

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

**1.1. Product identifier**

Product name : ENDOZYM Protease NP

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 SpA - Via Vittorio Arici 104 S.Polo - 25134 Brescia (BS) Italy

Tel. +39.030.2307.1 Fax +39.030.2307281

E-mail: [info@aeb-group.com](mailto:info@aeb-group.com) - Internet: [www.aeb-group.com](http://www.aeb-group.com)

E-mail tecnico competente/technical dept.: [sds@aeb-group.com](mailto:sds@aeb-group.com)

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AEB USA

111 N Cluff Avenue

Lodi CA 95240 (USA)

Tel: +1 2096258139 Fax: +1 2092248953

Email: [info@aebusa.com](mailto:info@aebusa.com) - Internet: [www.aeb-group.com](http://www.aeb-group.com)

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AEB AFRICA (PTY) LTD

18 Track Crescent, Cor. Station Road

Montague Gardens 7441

Cape Town (South Africa)

Tel.: +27 215512700 - Fax: +27 (0) 215511919

Email: [info@aeb.co.za](mailto:info@aeb.co.za) - Internet: [www.aeb-group.com](http://www.aeb-group.com)

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AEB OCEANIA PTY LTD

178A Wakaden Street

Griffith NSW 2680

T: 1300 704 971

Email: [aebocceania@aeb-group.com](mailto:aebocceania@aeb-group.com) - Internet: [www.aeb-group.com](http://www.aeb-group.com)

Produced by

AEB FRANCE Sarl - 10, rue du Stade - 68240 KAYSERSBERG-VIGNOBLE, France

#### 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

Switchboard: +61 1300 704 971 (GMT +9; Language: English)

## 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

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/doctor.

Contains:

Neutral protease

Ingredients: Glycerol, neutral protease, maltodextrin, potassium sorbate, sodium benzoate, water q.s. to 100.

For food, for brewing. Not intended for the final consumer. In accordance with current regulations on the specific matter.

For industrial use only.

### 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

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

## 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	IUB N°	CAS	EINECS	REACH
Glycerol substance for which there are Community workplace exposure limits	>= 25 < 50%			56-81-5	200-289-5	
Neutral protease	>= 3 < 5%	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Resp. Sens. 1, H334; STOT SE 3, H335	3.4.24.28	9001-92-7	232-642-4	

## 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**

If inhaled, may cause severe reactions, asthma or breathing difficulties

#### **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, CO<sub>2</sub>, 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**

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.  
Store in the original sealed package, away from light, in a dry, odor-free place at a temperature < 20 ° C. Do not freeze. Batch number (BN) and Best before date (EXP): see barcode

## **7.3. Specific end use(s)**

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

# **SECTION 8. Exposure controls/personal protection**

### 8.1. Control parameters

=====

Related to contained substances:

Glycerol:

Limit value - Eight hours

Australia 10 (1) mg/m<sup>3</sup>

Belgium 10 mg/m<sup>3</sup>

Canada - Ontario 10 mg/m<sup>3</sup>

Canada - Quebec 10 mg/m<sup>3</sup>

Finland 20 mg/m<sup>3</sup>

France 10 mg/m<sup>3</sup>

Germany (AGS) 200 (1) mg/m<sup>3</sup>

Germany (DFG) 200 (1) mg/m<sup>3</sup>

Ireland 10 mg/m<sup>3</sup>

New Zealand 10 (1) mg/m<sup>3</sup>

Poland 10 mg/m<sup>3</sup>

Singapore 10 mg/m<sup>3</sup>

South Africa Mining 10 ppm

South Korea 10 mg/m<sup>3</sup>

Spain 10 mg/m<sup>3</sup>

Switzerland 50 inhalable aerosols mg/m<sup>3</sup>

USA - OSHA 15 (1) mg/m<sup>3</sup>

5 (2) mg/m<sup>3</sup>

United Kingdom 10 mg/m<sup>3</sup>

Limit value - Short-term

Germany (AGS) 400 (1)(2) mg/m<sup>3</sup>

Germany (DFG) 400 (1)(2) mg/m<sup>3</sup>

Switzerland 100 inhalable aerosols mg/m<sup>3</sup>

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/m<sup>3</sup>)

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)

### 8.2. Exposure controls

Appropriate engineering controls:  
 Manufacture of food products:  
 No specific monitoring foreseen (act according to good practices and specific rules for the type of associated risk).



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	
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	ASTM D92
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	

Physical and chemical properties	Value	Determination method
pH	6.5 - 7.5	
Kinematic viscosity	not determined as considered not relevant for the characterization of the product	
Solubility	in water	
Water solubility	in water	
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

Neutral protease:

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

### 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  
Neutral protease: Ingestion - LD50 rat (mg/kg/24h bw): n.a.  
Skin contact - LD50 rabbit (mg/kg/24h bw): n.a.  
Inhalation - LD50 rat (mg/l/4h): n.a.

(b) skin corrosion/irritation: Glycerol: Not classified  
Neutral protease: Unavailable  
Glycerol: Not classified  
Neutral protease: Causes skin irritation

(c) serious eye damage/irritation: Glycerol: Not classified  
Neutral protease: Unavailable  
Glycerol: Not classified  
Neutral protease: Causes severe eye irritation

(d) respiratory or skin sensitisation: The product, if inhaled, can cause sensitization.  
Glycerol: Not classified  
Neutral protease: Unavailable

(e) germ cell mutagenicity: Glycerol: Not classified

Neutral protease: Unavailable

(f) carcinogenicity: Glycerol: Not classified

Neutral protease: Unavailable

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

Neutral protease: Unavailable

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

Neutral protease: It can irritate the respiratory tract

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

Neutral protease: Once sensitized, subsequent exposure to very low levels can trigger a strong allergic reaction.

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

Neutral protease: May cause sensitization by inhalation.

### 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

Neutral protease:

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 O<sub>2</sub> / g substance

ThOD (gO<sub>2</sub> / g) 1.217 g O<sub>2</sub> / g substance

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BOD (% of ThOD) 71% DTO

Neutral protease:  
Unavailable

### 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.

Neutral protease:  
Unavailable

### 12.4. Mobility in soil

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Related to contained substances:

Glycerol:

ground Product that penetrates easily into the ground.

Neutral protease:  
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 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 (EC) 1332/2008; see point 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

Points modified compared to previous release: 2.2. Label elements, 7.2. Conditions for safe storage, including any incompatibilities, 7.3. Specific end use(s), 9.1. Information on basic physical and chemical properties

Description of hazard statements set out in paragraph 3

H315 = Causes skin irritation.

H319 = Causes serious eye irritation.

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

H335 = May cause respiratory irritation.

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.

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

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

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.

Changes to the previous edition: update of label.

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