

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

1.1. Product identifier

Product name : ENDOZYM Rouge HR
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:

GHS07, GHS08

Hazard Class and Category Code(s):

Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1

Hazard statement Code(s):

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

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

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs, or edema
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):

GHS07, GHS08 - Danger

Hazard statement Code(s):

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.



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

Precautionary statements:

Prevention

P261 - Avoid breathing vapours/spray.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P284 - In case of inadequate ventilation wear respiratory protection.

Response

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or a doctor.

Contains:

Polygalacturonase, pectin lyase.

Ingredients: Polygalacturonase, potassium chloride, ammonium sulphate, pectin lyase, potassium sorbate, water q.s. to 100.

Food use, oenological use. 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

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
Polygalacturonase	>= 10 < 25%	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Resp. Sens. 1, H334; STOT SE 3, H335	3.2.1.15	9032-75-1	232-885-6	
Potassium chloride substance for which there are Community workplace exposure limits	>= 10 < 25%			7447-40-7	231-211-8	
Pectin lyase	>= 1 < 2,5%	Resp. Sens. 1, H334	4.2.2.10	9033-35-6	232-894-5	

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):

Take off immediately contaminated clothing.

Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately

Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

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 skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

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
Wear protective gloves/protective clothing/eye protection/face protection.
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 the original sealed packaging, away from light, in a cool, dry, odour-free place and at a temperature < 20°C. Do not freeze. Batch number (BN) and best before date (EXP): see barcodes.

7.3. Specific end use(s)

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

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:

Potassium chloride:

Limit value - Eight hours

Latvia: 5 mg/m³

- 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: Potassium chloride

DNEL

Systemic effects Long term Workers inhalation = 1064 (mg/m³)

Systemic effects Long term Workers dermal = 303 (mg/kg bw/day)

Systemic effects Long term Consumers inhalation = 273 (mg/m³)

Systemic effects Long term Consumers dermal = 182 (mg/kg bw/day)

Systemic effects Long term Consumers oral = 91 (mg/kg bw/day)

Systemic effects Short term Workers inhalation = 5320 (mg/m³)

Systemic effects Short term Workers dermal = 910 (mg/kg bw/day)

Systemic effects Short term Consumers inhalation = 1365 (mg/m³)

Systemic effects Short term Consumers dermal = 910 (mg/kg bw/day)

Systemic effects Short term Consumers oral = 455 (mg/kg bw/day)

PNEC

Sweet water = 0,1 (mg/l)

Sea water = 0,1 (mg/l)

STP = 10 (mg/l)

- Substance: Pectin lyase

PNEC

Sweet water = 0,052 (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

Wear mask

(b) Skin protection

(i) Hand protection

When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

(ii) Other

When handling the pure product, wear full protective clothing (generic workwear / antacid, safety shoes S3-EN ISO 20345) or other protective equipment, according to the instructions of the RSPP

(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	

Physical and chemical properties	Value	Determination method
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 - 5.5	
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

Irrelevant

9.2.2 Other safety characteristics

Irrelevant

10.1. Reactivity

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Related to contained substances:

Polygalacturonase:

Non pertinent.

Potassium chloride:

The product is not reactive under normal conditions of use, storage and transport.

Pectin lyase:

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

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:

Polygalacturonase:

None.

Potassium chloride:

None under recommended storage and handling conditions.

Pectin lyase:

None under recommended storage and handling conditions.

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: 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

Potassium chloride: Ingestion - DL50 rat (mg / kg / 24h pc): 3020

Contact avec la peau - CL50 rat / lapin (mg / kg / 24h pc): n.d.

Inhalation - DL50 rat (mg / l / 4h): n.d.

Pectin lyase: 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: If brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.

Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Not corrosive

Polygalacturonase: Irritating

Potassium chloride: Unclassified

Pectin lyase: Not irritating

(c) serious eye damage/irritation: If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Not corrosive

Polygalacturonase: Irritating

Potassium chloride: Unclassified

Pectin lyase: Not irritating

(d) respiratoryorskinsensitisation: The product, if inhaled, can cause sensitization.

Polygalacturonase: May cause sensitization by inhalation

Potassium chloride: Unclassified

Pectin lyase: Sensitizer: May cause sensitization by inhalation.

(e) germ cell mutagenicity: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Unavailable

(f) carcinogenicity: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Unavailable

(g) eproductivetoxicity: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Unavailable

(h) specific target organ toxicity (STOT) single exposure: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Unavailable

(i) specific target organ toxicity (STOT) repeated exposure: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Once sensitized, a severe allergic reaction can occur upon subsequent exposure to very low levels.

(j) aspiration hazard: Polygalacturonase: Unavailable

Potassium chloride: Unclassified

Pectin lyase: Unavailable

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:

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

Potassium chloride:

Acute toxicity - fish LC50 (mg / l / 96h): 880 (Pimephales promelas; (OECD method 203))

Acute toxicity - crustaceans EC50 (mg / l / 48h): 440 (Daphniamagna; (OECD method 202))

Acute toxicity algae EC50 (mg / l / 72h):> 100 (Desmodesmus subspicatus; (method OECD 201))

Chronic toxicity - fish NOEC (mg / l): nd Chronic toxicity - crustaceans NOEC (mg / l): nd

Chronic toxicity algae NOEC (mg / l / 72h):> 100 (Desmodesmus subspicatus; (method OECD 201))

Acute toxicity M-factor = 1

Chronic toxicity M-factor = 1

Pectin lyase:

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

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:

Polygalacturonase:

Unavailable

Potassium chloride:

It does not apply to inorganic substances.

Pectin lyase:

Readily biodegradable

12.3. Bioaccumulative potential

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Related to contained substances:

Polygalacturonase:

Unavailable

Potassium chloride:

It does not apply to inorganic substances.

Pectin lyase:

not available

12.4. Mobility in soil

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Related to contained substances:

Polygalacturonase:

Unavailable

Potassium chloride:

It must have been very mobile in the ground.

Pectin lyase:

not available

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) 1332/2008; see point 2.2
Regulation (EC) 1332/2008; see point 2.2

REGULATION (EU) No 1357/2014 - waste:
HP4 - Irritant — skin irritation and eye damage
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

Points modified from previous version:2. Hazards identification -3. Composition/information on ingredients- 7.3 Specific end uses- 8.1. Control parameters- 8.2. Exposure controls- 9. Physical and Chemical properties- 10. Stability and reactivity- 11.Toxicological information- 12. Ecological information, 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

H315 - Causes skin irritation. Classification procedure: Calculation method

H319 - Causes serious eye irritation. Classification procedure: Calculation method

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.

Changes to the previous edition: general update.
