essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

SAFETY DATA SHEET

LYSOZYME

Revision No. 3, October 2023; Complies with Reg (EU) 2020/878

INDEX

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE MANIFACTURING COMPANY 2

2. HAZARD IDENTIFICATION 2

3. COMPOSITION/INGREDIENT INFORMATION 3

4. FIRST AID MEASURES 3

5. FIRE-FIGHTING MEASURES 3

7. HANDLING AND STORAGE 4

8. EXPOSURE CONTROL/INDIVIDUAL PROTECTION 4

9. PHISICAL AND CHEMICAL PROPERTIES 5

11. TOXICOLOGICAL INFORMATION 6

12. ECOLOGICAL INFORMATION 7

13. DISPOSAL CONSIDERATIONS 7

14. TRANSPORTATION INFORMATION 8

15. REGULATORY INFORMATION 8

16. OTHER INFORMATION 9

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE MANIFACTURING COMPANY

1.1 Product identification
Chemical name: lysozyme
Trade names and synonyms: Lisozima
CAS: 12650-88-3
EC No: 235-747-3
REACH: 01-2120001171-82-XXXX

1.2 Relevant identified uses of the substance/mixture and uses not recommended:
Enzymes
Sector of use: Industrial uses [SU3], Food industries [SU4], Professional uses [SU22]
Product categories: technological adjuvant for oenological use.
Uses not recommended: do not use for uses other than those indicated.

1.3 Information about the supplier of the safety data sheet
essedielle srl
S.P. 538 km. 6,950 - CALDARI
66026 ORTONA (CH)
ITALY
Phone: +39 (0) 85 9031315
Qualified persons responsible for the safety data sheet: laboratorio@essedielle.com

1.4 Emergency telephone number: essedielle srl +39 (0) 85 9031315 – 0039 3668134126
Poison Control Center
S.S. Annunziata Hospital – Chieti +39 0871 1551219

2. HAZARD IDENTIFICATION

2.1. Classification of the substance or mixture
Criteria Regulation EC 1272/2008 (CLP):
Pictograms:
GHS08
Hazard class and category codes: Resp. Sens. 1
Hazard Indication Codes:
H334 - May cause allergic or asthmatic symptoms or breathing difficulties if inhaled
Product, if inhaled, may cause sensitization phenomena

2.2 Label elements
Labeling in accordance with Regulation (EC) No 1272/2008:
Symbols: pictograms, warning codes: **GHS08** - Danger.

Hazard Statements:
H334 - May cause allergic or asthmatic symptoms or difficulty breathing if inhaled.
Additional hazard statement codes: not applicable.
Cautionary Advice:
Prevention
P261 - Avoid breathing in dust.
P284 - When room ventilation is insufficient wear respiratory protective equipment.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

Reaction
P304+P340 - IF INHALED: Transport the casualty to fresh air and keep at rest in a position conducive to breathing.
P342+P311 - In case of respiratory symptoms: contact a POISON CENTER or physician.
Special provisions under Annex XVII of REACH and subsequent adaptations: none

2.3 Other dangers
The substance/mixture does NOT contain any PBT/vPvB substances according to Regulation (EC) 1907/2006, Annex XIII The use of this chemical agent entails the obligation of "Risk Assessment" by the employer according to the provisions of Legislative Decree No. 81 of April 9, 2008. Workers exposed to this chemical agent do not have to undergo health surveillance if the results of the risk assessment show that, in relation to the type and quantity of the hazardous chemical agent and the manner and frequency of exposure to this agent, there is only a "Moderate Risk" to the health and safety of workers and that the measures provided in the same Dlgs. are sufficient to reduce the risk.

3. COMPOSITION/INGREDIENT INFORMATION

3.1 Substances
Substance identification: none
Hazardous components under EC Regulation 1272/2008 (CLP) and their classification
Refer to section 16 for the full text of the hazard statements.

