

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

- **Product identifier**

- **Trade name:** Amphotericin B (10X) Solution

- **Article number:** 03-029-1

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

No further relevant information available.

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

Amphotericin B (10X) Solution is a concentrated mixture of anti-mycotic polyenes and is used in cell culture for the control of fungi, yeasts, molds and gram positive bacteria. Amphotericin B (10X) Solution prevents the contamination of cell cultures of by increasing the permeability of fungal plasma membranes.

- **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**



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



- **Signal word** Warning

- **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- **Precautionary statements**

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

P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P362 Take off contaminated clothing and wash before reuse.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

# Safety data sheet

according to 1907/2006/EC, Article 31

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### 3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1310-58-3	potassium hydroxide	0.563%
EINECS: 215-181-3	⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302	

- **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:** 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:** 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:**  
CO<sub>2</sub>, 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.  
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:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** (-10)-(-20)°C

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- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in the dark.
- **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:**

**1310-58-3 potassium hydroxide**

WEL Short-term value: 2 mg/m<sup>3</sup>

- **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.  
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 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:**



Tightly sealed goggles

## 9 Physical and chemical properties

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

**Form:** Liquid  
**Colour:** Not determined.

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· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not applicable.
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Ignition temperature:</b>	
<b>Decomposition temperature:</b>	Not determined.
· <b>Self-igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure at 20 °C:</b>	23 hPa
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Fully miscible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	>98 %
<b>VOC (EC)</b>	0.00 %
· <b>Other information</b>	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:** Irritant to skin and mucous membranes.

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- **on the eye:** Irritating effect.
- **Sensitisation:** Not available
- **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:  
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**

- |   |   |
|---|---|
| · <b>UN-Number</b>  |   |
| · <b>ADR, IMDG, IATA</b>  | UNI760  |
| · <b>UN proper shipping name</b>  |   |
| · <b>ADR</b>  | 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE) |
| · <b>IMDG, IATA</b>   | CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE)      |
| · <b>Transport hazard class(es)</b>   |   |
| · <b>ADR, IMDG, IATA</b>  |   |
|  |   |
| · <b>Class</b>  | 8 Corrosive substances.                             |
| · <b>Label</b>  | 8   |
| · <b>Packing group</b>  |   |
| · <b>ADR, IMDG, IATA</b>  | III   |
| · <b>Environmental hazards:</b>   |   |
| · <b>Marine pollutant:</b>  | No  |

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· <b>Special precautions for user</b>	Warning: Corrosive substances.
· <b>Danger code (Kemler):</b>	80
· <b>EMS Number:</b>	F-A,S-B
· <b>Segregation groups</b>	Alkalis
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN1760, CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE), 8, III

**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**  
H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.
- **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)  
Acute Tox. 4: Acute toxicity, Hazard Category 4  
Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A  
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2  
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2