

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/11/2018

Version 1

Reviewed on 03/11/2018

1 Identification

· **Product identifier**

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

· **Article number:** 05-710-1

· **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

· **Information department:** Product safety department.

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

2 Hazard(s) identification

· **Classification of the substance or mixture**



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Flam. Liq. 4 H227 Combustible liquid.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

Combustible liquid.

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Keep away from flames and hot surfaces. – No smoking.

Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

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If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

67-68-5	dimethyl sulfoxide
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<15%

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.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

PAC-1:

67-68-5	dimethyl sulfoxide	150 ppm
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	30 mg/m ³
144-55-8	sodium hydrogencarbonate	13 mg/m ³
1310-73-2	sodium hydroxide	0.5 mg/m ³
10035-04-8	CALCIUM CHLORIDE DIHYDRATE	16 mg/m ³
7791-18-6	Magnesium chloride hexahydrate	34 mg/m ³
113-24-6	sodium pyruvate	30 mg/m ³
10034-99-8	MAGNESIUM SULFATE HEPTAHYDRATE	33 mg/m ³
7647-01-0	hydrogen chloride	1.8 ppm
34487-61-1	sodium hydrogen 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bisphenolate S,S-dioxide	12 mg/m ³
98-92-0	nicotinamide	5.6 mg/m ³

PAC-2:

67-68-5	dimethyl sulfoxide	290 ppm
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	330 mg/m ³
144-55-8	sodium hydrogencarbonate	140 mg/m ³
1310-73-2	sodium hydroxide	5 mg/m ³
10035-04-8	CALCIUM CHLORIDE DIHYDRATE	170 mg/m ³
7791-18-6	Magnesium chloride hexahydrate	370 mg/m ³
113-24-6	sodium pyruvate	330 mg/m ³
10034-99-8	MAGNESIUM SULFATE HEPTAHYDRATE	370 mg/m ³
7647-01-0	hydrogen chloride	22 ppm
34487-61-1	sodium hydrogen 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bisphenolate S,S-dioxide	130 mg/m ³
98-92-0	nicotinamide	62 mg/m ³

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· PAC-3:		
67-68-5	dimethyl sulfoxide	1,800 ppm
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	2,000 mg/m ³
144-55-8	sodium hydrogencarbonate	840 mg/m ³
1310-73-2	sodium hydroxide	50 mg/m ³
10035-04-8	CALCIUM CHLORIDE DIHYDRATE	1,100 mg/m ³
7791-18-6	Magnesium chloride hexahydrate	1,600 mg/m ³
113-24-6	sodium pyruvate	2,000 mg/m ³
10034-99-8	MAGNESIUM SULFATE HEPTAHYDRATE	2,300 mg/m ³
7647-01-0	hydrogen chloride	100 ppm
34487-61-1	sodium hydrogen 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bisphenolate S,S-dioxide	790 mg/m ³
98-92-0	nicotinamide	690 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Prevent formation of dust.
- **Information about protection against explosions and fires:** 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:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

67-68-5 dimethyl sulfoxide
WEEL Long-term value: 250 ppm

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the 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

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- **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.

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Liquid
Color:	Light red
Odor:	Characteristic
Odor threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	100 °C (212 °F)

- **Flash point:** 89 °C (192.2 °F)

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:** 270 °C (518 °F)

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Not determined.

- **Explosion limits:**

Lower:	1.8 Vol %
Upper:	63 Vol %

- **Vapor pressure at 20 °C (68 °F):** 23 hPa (17.3 mm Hg)

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

Water: Fully miscible.

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

- **Viscosity:**

Dynamic:	Not determined.
Kinematic:	Not determined.

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· Solvent content:	
Organic solvents:	<15 %
Water:	>88 %
VOC content:	<15 %

Solids content:	<1.5%
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

7647-01-0	hydrogen chloride	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (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 of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · DOT, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· Section 355 (extremely hazardous substances):
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7647-01-0	hydrogen chloride
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· Section 313 (Specific toxic chemical listings):
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7647-01-0	hydrogen chloride
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· TSCA (Toxic Substances Control Act):

67-68-5	dimethyl sulfoxide
7647-14-5	sodium chloride
50-99-7	glucose
7365-45-9	4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
144-55-8	sodium hydrogencarbonate
9004-67-5	Methyl cellulose 4000CP
56-85-9	levoglutamide
7447-40-7	potassium chloride
1310-73-2	sodium hydroxide
72-19-5	L-threonine
7558-79-4	disodium hydrogenorthophosphate
657-27-2	lysine hydrochloride
113-24-6	sodium pyruvate
7647-01-0	hydrogen chloride
147-85-3	L-proline
61-90-5	L-leucine
72-18-4	valine
73-32-5	L-isoleucine
63-91-2	3-phenyl-L-alanine
60-18-4	tyrosine
56-45-1	L-serine
56-89-3	cystine
128446-35-5	(2-Hydroxypropyl)- β -cyclodextrin
87-89-8	myo-inositol
63-68-3	L-methionine
67-48-1	choline chloride
56-86-0	glutamic acid
56-84-8	aspartic acid
56-41-7	L-alanine
34487-61-1	sodium hydrogen 4,4'-(3H-2,1-benzoxathiol-3-ylidene)bisphenolate S,S-dioxide

· Proposition 65
· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

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· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

7647-01-0 hydrogen chloride

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard statements**

Combustible liquid.

Causes skin irritation.

Causes serious eye irritation.

· **Precautionary statements**

Keep away from flames and hot surfaces. – No smoking.

Wash thoroughly after handling.

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of water.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Specific treatment (see on this label).

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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.

· **Department issuing SDS:** Product safety department.

· **Contact:** Ms. BADICHI GITLIN

· **Date of preparation / last revision** 03/11/2018 / -

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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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)
NFPA: National Fire Protection Association (USA)
HMS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flam. Liq. 4: Flammable liquids – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

US