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# Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.03.2020

Version 1

Revision date: 22.03.2020

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

- · Product identifier
- Trade name: <u>MSCgo<sup>TM</sup> Adipogenic</u> SF XF Supplement mix 1
- · Article number: 05-331-1-01
- **Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- $\cdot$  Application of the substance / the mixture

 $MSCgo^{TM}$  Adipogenic Differentiation Medium is a serum-free and xeno-free formulation developed for optimal differentiation of human mesenchymal stem cells (hMSC) to mature adipocytes. The  $MSCgo^{TM}$  Adipogenic Differentiation Medium kit includes a basal medium and two supplement mixes, containing all growth factors and supplements necessary for a complete adipogenic differentiation medium.

- $\cdot$  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 GHS06 skull and crossbones Acute Tox. 3 H301 Toxic if swallowed. GHS08 health hazard Repr. 1A H360-H362 May damage fertility or the unborn child. May cause harm to breast-fed children. STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure. GHS05 corrosion Eye Dam. 1 H318 Causes serious eye damage. GHS07 Skin Sens. 1 H317 May cause an allergic skin reaction. · Label elements · Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation. (Contd. on page 2)



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Version 1 Revision date: 22.03.2020 Printing date 30.03.2020 Trade name: MSCgo<sup>™</sup> Adipogenic SF XF Supplement mix 1 (Contd. of page 1) · Hazard pictograms GHS05 GHS06 GHS08 · Signal word Danger · Hazard-determining components of labelling: Indometacin 3,7-dihydro-3-isobutyl-1-methyl-1H-purine-2,6-dione · Hazard statements H301 Toxic if swallowed. H318 Causes serious eye damage. H317 May cause an allergic skin reaction. H360-H362 May damage fertility or the unborn child. May cause harm to breast-fed children. *H373* May cause damage to organs through prolonged or repeated exposure. · Precautionary statements P263 Avoid contact during pregnancy and while nursing. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. P321 Specific treatment (see on this label). P330 Rinse mouth. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P362+P364 Take off contaminated clothing and wash it before reuse. P405 Store locked up. P501 Dispose of contents/container in accordance with local/regional/national/international regulations. · Other hazards

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components: 3,7-dihydro-3-isobutyl-1-methyl-1H-purine-2,6-dione CAS: 28822-58-4 <15.0% 🕐 Acute Tox. 4, H302 CAS: 53-86-1 Indometacin <10.0% EINECS: 200-186-5 🛞 Acute Tox. 2, H300; 🚸 Repr. 1A, H360-H362; STOT RE 1, H372; 🗞 Eye Dam. 1, H318; 🕦 Skin Sens. 1, H317; Aquatic Chronic 3, H412 CAS: 67-68-5 dimethyl sulfoxide <85.0% EINECS: 200-664-3

# · Additional information:

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

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· Results of PBT and vPvB assessment · **PBT:** Not applicable. · vPvB: Not applicable. 3 Composition/information on ingredients · Chemical characterisation: Mixtures



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# 4 First aid measures

#### · Description of first aid measures

- · General information:
- Immediately remove any clothing soiled by the product.
- In case of irregular breathing or respiratory arrest provide artificial respiration.
- After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: Do not induce vomiting; call for medical help immediately.
- 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: Wear self-contained respiratory protective device.

#### 6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Use personal protective equipment. Clean contaminated surfaces thoroughly. Do not touch or walk through spilled material.
- · Environmental precautions: Do not allow product to reach sewage system or any water course.
- *Methods and material for containment and cleaning up:* Absorb liquid components with liquid-binding material. Dispose of the material collected according to regulations. Ensure adequate ventilation.

#### • **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
- Ensure good ventilation/exhaustion at the workplace.
- Prevent formation of aerosols.
- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- $\cdot$  Requirements to be met by storerooms and receptacles: (-10)-(-20)  $^{\circ}C$

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- Information about storage in one common storage facility: Store in a well-ventilated place. Keep cool. • Further information about storage conditions:
- Store away from incompatible materials. See Section 10 for information on Incompatible Materials. Keep out of the reach of children.
- 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: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Avoid contact with the eyes and skin.
- Avoid contact with the eyes and skin.
- 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:



Protective gloves

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.

Wear protective gloves. Butyl or nitrile rubber gloves are recommended. Consult manufacturer specifications for further information.

#### · 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:* 



Tightly sealed goggles



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Wear safety glasses with side shields.

Information on basic physical and chem	nical properties	
General Information	neur properties	
Appearance:		
Form:	Solution	
Colour:	Colorless	
Odour:	Uncharacteristic.	
Odour threshold:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	2: 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:	0.6 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:		
Organic solvents:	<85.0 %	
VOC (EC)	<85.0 %	
Solids content:	<20.0 %	
Other information	No further relevant information available.	

# 10 Stability and reactivity

 $\cdot \textit{Reactivity Contact with incompatible materials. Sources of ignition. Exposure to heat.}$ 

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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 Contact with incompatible materials. Sources of ignition. Exposure to heat.
- Incompatible materials: Strong oxidizers. Perchlorates.
- Hazardous decomposition products: No dangerous decomposition products known.

## 11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity
- Toxic if swallowed.
- · LD/LC50 values relevant for classification:

67-68-5 dimethyl sulfoxide

Oral LD50 14,500 mg/kg (rat)

- · Primary irritant effect:
- Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation
- Causes serious eye damage.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- · 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

May damage fertility or the unborn child. May cause harm to breast-fed children.

- STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure
- May cause damage to organs through prolonged or repeated exposure.
- · Aspiration hazard Based on available data, the classification criteria are not met.

## 12 Ecological information

- · Toxicity
- · Aquatic toxicity: Very toxic to 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 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

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

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Transport/Additional information:
 ADR
 Limited quantities (LQ)
 Excepted quantities (EQ)
 Transport category
 Transport category
 Tunnel restriction code



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·IMDG			
· Limited quantities (LQ)	100 ml		
• Excepted quantities (EQ)	Code: E4		
	Maximum net quantity per inner packaging: 1 ml		
	Maximum net quar	ntity per outer packaging: 500 ml	
• UN "Model Regulation": UN 2810 TOXIC LIQUID, ORGAN (INDOMETACIN), 6.1, II			

# 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.
- · Seveso category H2 ACUTE TOXIC
- $\cdot$  Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- $\cdot$  Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 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

H300 Fatal if swallowed.
H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
H372 Causes damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

· 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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 2: Acute toxicity - oral – Category 2 Acute Tox. 3: Acute toxicity - oral - Category 3 Acute Tox. 4: Acute toxicity - oral - Category 4



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Eye Dam. 1: Serious eye damage/eye irritation – Category 1 Skin Sens. 1: Skin sensitisation – Category 1 Repr. 1A: Reproductive toxicity – Category 1A STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1 STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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