

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

### 1.1. Product identifier

Product form	: Mono constituent substance
Trade name	: Lysozyme HCl form heat treated from Hen Egg White (LYSOHT®)
IUPAC name	: Lysozyme, hydrochloride
EC-No.	: 232-954-0
CAS-No.	: 9066-59-5
REACH registration No.	: 01-2120086351-59-0000
Formula	: $C_{616}H_{963}N_{193}O_{182}S_{10} \times HCl$
Synonyms	: Muramidase; Lysozyme hydrochloride; Mucopeptide N-acetylmuramoyl hydrolase; Lysozyme; Lysozyme hydrochloride (free range quality); Lysozyme granulate; Lysolac granulate; Inoavapure 300.

### 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.

#### 1.2.2. Uses advised against

Restrictions on use : Contact supplier for more information on uses.

### 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
Hazard statements (CLP)	: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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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.  
P501 - Dispose of contents/container to according to national or local regulations.

### 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

The substance is not 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

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono constituent substance

Name	Product identifier	%
Lysozyme Hydrochloride	CAS-No.: 9066-59-5 EC-No.: 232-954-0 REACH-no: 01-2120086351-59-0000	≥ 95

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.

First-aid measures after skin contact : Remove all contaminated clothing and footwear. Wash skin thoroughly with mild soap and water. Seek medical attention if ill effect or irritation develops.

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. Seek immediate medical advice.

First-aid measures after ingestion : Rinse mouth out with water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Seek immediate medical advice.

### 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 : Carbon dioxide (CO<sub>2</sub>), dry chemical powder, foam. Water spray jet.

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

Hazardous decomposition products in case of fire : Toxic fumes may be released.

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### 5.3. Advice for firefighters

- Protective equipment for firefighters : Use a self-contained breathing apparatus and also a protective suit. Helmet. EN 469.
- Other information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

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

- General measures : Ensure adequate ventilation. Avoid generation of dust. Avoid breathing dust, mist or spray. Avoid contact with skin and eyes.

#### 6.1.1. For non-emergency personnel

- Protective equipment : Do not attempt to take action without suitable protective equipment. Wear suitable protective clothing, gloves and eye or face protection. Wear personal protective equipment. Wear respiratory protection.
- Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

#### 6.1.2. For emergency responders

- Protective equipment : Wear recommended personal protective equipment. Do not enter fire area without proper protective equipment, including respiratory protection.
- Emergency procedures : Evacuate unnecessary personnel. In case of leakage, eliminate all ignition sources.

### 6.2. Environmental precautions

Avoid release to the environment. Do not allow to enter into surface water or drains.

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

- Methods for cleaning up : Wear recommended personal protective equipment. Ventilate area. Sweep up or vacuum up the product. Avoid dust formation. Collect all waste in suitable and labelled containers and dispose according to local legislation. Clean contaminated surfaces with an excess of water. Mechanically recover the product.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Additional hazards when processed : Generation of airborne dust.
- Precautions for safe handling : Avoid dust formation. Avoid contact with skin, eyes and clothing.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace.

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

- Technical measures : Use grounded electrical/mechanical equipment.
- Storage conditions : Keep only in original container. Store tightly closed in a dry, cool and well-ventilated place. (<65% RH). Keep out of direct sunlight. Protect from moisture. Keep container tightly closed. Handle uncleaned empty containers as full ones.
- Heat and ignition sources : Keep away from open flames, hot surfaces and sources of ignition.

### 7.3. Specific end use(s)

No additional information available

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### 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

No additional information available

##### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

###### Appropriate engineering controls:

Provide adequate ventilation.

##### 8.2.2. Personal protection equipment

###### Personal protective equipment:

Safety glasses. Gloves. Wear a mask. Dust/aerosol mask with filter type P2.

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



##### 8.2.2.1. Eye and face protection

###### Eye protection:

Use eye protection according to EN 166.

##### 8.2.2.2. Skin protection

###### Skin and body protection:

Chemical resistant protective apron / clothing (tested to EN 14605 or equivalent).

###### Hand protection:

Chemical resistant gloves (according to European standard NF ISO 374-1 or equivalent). Nitrile-rubber protective gloves. Thickness. > 0.4 mm. Breakthrough time : > 480 min

###### Other skin protection

###### Materials for protective clothing:

Wear suitable protective clothing

##### 8.2.2.3. Respiratory protection

###### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. Particle filter with medium efficiency for solid and liquid particles (e.g. EN 143 or 149, Type P2 or FFP2)

##### 8.2.2.4. Thermal hazards

No additional information available

##### 8.2.3. Environmental exposure controls

###### Environmental exposure controls:

Do not allow uncontrolled discharge of product into the environment. The final disposal of this material should be supervised by a specialist, following applicable environmental legislation.

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### Other information:

Handle in accordance with good industrial hygiene and safety procedures.

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: White to off-white.
Appearance	: White granules.
Molecular mass	: 14400 g/mol
Odour	: Almost odorless. 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	: Non oxidizing.
Explosive limits	: Not applicable
Lower explosion limit	: Not determined
Upper explosion limit	: Not determined
Flash point	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: ≈ 208 °C
pH	: 3.0 - 3.6 (2 % water solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Solubility	: Insoluble in oils/fats. Water: 285 g/l @ 20 °C and pH 4
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: -2 @25 °C
Vapour pressure	: 147 Pa @20°C
Vapour pressure at 50°C	: Not determined
Density	: 0.3 – 0.4 g/cm <sup>3</sup> Tapped density
Relative density	: 0.988 g/cm <sup>3</sup> @20 °C
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

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

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions of use.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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### 10.4. Conditions to avoid

Moisture. Direct sunlight.

