

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

1.1. Product identifier

Product name : LYSOCID W REACH N. 01-2120001171-82-XXXX

Product code: refer to sales department

Chemical Name: Lysozyme CAS: 12650-88-3 - EC No: 235-747-3 - REACH: 01-2120001171-82-XXXX

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

Enzyme

Sectors of use:

Industrial Manufacturing[SU3], Manufacture of food products[SU4], Public domain (administration, education, entertainment, services, craftsmen)[SU22]

Product category:

Process aid for enological use

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

CAS 12650-88-3 EINECS 235-747-3 REACH 01-2120001171-82-XXXX

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 dust.

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

Disposal

P501 - Dispose of contents/container to local/regional/national/international regulations

Contains:

Lysozyme

Information concerning the components: lysozyme(a).

Only for professional use. Food use, oenological use. In accordance with current regulations on the specific matter.

(a)= Eggs and products thereof (<Eggs and products thereof>in compliance with Regulation (EU) No 1169/2011 - Annex II and subsequent additions and modifications)

2.3. Other hazards

The substance / mixture does NOT contain substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Dlgs n. 81. April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and quantity of dangerous chemical agent and method and frequency of exposure to the agent, there is only a "moderate Risk" for the health and safety of workers and that the measures laid down in the Decree are sufficient to reduce the risk.

SECTION 3. Composition/information on ingredients

3.1 Substances

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACH
Lysozyme	100%	Resp. Sens. 1, H334		12650-88-3	235-747-3	01-2120001 171-82-XXX X

3.2 Mixtures

Irrilevant

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 hazardous. It's possible to give activated charcoal in water or medicinal mineral vaseline oil.

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

In case of inhalation it may cause allergic symptoms, asthma or respiratory 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, 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 and if you use halogenated extinguishers (Halon 1211 fluobrene, Solkan 123, NAF, etc...)
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

Inform the competent 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 elimination.

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

In residential areas do not use on large surfaces.

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.

7.3. Specific end use(s)

Industrial Manufacturing:

Handle with extreme caution.

Store in a well ventilated place away from heat sources.

Manufacture of food products:

Handle with care.

Store in a clean, dry, ventilated area away from heat and direct sunlight.

Keep container tightly closed.

Public domain (administration, education, entertainment, services, craftsmen):

Handle with care. Store in a ventilated area and away from heat, keep the container tightly closed.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls



Appropriate engineering controls:

Industrial Manufacturing:

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

Manufacture of food products:

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

Public domain (administration, education, entertainment, services, craftsmen):

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) or other protective equipment, according to the instructions of the employer

(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
Appearance	white powder or granules	
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	
pH	3,5 ± 0,5 (20°C; sol. 2%)	
Melting point/freezing point	not determined as considered not relevant for the characterization of the product	
Initial boiling point and boiling range	not determined as considered not relevant for the characterization of the product	
Flash point	non flammable	ASTM D92
Evaporation rate	not determined as considered not relevant for the characterization of the product	
Flammability (solid, gas)	not determined as considered not relevant for the characterization of the product	
Upper/lower flammability or explosive limits	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	
Vapour density	not determined as considered not relevant for the characterization of the product	
Relative density	not determined as considered not relevant for the characterization of the product	
Solubility	not determined as considered not relevant for the characterization of the product	
Water solubility	not determined as considered not relevant for the characterization of the product	
Partition coefficient: n-octanol/water	not determined as deemed not relevant to 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	
Viscosity	not determined as deemed not relevant to the characterization of the product	
Explosive properties	not determined as considered not relevant for the characterization of the product	
Oxidising properties	not determined as considered not relevant for the characterization of the product	

9.2. Other information

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

Stable storage conditions

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

Nothing to report

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products should be considered; the nature of decomposition products known.

SECTION 11. Toxicological information

11.1. Information on toxicological effects

ATE oral = ∞
ATE dermal = ∞
ATE inhal = ∞

(a) acute toxicity: Lysozyme: Ingestion-rat LD50 (mg/kg/bw 24h): > 5050

Skin contact-LC50 rat/coniglio (mg/kg/bw 24h): > 5050

Inhalation-rat LD50 (mg/l/4h): > 2.51

(b) skin corrosion/irritation Lysozyme: Non-corrosive

Lysozyme: Non-irritating

(c) serious eye damage/irritation: Lysozyme: Non-corrosive

Lysozyme: Non-irritating

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

Lysozyme: Respiratory sensitizer

(e) germ cell mutagenicity: Lysozyme: Not available

(f) carcinogenicity: Lysozyme: Not available

(g) reproductive toxicity: Lysozyme: Not available

(h) specific target organ toxicity (STOT) single exposure: Lysozyme: Not available

(i) specific target organ toxicity (STOT) repeated exposure Lysozyme: Not available

(j) aspiration hazard: Lysozyme: Not available

SECTION 12. Ecological information

12.1. Toxicity

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Related to contained substances:

Lysozyme:

Acute toxicity-fish LC50 (mg/l/96h): n.a.

Acute toxicity-crustacea EC50 (mg/l/48h): n.a.

Acute algae toxicity ErC50 (mg/l/72-96h): n.a.

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

12.2. Persistence and degradability

Readily biodegradable

12.3. Bioaccumulative potential

Not available

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

Not classified as PBT and vPvB

12.6. 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. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to local and National rules in force

SECTION 14. Transport information

14.1. UN 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. Transport in bulk according to Annex II of MARPOL73/78 and IBC Code

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
Substances subject to authorisation (Ann. XIV Reg. CEC 1907/2006): the product does not contain SVHC
Reg. EC 648/04: see 2.2
Reg. (EU) n. 1169/2011: see 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

Points modified compared to previous release: 2.2. Label elements

Description of hazard statements set out in paragraph 3

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

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 (EC) n. 648 of 31/03/04 (on detergents) 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.

Procedure used to classify under CLP mixture (Reg . EC 1272/2008): classification method

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: label variation.
