



Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

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: <u>BIOMIMESYS[®] Adipose Tissue</u>
- 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.





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: BIOMIMESYS® Adipose Tissue

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, Skin Irrit. 2, H315 H318; |
| 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.





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: <u>BIOMIMESYS[®] Adipose Tissue</u>

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</p>
- · 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 signifiant 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.





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: BIOMIMESYS® Adipose Tissue

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

Colour: specification Characteristic

Odour threshold: Not determined.pH-value: Not determined.

· Change in condition

Melting point/Melting range:
Boiling point/Boiling range:
Flash point:
Flammability (solid, gaseous):
Ignition temperature:

Undetermined.
Not applicable.
Not applicable.
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:
Upper:
Not determined.
Vapour pressure:
Not determined.
Density:
Not determined.
Relative density:
Not determined.
Vapour density:
Not determined.
Not determined.
Not determined.
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.





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: BIOMIMESYS® Adipose Tissue

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.

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:





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: BIOMIMESYS® Adipose Tissue

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.





Printing date: 01.03.2018 Version number: 1 Revision 01.03.2018

Trade name: BIOMIMESYS® Adipose Tissue

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