

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

- **Product identifier**

- **Trade name:** Gentamycin sulfate solution 50mg/ml

- **Article number:** 03-035-1

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

No further relevant information available.

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

Gentamycin Sulfate Solution is a 50 mg/mL broad-spectrum aminoglycoside antibiotic solution used as a supplement to cell culture media to control bacterial contamination. The Gentamicin Sulfate Solution is effective against gram positive and gram negative bacteria. Gentamicin Sulfate inhibits protein synthesis, leading to the death of susceptible bacteria.

- **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**



GHS08 health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



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.

- **Hazard pictograms**



GHS08

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Gentamicin sulfate

- **Hazard statements**

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

- **Precautionary statements**

P285 In case of inadequate ventilation wear respiratory protection.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P321 Specific treatment (see on this label).

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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:**

CAS: 1405-41-0	Gentamicin sulfate	7.404%
EINECS: 215-778-9	⚠ Resp. Sens. 1, H334; ⚠ Skin Sens. 1, H317	

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
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.
- **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.

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:** Not required.
- **Methods and material for containment and cleaning up:**
No special measures required.
Dispose contaminated material as waste according to item 13.
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.

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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:** *No special measures required.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** *Ambient temperature*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:** *None.*
- **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
Wash hands before breaks and at the end of work.*
- **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 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:** *Not required.*

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9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Liquid
· Colour:	Colorless to yellowish
· 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 %
· Water:	>92 %
· 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.

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· **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:***Sensitisation possible through inhalation.**Sensitisation possible through skin contact.*· **Additional toxicological information:***The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:**Harmful**Irritant*

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:** *Generally not hazardous for 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***Must not be disposed together with household garbage. Do not allow product to reach sewage system.*· **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*

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|--|-----------------|
| · 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.

- **Relevant phrases**
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **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)
Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

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