3.2 Mixture

Substance	Concentration	Classification	CAS	EINECS	REACH
Lysozyme	100%	Resp. Sens. 1, H334	12650-88-3	235-747-3	01-2120001171-82-XXXX

4. FIRST AID MEASURES

4.1 Description first aid measures
In case of inhalation: take the injured person to fresh air. If breathing is difficult give oxygen or practice artificial respiration.
In case of skin contact: remove contaminated clothing immediately. Immediately wash areas of the body that have come in contact with the toxicant, even if only suspected, with plenty of running water and soap if necessary. Wash the body completely (shower or bath).
In case of eye contact: Immediately flush with running water with open eyelids for at least 15 minutes. Consult an ophthalmologist. Protect the uninjured eye.
In case of ingestion: induce vomiting. Seek immediate medical attention, showing the security data sheet.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing means
Suitable extinguishing means
Water. Carbon dioxide (CO2).
Extinguishing media that should not be used for safety reasons
None in particular

5.2 Special hazards from combustion products
It can decompose at high temperatures releasing toxic gases. Ammoniacal. Phosphorus oxides.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

5.3 Recommendations for fire suppression operators
Use respiratory protection. Safety helmet and full protective clothing. Water mist can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in closed and poorly ventilated places and in any case if using halogenated extinguishing agents (fluobrene, solkane 123, naf etc.). Cool containers with water jets.

5.4 Other information
Water used in firefighting that is contaminated with the product must be disposed of in accordance with local regulations.

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

6.1 Personal precautions, personal protective equipment and emergency procedures
Wear personal protective equipment. Move people to a safe place. Refer to the protective measures set out in section 7 and 8.

6.2 Environmental precautions
Prevent penetration into the soil/subsoil. Prevent runoff into surface water or sewage system.

6.3 Methods and materials for containment and remediation
Small quantities: wash with plenty of water.

6.4 Reference to other sections
See also paragraph 8 and 13

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Do not eat or drink while working.
Also refer to section 8 for recommended protective equipment.

7.2 Conditions for safe storage, including any incompatibilities
Incompatible materials: none in particular.
See also section 10 below.
Indication for premises: adequately ventilated premises.

7.3 Specific end uses
Food industries: handle with care. Store in a clean, dry and ventilated environment, away from heat sources and direct sunlight. Keep container tightly closed.
Industrial uses: handle with extreme care. Store in a well-ventilated place and away from heat sources.
Professional uses: handle with caution.

8. EXPOSURE CONTROL/INDIVIDUAL PROTECTION

8.1 Control parameters
Related to contained substances: no data available.

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

8.2 Exposure controls

Eye protection
Wear safety glasses with side shields according to EN 166. Operate according to good working practices in any case.

Skin protection
No special precautions are required for normal use.

Hand protection
Use chemical-resistant protective gloves (EN 374-1/EN374-2/EN374-3) When handling the pure product, wear full skin protection clothing (generic/anti-acid work dress, S3-EN ISO 20345 safety shoes) or other protective equipment as directed by the RSPP.

Respiratory protection
During manual operations in case of inadequate ventilation, use mask with dust filter - White, P (EN 143) unless otherwise specified by RSPP and/or environmental hygiene survey assessments.

Thermal hazards
None

Environmental exposure controls
None

9. PHISICAL AND CHEMICAL PROPERTIES

9.1 Information on general physical and chemical properties

Appearance	White granules
Shape	Powder/granules
Color	Beige/White
Odor	Odorless
Olfactory threshold	None
Ph value	4 sol 5%
CHANGE OF STATE	
Melting point/interval	Not determined
Boiling point/interval	Not determined
Flash point	Not determined
Flammability (solids, gases)	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	Not determined
Explosive properties	Not determined
Lower flammability limits	Not determined
Upper flammability limits	Not determined
Vapor pressure at 20°C	Not determined
Density at 20°C	0.35 g/dm^3

