

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

- **Product identifier**

- **Trade name:** BIO-AMF™-1 Basal Medium

- **Article number:** 01-190-1

- **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

- **Application of the substance / the mixture**

BIO-AMF™-1 is designed for the primary culture of human amniotic fluid cells and chorionic villi (CV) samples in both open (5% CO₂) and closed systems. The medium allows rapid growth of amniocytes or chorionic villi for use in karyotyping.

No supplementation with serum or serum-substitutes is necessary. This medium consists of two components: basal medium and frozen supplement.

- **Details of the supplier of the safety data sheet**

- **Manufacturer/Supplier:**

Biological Industries Israel Beit Haemek Ltd.

BEIT HAEMEK 25115

ISRAEL

michalb@bioind.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:** For the wording of the listed risk phrases refer to section 16.

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.

- **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.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, 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** 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 measures required.
- **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:**
BIO-AMF™-1 Basal Medium is stable for 15 months from production date when stored at 2-8°C.
BIO-AMF™-1 Supplement is stable for 24 months from production date when stored at -20°C.
The complete medium is stable for 14 days when stored at 2-8°C. Do not freeze the complete medium.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Protect from exposure to the 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.
- **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

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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:** Not required.

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Liquid

Colour: Red

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

· **Flash point:** Not applicable.

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

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

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:**

Organic solvents: 0.0 %

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Water:	>85 %
VOC (EC)	0.00 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **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:** Not available
- **on the eye:** Not available
- **Sensitisation:** Not available
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **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:** Not known to be hazardous to water.
- **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

- | | |
|---|-----------------|
| · UN-Number
· ADR, IMDG, IATA | not regulated |
| · UN proper shipping name
· ADR, IMDG, IATA | not regulated |
| · Transport hazard class(es)
· ADR, 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 MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **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 MSDS:** 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)

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