

**Trade name: BIOMIMESYS® Adipose tissue**

## **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](mailto: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
· <b>Additional information:</b> 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:**

- CO<sub>2</sub>, 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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· <b>Self-igniting:</b>	<i>Product is not self igniting.</i>
· <b>Danger of explosion:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Explosion limits:</b>	
<b>Lower:</b>	<i>Not determined.</i>
<b>Upper:</b>	<i>Not determined</i>
· <b>Vapour pressure:</b>	<i>Not determined.</i>
· <b>Density:</b>	<i>Not determined.</i>
· <b>Relative density :</b>	<i>Not determined.</i>
· <b>Vapour density :</b>	<i>Not determined.</i>
· <b>Evaporation rate :</b>	<i>Not determined.</i>
· <b>Solubility in / Miscibility with water:</b>	<i>Insoluble.</i>
· <b>Segregation coefficient (n-octanol/water):</b>	<i>Not determined.</i>
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	<i>Not determined.</i>
· <b>Kinematic:</b>	<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® Adipose tissue****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*