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

Relative density	Not determined
Vapor density at 20°C	Not determined
Evaporation rate	Not determined
Solubility in/Miscibility with water:	At 20 °C: completely miscible and soluble in water
Specific rotation	Not determined
Partition coefficient: n-octanol/water	Not determined
Dynamic Viscosity at 20 °C	Not determined
Kinematic Viscosity	Not determined

9.2. Other information

Molecular mass	Not determined
Conductivity	Not determined
Liposolubility	Not determined
Particular properties groups of substances	
Other Useful Information	None

10. STABILITY AND RESPONSIVENESS

10.1 Responsiveness
Under normal conditions, it is completely stable in air and light.

10.2 Chemical stability:
Under normal conditions, it is completely stable in air and light.

10.3 Possibility of dangerous reactions
No dangerous reaction

10.4 Conditions to be avoided
None in particular

10.5 Incompatible materials
None in particular

10.6 Hazardous decomposition products
None

11. TOXICOLOGICAL INFORMATION

11.1 Information on hazard effects
Toxicological information regarding the mixture: the product is nontoxic

Unless otherwise specified, the data required by Regulation 453/2010/EC below are intended to be undetermined:

ATE (mix) oral = ∞
ATE (mix) dermal = ∞
ATE (mix) inhal = ∞

essedielle srl
Loc. Macinini Fraz. Caldari
66026 Ortona (CH)
Num. REA CH-72915
P.IVA e CF: 00639090695
Codice Univoco SUBM70N
Capitale Sociale € 100.000,00

(a) acute toxicity:
Ingestion - LD50 rat (mg/kg/24h bw): >5050
Skin contact - LC50 rat/rabbit (mg/kg/24h bw): >5050
Inhalation - LD50 rat (mg/l/4h): >2.51.
(b) corrosion / skin irritation: based on available data the classification criteria are not met.
(c) severe eye injury/irritation: based on available data the classification criteria are not met.
(d) respiratory tract or skin sensitization: based on available data the classification criteria are not met.
(e) germ cell mutagenicity: based on available data the classification criteria are not met.
(f) carcinogenicity: based on available data, the classification criteria are not met.
(g) reproductive toxicity: based on available data, the classification criteria are not met.
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met.
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met.
(j) aspiration hazard: based on available data the classification criteria are not met.

11.2. Health hazards
Eye contact: accidental contact of the product with the eyes may cause irritation.
Skin contact: the product is non-irritating. Repeated and prolonged direct contact may degrease and irritate the skin, causing dermatitis in some cases.
Ingestion: ingested product may cause irritation of the mucous membranes of the throat and digestive tract resulting in abnormal digestive symptoms and intestinal disorders.
Inhalation: prolonged exposures to vapors or mists of the product may cause respiratory tract irritation.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
a) Acute aquatic toxicity
Acute toxicity - fish LC50 (mg/l/96h): n.d.
Acute toxicity - crustaceans EC50 (mg/l/48h): n.d.
Acute toxicity algae ErC50 (mg/l/72-96h): n.d.

12.2 Persistence and degradability
Easily biodegradable oenological product.

12.3 Bioaccumulative potential
N.A.

12.4 Mobility in soil
N.A.

12.5 Results of PBT and vPvB assessment vPvB substances: None **- PBT substances:** None

12.6 Other adverse effects
Avoid discharge into sewers or waterways.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
PRODUCT
Dispose of contents/container in accordance with authorized collector's sorting instructions. Recover if possible. Operate in accordance with applicable local and national regulations. Sewer

disposal recommendations: no undesirable effect on the operation of water treatment plants under normal use in accordance with recommendations.

CONTAMINATED PACKAGING

Empty packaging residues. Dispose of contents/container in accordance with the sorting instructions of the authorized collector.

