

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
 Trade name : Lysozyme Hydrochloride Liquid (LL)  
 Synonyms : Muramidase; Lysozyme hydrochloride LL; Mucopeptide N-acetylmuramoyl hydrolase; Lysozyme; Lysolac

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : Inactivation of bacteria in selected food products

Full text of use descriptors: see section 16

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Bioseutica B.V.  
 Landbouwweg 83  
 3899 BD Zeewolde  
 The Netherlands  
 T +31 (0) 365226300  
 E-mail: hbeuker@bioseutica.com

#### 1.4. Emergency telephone number

Emergency number : QESH Manager Bioseutica BV  
 +31-(0)36- 5234059 (business hours)  
 +31-(0)6- 12376175 (24 hours)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Respiratory sensitisation, Category 1 H334

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger  
 Contains : Lysozyme, hydrochloride  
 Hazard statements (CLP) : H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 Precautionary statements (CLP) : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P284 - Wear respiratory protection.  
 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 doctor.

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P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII  
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII  
Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Lysozyme, hydrochloride	CAS-No.: 9066-59-5 EC-No.: 232-954-0 REACH-no: 01-2120086351-59	20 – 23	Resp. Sens. 1, H334

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Move the affected person away from the contaminated area and into the fresh air.
First-aid measures after skin contact	: Rinse immediately with plenty of water for 15 minutes. Seek medical attention if tissue appears damaged or if pain or irritation persists.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation persists.
First-aid measures after ingestion	: Rinse mouth thoroughly with water. Do not induce vomiting. Seek medical attention if ill effect or irritation develops.

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

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Water. Carbon dioxide (CO <sub>2</sub> ), dry chemical powder, foam. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None known.

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### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
Explosion hazard	: None known.
Hazardous decomposition products in case of fire	: Toxic gases and fumes may be released in a fire.

### 5.3. Advice for firefighters

Firefighting instructions	: Evacuate personnel to a safe area. Prevent runoff from entering drains, sewers or waterways.
Protective equipment for firefighters	: Use self-contained breathing apparatus and chemically protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid breathing dust/fume/gas/mist/vapours/spray.
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#### 6.1.1. For non-emergency personnel

Protective equipment	: Wear suitable protective clothing gloves, and eye/face protection.
Emergency procedures	: Avoid contact with skin and eyes. Avoid release to the environment. Immediately contact emergency personnel.

#### 6.1.2. For emergency responders

Protective equipment	: Use personal protective equipment as required.
Emergency procedures	: Evacuate area. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

### 6.2. Environmental precautions

Prevent contamination of soil, drains and surface waters. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

For containment	: Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Methods for cleaning up	: Wash contaminated area with large amounts of water. Wash the spilled material carefully away with water under low pressure. Collect up the product and place it in a spare container suitably labelled. Dispose of in a safe manner in accordance with local/national regulations.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed	: None known.
Precautions for safe handling	: Avoid inhalation of product. Avoid repeated or prolonged skin contact. Ensure adequate ventilation.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Provide local exhaust or general room ventilation.
Storage conditions	: Store tightly closed in a dry, cool and well-ventilated place.
Maximum storage period	: 18 months
Storage temperature	: 5 – 25 °C
Heat and ignition sources	: Keep away from open flames, hot surfaces and sources of ignition.
Packages and containers:	: Keep only in original container.

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### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

Lysozyme, hydrochloride (9066-59-5)	
<b>DNEL/DMEL (Workers)</b>	
Acute - systemic effects, dermal	Not applicable
Acute - systemic effects, inhalation	Not applicable
Acute - local effects, dermal	Not applicable
Acute - local effects, inhalation	Not applicable
Long-term - systemic effects, dermal	Not applicable
Long-term - local effects, dermal	Not applicable
Long-term - systemic effects, inhalation	Not applicable
Long-term - local effects, inhalation	Not applicable
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	Not applicable
PNEC aqua (marine water)	Not applicable
PNEC aqua (intermittent, freshwater)	Not applicable
PNEC aqua (intermittent, marine water)	Not applicable
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	Not applicable
PNEC sediment (marine water)	Not applicable
<b>PNEC (Soil)</b>	
PNEC soil	Not applicable
<b>PNEC (Oral)</b>	
PNEC oral (secondary poisoning)	Not applicable
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	Not applicable

#### 8.1.5. Control banding

No additional information available

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### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

**Appropriate engineering controls:**

Provide local exhaust or general room ventilation. A washing facility/water for eye and skin cleaning purposes should be present.

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Gloves. Safety glasses. Protective clothing.

**Personal protective equipment symbol(s):**



##### 8.2.2.1. Eye and face protection

**Eye protection:**

Chemical goggles or safety glasses. DIN EN 166

##### 8.2.2.2. Skin protection

**Skin and body protection:**

Wear suitable protective clothing. EN 14605

**Hand protection:**

Wear suitable gloves tested to EN 374. NBR (Nitrile rubber). Break through time:  $\geq 480$  min. Material thickness: 0,38 mm.

