

Printing date: 01.03.2018

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Trade name: **BIOMIMESYS® Liver**

Safety data sheet

according to 1907/2006/EC, Article 31

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

1.1 Product identifier

· Trade name: **BIOMIMESYS® Liver**

1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

· **Application of the substance / the preparation :** Preparation

1.3 Details of the supplier of the safety data sheet

· **Manufacturer/Supplier:**

HCS Pharma

250 rue Salvador Allende, 59120 LOOS

tel: +33(0)9 72 44 83 88

Mail: hello@biomimesys.com

1.4 Emergency telephone number:

France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59

Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24)

UK : +44 (0)-870-190-6777 (CARECHEM24)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

· **Classification according to Regulation**

(EC) No 1272/2008 : The product is not classified according to the CLP regulation.

2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008** Not classified as hazardous for transport

· **Hazard pictograms** Not classified as hazardous for transport

· **Signal word** Not classified as hazardous for transport

· **Hazard statements** Not classified as hazardous for transport

2.3 Other hazards

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

- **Description:** Mixture: consisting of the following components.
- **Dangerous components:** Not classified as hazardous for transport
- **Other components:**

CAS: 9067-32-7

SODIUM HYALURONAT

TAIL RAT TYPE I COLLAGEN-SOLUTION



Eye Dam. 1,
H318;



Skin Irrit. 2, H315

- **Additional information:** For the wording of the listed risk phrases, ref section 16

SECTION 4: First aid measures

4.1 Description of first aid measures

- **General information:** No special measures required.
- **After excessive inhalation:** Provide fresh air; consult a doctor in case of medical complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult a doctor.

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

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed :

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Suitable extinguishing agents:

- CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture: No further relevant information available.

5.3 Advice for firefighters

- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures : Not required.

6.2 Environmental precautions: Do not allow the product to enter sewers/ surface water or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4 Reference to other sections :

See Section 7 for information on safe handling.

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

SECTION 7: Exposure controls/personal protection

7.1 Precautions for safe handling : No special measures required.

· **Information about fire - and explosion protection:** No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** <8 °C

· **Information about storage in one common storage facility:** <8 °C

· **Further information about storage conditions:** None.

7.3 Specific end use(s) : No further relevant information available.

SECTION 8: Handling and storage

· **Additional information about design of technical facilities:** No further data; see section 7.

8.1 Control parameters

· **Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:**

The most current valid lists have been used as a basis for the production of this document.

8.2 Exposure controls

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:** Not required.

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- **Protection of hands:** Not required.
- **Gloves material :**
The selection of suitable gloves does not depend only on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.
- **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:

lyophilized
According to product
specification

Colour:

· Odour:

Characteristic

· Odour threshold:

Not determined.

· pH-value:

Not determined.

· Change in condition

· Melting point/Melting range:

Undetermined.

· Boiling point/Boiling range:

Undetermined.

· Flash point:

Not applicable.

· Flammability (solid, gaseous):

Not applicable.

· Ignition temperature:

Not applicable.
Not

· Decomposition temperature:

determined.

· Self-igniting:

Product is not self igniting.

· Danger of explosion:

Product does not present an explosion hazard.

· Explosion limits:

Lower:

Not determined.

Upper:

Not determined

· Vapour pressure:

Not determined.

· Density:

Not determined.

· Relative density :

Not determined.

· Vapour density :

Not determined.

· Evaporation rate :

Not determined.

· Solubility in / Miscibility with water:

Insoluble.

· Segregation coefficient (n-octanol/water):

Not determined.

· Viscosity:

· Dynamic:

Not determined.

· Kinematic:

Not determined.

9.2 Other information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications. **10.3 Possibility of hazardous reactions :** No dangerous reactions known.

10.4 Conditions to avoid : No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

· **Acute toxicity**

· **Primary irritant effect:**

· **On the skin:** Based on available data, the classification criteria are not met.

· **On the eyes:** Based on available data, the classification criteria are not met.

· **Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

· **Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

· **Carcinogenicity:** Based on available data, the classification criteria are not met.

· **Reproductive toxicity:** Based on available data, the classification criteria are not met.

· **STOT-single exposure:** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure:** Based on available data, the classification criteria are not met.

· **Aspiration hazard:** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

· **Aquatic toxicity:** No further relevant information available.

12.2 Persistence and degradability : No further relevant information available.

12.3 Bioaccumulative potential : No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Trade name: BIOMIMESYS® Liver

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

12.6 Other adverse effects : No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number

- **ADR, ADN, IMDG, IATA** Not classified as hazardous for transport

14.2 UN proper shipping name

- **ADR, ADN, IMDG, IATA** Not classified as hazardous for transport

14.3 Transport hazard class(es)

- **ADR, IMDG, IATA**

· Class

Not classified as hazardous for transport

14.4 Packing group

- **ADR, IMDG, IATA**

Not classified as hazardous for transport

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of

- **Marpol and the IBC Code** Not applicable.

- **UN "Model Regulation":** Not classified as hazardous for transport

SECTION 15: Regulatory information

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

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IGHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative