctor.

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 experiencing respiratory symptoms: Call a POISON CENTER or a doctor.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:

Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective clothing.

The water spray can be used to protect the people involved in the extinction.

You may also use self-contained breathing apparatus, especially when working in confined and poorly ventilated areas.

Keep containers cool with water spray

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 vapors
Handle the product after consulting all other sections of this safety data sheet.
At work do not eat or drink.
See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original sealed package, protected from light, in a cool, dry, odour-free place and at a temperature < 20°C.
Do not freeze. Lot number (BN) and best before (EXP): see barcodes

7.3. Specific end use(s)

Manufacture of food products:
Handle with care.
Store in the original sealed package, protected from light, in a cool, dry, odour-free place and at a temperature < 20°C.
Do not freeze. Lot number (BN) and best before (EXP): see barcodes

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)

intermittent emissions = 8,85 (mg/l)

ground = 0,141 (mg/kg ground)

- Substance: Beta-glucanase

PNEC

Sweet water = 0,0052 (mg/l)

Sea water = 0,00052 (mg/l)

STP = 65 (mg/l)

ground = 0,001 (mg/kg ground)

- Substance: Xylanase

PNEC

Sweet water = 0,0222 (mg/l)

Sea water = 0,0022 (mg/l)

STP = 65 (mg/l)

ground = 0,00295 (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	Liquid	
Colour	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	

Physical and chemical properties	Value	Determination method
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	3.5-8.5	
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

No data available.

9.2.2 Other safety characteristics

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

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Related to contained substances:

Glycerol:

Reacts with: Strong acids. Strong foundations

Beta-glucanase:

Not relevant.

Xylanase:

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

Beta-glucanase:

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

Xylanase:

Unavailable

10.5. Incompatible materials

None 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

Beta-glucanase: 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

Xylanase: 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

(b) skincorrosion/irritation: Glycerol: Not classified

Beta-glucanase: Unavailable

Xylanase: Unavailable

Glycerol: Not classified

Beta-glucanase: Not classified

Xylanase: Not irritating

(c) serious eye damage/irritation: Glycerol: Not classified

Beta-glucanase: Unavailable

Xylanase: Unavailable

Glycerol: Not classified

Beta-glucanase: Unavailable

Xylanase: Not irritating

(d) respiratory or skin sensitisation: The product, if inhaled, can cause sensitization.

Glycerol: Not classified

Beta-glucanase: Once sensitized, a severe allergic reaction can occur upon subsequent exposure to very low levels.

Xylanase: Respiratory sensitizer: Once sensitized, a severe allergic reaction may occur upon subsequent exposure to very low levels.

(e) germ cell mutagenicity: Glycerol: Not classified

Beta-glucanase: Not classified

Xylanase: Not classified

(f) carcinogenicity: Glycerol: Not classified

Beta-glucanase: Not classified

Xylanase: Unavailable

(g) reproductive toxicity: Glycerol: Not classified - Does not affect fertility. Non-toxic for development.

Beta-glucanase: Unavailable

Xylanase: Not classified

(h) specific target organ toxicity (STOT) single exposure: Glycerol: Not classified Ingestion may cause nausea, vomiting and avoidance.

Beta-glucanase: Unavailable

Xylanase: Unavailable

(i) specific target organ toxicity (STOT) repeated exposure: Glycerol: Not classified

Beta-glucanase: Not classified

Xylanase: Not classified

(j) aspiration hazard: Glycerol: Inhalation: May cause irritation to the respiratory tract and other mucous membranes.

Beta-glucanase: May cause sensitization by inhalation

Xylanase: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

11.2. Information on other hazards

No data available.

SECTION 12. Ecological information

12.1. Toxicity

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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*

Beta-glucanase:

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

Xylanase:

Acute toxicity - fish LC50 (mg / l / 96h): nd

Acute toxicity - crustaceans EC50 (mg / l / 48h): nd

Acute toxicity algae ErC50 (mg / l / 72-96h): nd
Chronic toxicity - fish NOEC (mg / l): nd
Chronic toxicity - crustaceans NOEC (mg / l): nd
Chronic toxicity algae NOEC (mg / l): nd

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

Beta-glucanase:

Easily biodegradable

Xylanase:

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.

Beta-glucanase:

No bioaccumulation potential

Xylanase:

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.

Beta-glucanase:

Unavailable

Xylanase:

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

No data available.

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 contained substances (All. XVII Reg. EC 1907/2006): not applicable
Substances in Candidate List (art. 59 Reg. EC 1907/2006): the product does not contain SVHC in a proportion $\geq 0.1\%$.
Substances subject to authorisation (Ann. XIV Reg. CEC 1907/2006): the product does not contain SVHC in a proportion $\geq 0.1\%$.

Reg. (EU) n. 1169/2011: see 2.2

Regulation (EU) 1332/2008; see p.2.2

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

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

Classification according to Regulation (EC) Nr. 1272/2008

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.

Regulation (UE) n. 1169/2011 (on the provision of food information to consumers)

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

Regulation (EU) 1332/2008 (Food enzymes)

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 Estimati

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 supplier
- GESTIS DNEL Database: <http://www.dguv.de/ifa/gestis/gestis-dnel-datenbank/index-2.jsp>
- 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: first issue.
