

## **Safety data sheet**

**according to 1907/2006/EC, Article 31**

Printing date 11.03.2018

Version 1

Revision date: 11.03.2018

### **1 Identification of the substance/mixture and of the company/undertaking**

· **Product identifier**

· **Trade name:** CryoStem hPSC Freezing Medium

· **Article number:** 05-710-1

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

· **Application of the substance / the mixture**

CryoStem Freezing Medium is a ready-to-use solution for the serum-free, animal component-free cryopreservation of human embryonic stem (ES) cells and induced pluripotent stem (iPS) cells. Cells preserved with CryoStem Freezing Medium show high viability and recovery after thawing, and express typical pluripotent markers in culture. CryoStem Freezing Medium maintains xeno-free conditions during cryopreservation when culturing cells in a xeno-free environment. CryoStem Freezing Medium has been tested on human ES cells (H1, H9 and HuES9). Superior results were obtained in comparison with both serum-containing freezing media as well as competing serum-free products.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Biological Industries Israel Beit Haemek Ltd.

BEIT HAEMEK 25115

ISRAEL

michalb@bioind.com

· **Further information obtainable from:** Product safety department.

· **Emergency telephone number:** During normal opening times: +972/4/9962467

### **2 Hazards identification**

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

· **Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

· **Precautionary statements**

P264 Wash thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

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P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 67-68-5	dimethyl sulfoxide	<15%
EINECS: 200-664-3	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Expl. 1.5, H205	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of 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 doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Avoid formation of dust.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** No special measures required.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Prevent formation of dust.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** 2-8 °C
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** Not required
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
*The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.*
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
*In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.*
- **Protection of hands:**  
*The glove material has to be impermeable and resistant to the product/substance/preparation  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**  
*The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies 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 prior to the application.*
- **Penetration time of glove material**  
*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*
- **Eye protection:** Not required.

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### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Liquid
· <b>Colour:</b>	Light red
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· <b>Melting point/freezing point:</b>	Undetermined.
· <b>Initial boiling point and boiling range:</b>	100 °C

· **Flash point:** 89 °C

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** 270 °C

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	1.8 Vol %
· <b>Upper:</b>	63 Vol %

· **Vapour pressure at 20 °C:** 23 hPa

· **Density:** Not determined.

· **Relative density:** Not determined.

· **Vapour density:** Not determined.

· **Evaporation rate:** Not determined.

· **Solubility in / Miscibility with water:**

Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.

· **Solvent content:**

· <b>Organic solvents:</b>	<15 %
· <b>Water:</b>	>88 %
· <b>VOC (EC)</b>	<15 %

· **Solids content:** <1.5 %

· **Other information:** No further relevant information available.

### 10 Stability and reactivity

· **Reactivity:** No further relevant information available.

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- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** 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.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                                                             |                 |
|-----------------------------------------------------------------------------|-----------------|
| · <b>UN-Number</b>                                                          |                 |
| · <b>ADR, IMDG, IATA</b>                                                    | not regulated   |
| · <b>UN proper shipping name</b>                                            |                 |
| · <b>ADR, IMDG, IATA</b>                                                    | not regulated   |
| · <b>Transport hazard class(es)</b>                                         |                 |
| · <b>ADR, IMDG, IATA</b>                                                    |                 |
| · <b>Class</b>                                                              | not regulated   |
| · <b>Packing group</b>                                                      |                 |
| · <b>ADR, IMDG, IATA</b>                                                    | not regulated   |
| · <b>Environmental hazards:</b>                                             | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                             | not regulated   |

### 15 Regulatory information

- **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.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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.*

- **Relevant phrases**  
*H205 May mass explode in fire.*  
*H315 Causes skin irritation.*  
*H319 Causes serious eye irritation.*
- **Department issuing SDS:** Product safety department.
- **Contact:** Ms. BADICHI GITLIN
- **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*  
*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*  
*EINECS: European Inventory of Existing Commercial Chemical Substances*

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*ELINCS: European List of Notified Chemical Substances*

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

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Expl. 1.5: Explosives – Division 1.5*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

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