

Page 1/6

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 23.03.2020 Revision 1 Revision date: 23.03.2020

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

- · Product identifier
- · Trade name: MSCgoTM Rapid Osteogenic SF, XF
- · Article number: 05-442-1
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture

 $MSCgo^{TM}$ Rapid Osteogenic Differentiation Medium is a serum-free (SF), xeno-free (XF), complete, and ready to use formulation developed for optimal differentiation of human mesenchymal stem cells (hMSC) to mature osteocytes. The $MSCgo^{TM}$ Rapid Osteogenic Differentiation Medium is validated to efficiently differentiate hMSC from a variety of sources, including bone marrow (BM-MSC), adipose tissue (AT-MSC), and umbilical cord tissue (UC-MSC).

- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Biological Industries Israel Beit Haemek Ltd.

BEIT HAEMEK 2511500

ISRAEL

Michal.badihi@sartorius.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

 The product is not classified, according to the CLP regulation.
- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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: Void
- · Additional information:

All other ingredients in the proportions used are considered non-hazardous by regulating bodies worldwide

4 First aid measures

- · Description of first aid measures
- · General information: No special measures required.

(Contd. on page 2)



Page 2/6

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 23.03.2020 Revision 1 Revision date: 23.03.2020

Trade name: MSCgoTM Rapid Osteogenic SF, XF

(Contd. of page 1)

- · 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. If symptoms persist, consult a doctor.
- · After swallowing: Wash mouth with water if person is conscious and seek medical advice.
- · 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: Use fire extinguishing methods suitable to surrounding conditions.
- · 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 Not required
- · Environmental precautions: No special measures required.
- · 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.

7 Handling and storage

- · Handling:
- · Precautions for safe handling No special precautions are necessary if used correctly.
- · 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 $^{\circ}$ C-8 $^{\circ}$ 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.

(Contd. on page 3)





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(Contd. of page 2)

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Protection of hands:

The glove material has to be impermeable and ressistante to the product/substace/preperation

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: Safety glasses

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· Information on basic physical and chem	ical properties
· General Information	
· Appearance:	
Form:	Solution
Colour:	Clear red
· Odour:	Uncharacteristic.
· Odour threshold:	Not determined.
· pH-value at 20 °C:	7.1-7.6
· Change in condition	
Melting point/freezing point:	0 °C
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not applicable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	23 hPa
· Density at 20 °C:	1 g/cm³
· Relative density	Not determined.

(Contd. on page 4)



Page 4/6

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 23.03.2020 Revision 1 Revision date: 23.03.2020

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Biological Industries

		(Contd. of page
· Vapour 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.	
· Solvent content:		
Organic solvents:	0.0 %	
Water:	>97.0 %	
VOC (EC)	<0.1 %	
Solids content:	<0.3 %	
· 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 Based on available data, the classification criteria are not met.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation 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.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: Not toxic to the aquatic life
- · Persistence and degradability No further relevant information available.

(Contd. on page 5)



Page 5/6

Safety data sheet according to 1907/2006/EC, Article 31

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(Contd. of page 4)

- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Not hazardous for water.
- · Results of PBT and vPvB assessment
- \cdot **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation No special recommendation
- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

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

15 Regulatory information

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture} \\$
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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Page 6/6

Safety data sheet according to 1907/2006/EC, Article 31

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Trade name: MSCgoTM Rapid Osteogenic SF, XF

(Contd. of page 5)

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
- · 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

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

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