

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:

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| | |
|--|---|
| CAS: 9067-32-7 | SODIUM HYALURONATE |
| . | TAIL RAT TYPE I COLLAGEN-SOLUTION |
| |  Eye Dam. 1, H318;  Skin Irrit. 2, H315 |
| · Additional information: For the wording of the listed risk phrases, refer to 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.

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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.
- **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 |
| Colour: | According to product specification |
- **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.
- **Decomposition temperature:** Not determined.

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| | |
|---|--|
| · Self-igniting: | <i>Product is not self igniting.</i> |
| · Danger of explosion: | <i>Product does not present an explosion hazard.</i> |
| · Explosion limits: | |
| Lower: | <i>Not determined.</i> |
| Upper: | <i>Not determined</i> |
| · Vapour pressure: | <i>Not determined.</i> |
| · Density: | <i>Not determined.</i> |
| · Relative density : | <i>Not determined.</i> |
| · Vapour density : | <i>Not determined.</i> |
| · Evaporation rate : | <i>Not determined.</i> |
| · Solubility in / Miscibility with water: | <i>Insoluble.</i> |
| · Segregation coefficient (n-octanol/water): | <i>Not determined.</i> |
| · Viscosity: | |
| · Dynamic: | <i>Not determined.</i> |
| · Kinematic: | <i>Not determined.</i> |

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 (carcinogenity, 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.*

Trade name: **BIOMIMESYS® LIVER****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:**

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