13.2 HP Phrases

None

14. TRANSPORTATION INFORMATION

14.1 UN Number

Not dangerous goods under transport regulations.
UN number (ADR): not applicable
UN number (IMDG): not applicable
UN number (IATA): not applicable
UN number (ADN): not applicable
UN number (RID): not applicable

14.2 UN proper shipping name

Official transport designation (ADR): not applicable
Official transport designation (IMDG): not applicable
Official transport designation (IATA): not applicable
Official transport designation (ADN): not applicable
Official transport designation (RID): not applicable

14.3 Transport hazard class(es)

ADR Transport hazard classes (ADR): not applicable
IMDG Transport hazard classes (IMDG): not applicable
IATA Transport-related hazard classes (IATA): not applicable
ADN Transport-related hazard classes (ADN): not applicable

14.4 Packing group

Packing group (ADR): not applicable
Packing group (IMDG): not applicable
Packing group (IATA): not applicable
Packing group (ADN): not applicable
Packing group (RID): not applicable

14.5 Environmental hazards Marine pollutant

No

14.6 Special precautions for users.

N.A.

14.7 Transport of bulk according to MARPOL Annex II and the IBC Code

N.A.

15. REGULATORY INFORMATION

15.1 Health, safety and environmental laws and regulations specific to the substance or mixture

Legislative Decree 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances)

Legislative Decree 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations)
D.M. Labor 26/02/2004 (Occupational exposure limits)
Ministerial Decree 03/04/2007 (Implementation of Directive No. 2006/8/EC)
Regulation (EC) No. 1907/2006 (REACH)
Regulation (EC) No. 1272/2008 (CLP)
Regulation (EC) No 790/2009 (ATP 1 CLP)
Regulation (EU) No 453/2010 (Annex I)
Regulation (EU) No 286/2011 (ATP 2 CLP)
Restrictions on the product or substances contained under Annex XVII of the Regulation (EC) 1907/2006 (REACH) and subsequent adaptations: None
Where applicable, please refer to the following regulations:
Ministerial Circulars 46 and 61 (Aromatic Amines).
Legislative Decree No. 238 of September 21, 2005 (Seveso Ter Directive).
EC Regulation No. 648/2004 (Detergents).
Royal Decree January 9, 1927, no. 147 (Toxic Gases)
D.L. 3/4/2006 n. 152 Environmental regulations.

15.2 Chemical safety assessment
No

16. OTHER INFORMATION

This sheet cancels and replaces any previous edition.

This document was prepared by a technician who is competent in SDS and has received appropriate training.

Main bibliographic sources
ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition -Van Nostrand Reinold
CCNL - Annex 1
National Institute of Health - National Inventory of Chemical Substances.

The information contained herein is based on our knowledge as of the date above.
They refer only to the product indicated and do not constitute a guarantee of any particular quality. The user is responsible for ensuring the suitability and completeness of this information in relation to the specific use to be made of it.

LEGEND SYMBOLS
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS: Service of the Chemical Abstract (division of the American Chemical Society).
CLP: Classification, Labeling, Packaging.
DNEL: Derived no-effect level.
EINECS: European inventory of existing chemicals on the market.
GefStoffVO: Ordinance on hazardous substances, Germany.
GHS: General harmonized system of classification and labeling of chemicals.
IATA: International Air Transport Association.
IATA-DGR: Regulations for the transportation of dangerous goods of the "International Air Transport Association"(IATA).
ICAO: International Civil Aviation Organization.
ICAO-TI: Technical Instructions of the "International Civil Aviation Organization"(ICAO).
IMDG: International Maritime Dangerous Goods Code.

INCI: International nomenclature of cosmetic ingredients.
KSt: Coefficient of explosion.
LC50: Lethal concentration for 50 percent of the population tested.
LD50: Lethal dose for 50 percent of the population tested.
N.A.: Not Available
PNEC: Predicted no-effect concentration.
RID: Regulations concerning the international transport of dangerous goods by rail.
STE: Short-term exposure.
STEL: Short-term exposure limit.
STOT: Specific target organ toxicity.
TLV: Threshold limit value.
TWATLV: Threshold limit value for an 8-hour weighted average exposure per day. (ACGIH standard).
WGK: German water hazard class.