

Safety Data Sheet

acc. to OSHA HCS

Printing date 03/11/2018

Version 1

Reviewed on 01/01/2018

1 Identification

· **Product identifier**

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

· **Article number:** 05-712-1

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

MSC Freezing Medium is a chemically defined, animal component-free and protein-free formulation, designed for optimal cryopreservation of human mesenchymal stem cells from a variety of sources, including bone marrow (BM-MSC), adipose tissue (AT-MSC) and umbilical cord tissue (UC-MSC).

When culturing cells under serum free conditions, it is important to cryopreserve the cells also in a solution free of serum. The novel MSC Freezing Solution contains methylcellulose and DMSO in place of serum. After freezing and thawing, a very high percentage of viable hMSCs are obtained with excellent attachment ability as well as growth performance.

· **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**



GHS07

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	<15%
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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:** Protect from heat and direct sunlight.
- **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 | <i>not regulated</i> |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | <i>not regulated</i> |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | <i>not regulated</i> |
| · Packing group | |
| · DOT, IMDG, IATA | <i>not regulated</i> |
| · Environmental hazards: | |
| · Marine pollutant: | <i>No</i> |
| · Special precautions for user | <i>Not applicable.</i> |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | <i>Not applicable.</i> |
| · UN "Model Regulation": | <i>not regulated</i> |

15 Regulatory information

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

 · **Section 355 (extremely hazardous substances):**

7647-01-0	hydrogen chloride
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· Section 313 (Specific toxic chemical listings):

7647-01-0 hydrogen chloride

· 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
56-86-0	glutamic acid
67-48-1	choline chloride
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.

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· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **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)

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IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
ACGIH: American Conference of Governmental Industrial Hygienists
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)
HMIS: 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