**Other skin protection**

**Materials for protective clothing:**

Wear suitable protective clothing. EN 14605

##### 8.2.2.3. Respiratory protection

**Respiratory protection:**

Half/ full mask with filter for organic vapours . In confined space use self-contained breathing apparatus. EN 141. EN 140. EN 136

##### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Clear to light yellow.
Appearance	: Clear. Transparent.
Odour	: Almost odourless; lightly sweetish.
Odour threshold	: Not available
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flammability	: Not flammable
Explosive properties	: not explosive.
Oxidising properties	: Not oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not determined
Upper explosion limit	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined

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pH	: 3.0 – 3.6
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: 7 mPa.s (Brookfield 20 °C) (22%)
Solubility	: Soluble in water. Insoluble in oils/fats.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not determined
Vapour pressure at 50°C	: Not determined
Density	: 1.05 – 1.06 g/ml
Relative density	: Not determined
Relative vapour density at 20°C	: Not determined
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Fat solubility : Insoluble

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

### 10.4. Conditions to avoid

None known.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

No hazardous decomposition products under suitable storage and usage conditions as prescribed.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Lysozyme, hydrochloride (9066-59-5)	
LD50 oral rat	> 5050 mg/kg bodyweight Animal: rat, Guideline: EPA OPPTS 870.1100 (Acute Oral Toxicity)
LD50 dermal rabbit	> 5050 mg/kg
LC50 Inhalation - Rat	> 2.51 mg/l/4h

Skin corrosion/irritation	: Not classified pH: 3.0 – 3.6
Serious eye damage/irritation	: Not classified pH: 3.0 – 3.6

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Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified (Mutagenicity : Ames test : negative. Chromosomal aberrations mammalian cells. Gene-mutations mammalian cells. Negative)
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

### Lysozyme Hydrochloride Liquid (LL)

Viscosity, kinematic	Not determined
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## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %
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### 11.2.2. Other information

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	:
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### Lysozyme, hydrochloride (9066-59-5)

LC50 - Fish [1]	> 1 g/l Test organisms (species): Cyprinus carpio
LC50 - Fish [2]	> 1 g/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 72h - Algae [1]	97 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)

### 12.2. Persistence and degradability

### Lysozyme Hydrochloride Liquid (LL)

Persistence and degradability	Readily biodegradable.
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### 12.3. Bioaccumulative potential

### Lysozyme Hydrochloride Liquid (LL)

Bioaccumulative potential	No potential for bioaccumulation.
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### Lysozyme, hydrochloride (9066-59-5)

Bioaccumulative potential	No potential for bioaccumulation.
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### 12.4. Mobility in soil

### Lysozyme Hydrochloride Liquid (LL)

Mobility in soil	Not determined
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Lysozyme Hydrochloride Liquid (LL)	
Ecology - soil	No data available.
Lysozyme, hydrochloride (9066-59-5)	
Additional information	The substance is expected not to evaporate from the water surface into the atmosphere, on the basis of its chemical properties.

### 12.5. Results of PBT and vPvB assessment

Lysozyme Hydrochloride Liquid (LL)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container to comply with applicable local, national and international regulations.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated

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### Transport by sea

Not regulated

### Air transport

Not regulated

### Inland waterway transport

Not regulated

### Rail transport

Not regulated

## 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	Lysozyme Hydrochloride Liquid (LL)

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

##### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

##### Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV, Annex 1).  
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

##### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed  
SZW-lijst van mutagene stoffen : None of the components are listed  
SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed  
SZW-lijst van reprotoxische stoffen –  
Vruchtbaarheid : None of the components are listed

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SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

### Denmark

Danish National Regulations : Young people under 18 years are not allowed to use the product

## 15.2. Chemical safety assessment

CSA has not been established

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
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Sources of Key data : Bioseutica B.V. - The Netherlands. Classification is based on the harmonized classification of enzymes according to "AMFEP Fact Sheet on Enzymes and the EU Regulation on classification, labelling and packaging of substances and mixtures (EC No 1272/2008, "CLPRegulation")".

Other information : The information presented in this Safety Data Sheet is based on current knowledge and is believed to be complete and accurate. It describes the product for the purposes of health, safety and environment requirements only and shall, therefore, be used only as a guide. The data refers to a specific product and may not be valid for combined uses with other products. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. The Supplier of this SDS shall not be responsible for any damage or injury resulting from abnormal use or from any failure to adhere to recommended practices. It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product. Such information is actually to be best of our knowledge and beliefs accurate as reliable.

Full text of H- and EUH-statements:	
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitisation, Category 1

Full text of use descriptors	
ERC1	Manufacture of the substance
ERC4	Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
PROC15	Use as laboratory reagent
PROC4	Chemical production where opportunity for exposure arises
PROC5	Mixing or blending in batch processes
PROC8a	Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities
PROC9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Resp. Sens. 1	H334	Calculation method

Safety Data Sheet (SDS), EU

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