

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.07.2020

Version 2

Revision date: 22.11.2017

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

· **Product identifier**

· **Trade name:** MSC NutriStem® XF Supplement Mix

· **Article number:** 05-201-1

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

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

MSC NutriStem® XF Medium is a defined, serum-free, xeno-free culture medium designed for optimal growth and expansion of human mesenchymal stem/stromal cells (hMSC) derived from a variety of sources, including bone marrow (BM-MSC), adipose tissue (AT-MSC) and umbilical cord matrix (UC-MSC). MSC NutriStem® XF Medium supports long-term growth of hMSC while maintaining their self-renewal and multi-lineage differentiation potential.

· **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.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

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- **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 protective equipment required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Use personal protective equipment. Clean contaminated surfaces thoroughly.
- **Environmental precautions:** Use personal protective equipment. Clean contaminated surfaces thoroughly.
- **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.
Avoid freeze/thaw cycles
- **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:** (-10)-(-20) °C
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Avoid exposure to light.
- **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.

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- **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:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** *Not required*
- **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:** *Safety glasses*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solution
Colour:	Clear
Odour:	Uncharacteristic.
Odour threshold:	Not determined.
- **pH-value:** *Not applicable.*
- **Change in condition**

Melting point/freezing point:	Undetermined.
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.
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Upper:	Not determined.
· 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:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Water:	>70.0 %
VOC (EC)	0.00 %
· Solids content:	<1.0 %
· 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 (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.

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12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** Not toxic to the aquatic life
- **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** No special recommendation
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- | | |
|-----------------------------------------------------------------------------|-----------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

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· **UN "Model Regulation":** 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.
- **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
- **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