### 10.5. Incompatible materials

Avoid the contact with metallic surfaces

### 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 [EPA OPPTS 870.1100]
LD50 dermal rabbit	> 5050 mg/kg [EPA OPPTS 870.1200]
LC50 Inhalation - Rat	2.51 mg/l/4h [EPA OPPTS 870.1300]

Skin corrosion/irritation : Not classified  
pH: 3.0 - 3.6 (2 % water solution)

Additional information : Not irritant [EPA OPPTS 870.2500]

Serious eye damage/irritation : Not classified  
pH: 3.0 - 3.6 (2 % water solution)

Additional information : Not irritant [EPA OPPTS 870.2400]

Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Respiratory system - Epidemiological data in the work-place (human) - sensitiser - read across from "lysozyme"

Additional information : Skin - Buehler test (guinea pig) - not sensitising [EPA OPPTS 870.2600]

Germ cell mutagenicity : Not classified

Additional information : In vitro - Ames test (S. typhimurium) - negative - read across from "lipase"  
In vitro - Ames test (human lymphocytes) - negative - read across from "alkaline cellulase"  
In vitro - Mammalian chromosome aberration test (S. typhimurium) - negative - read across from "lipase"  
In vivo - Mammalian chromosome aberration test (rat) - negative - read across from "alkaline cellulase"

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Additional information : NOEL oral (rabbit) > 200 mg/kg (during organogenesis) - read across from "lysozyme"  
NOEL oral (mouse) > 200 mg/kg (during organogenesis) - read across from "lysozyme"

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Additional information : NOAEL oral (rat) > 500 mg/kg (5 months) - read across from "lysozyme"  
NOAEL oral (dog) > 500 mg/kg (12 months) - read across from "lysozyme"

Aspiration hazard : Not classified

#### Lysozyme Hydrochloride (9066-59-5)

Viscosity, kinematic	Not applicable
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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 substance is not 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

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### 11.2.2. Other information

Potential Adverse human health effects and symptoms : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

## SECTION 12: Ecological information

### 12.1. Toxicity

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 (Cyprinus carpio) - read-across from "lipase" [OECD 203]
LC50 - Fish [2]	> 1 g/l (Danio rerio) - read-across from "alkaline cellulose" [ISO 7346-1]
EC50 - Crustacea [1]	> 1 g/l 24 h - read-across from "lipase" [OECD 202]
EC50 72h - Algae [1]	> 97 mg/l Desmodesmus subspicatus - read-across from "lipase" [OECD 201]

### 12.2. Persistence and degradability

Lysozyme Hydrochloride (9066-59-5)	
Persistence and degradability	Product is biodegradable. The substance is an enzyme (biological material); therefore it can be considered ready biodegradable. No specific information exists on the abiotic degradation of the substance in the environment via hydrolysis or photolysis. However, considering that enzymes generally have a great biodegradation potential, possible abiotic degradation mechanisms in the environmental is expected to be of lower significance compared to biodegradation process.

### 12.3. Bioaccumulative potential

Lysozyme Hydrochloride (9066-59-5)	
Partition coefficient n-octanol/water (Log Pow)	-2 @25 °C
Bioaccumulative potential	The substance is expected to be characterized by a low bioaccumulative potential, on the basis of its negative partition coefficient octanol-water.

### 12.4. Mobility in soil

Lysozyme Hydrochloride (9066-59-5)	
Mobility in soil	The substance is expected not to evaporate from the water surface into the atmosphere, on the basis of its physical properties.

### 12.5. Results of PBT and vPvB assessment

Lysozyme Hydrochloride (9066-59-5)	
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 substance is not 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.

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### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to the Directive 2008/98/CE. Dispose of in a safe manner in accordance with local/national regulations. Empty containers should be taken for recycling, recovery or waste in accordance with local regulation.

## SECTION 14: Transport information

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

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

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### 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

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### 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)

Not listed on REACH Annex XVII

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

Not listed on REACH Annex XIV (Authorisation List)

###### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

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

Not listed on the PIC list (Regulation EU 649/2012)

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

Not listed on the POP list (Regulation EU 2019/1021)

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

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

###### 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

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the Vietnam National Chemical Database (as amended through 31 July 2018)

###### Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

###### Netherlands

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed

SZW-lijst van reprotoxische stoffen – : The substance is not listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

#### 15.2. Chemical safety assessment

CSA has not been established

### SECTION 16: Other information

#### Indication of changes

Section	Changed item	Change	Comments
	SDS EU format according to COMMISSION REGULATION (EU) 2020/878		

#### Abbreviations and acronyms:

SDS	Safety Data Sheet
CAS	CAS - Chemical Abstracts Service

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Abbreviations and acronyms:	
GHS	GHS - Globally Harmonised System
CSR	CSR - Chemical Safety Report
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
DNEL	Derived-No Effect Level
EC50	Effective concentration for 50 percent of test population (median effective concentration)
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Lethal concentration for 50 percent of test population (median lethal concentration)
LD50	Lethal dose for 50 percent of test population (median lethal dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
RID	Regulation concerning the International Carriage of Dangerous Goods by Railways
PVC	PVC (Polyvinyl chloride).
PNEC	Predicted No-Effect Concentration
PBT	Persistent Bioaccumulative Toxic
vPvB	Very Persistent and Very Bioaccumulative
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No 1907/2006

Sources of Key data

: Supplier information. Safety Data Sheet. REACH registration dossier.

Other information

: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. 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.

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

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.