

PRODUCT SAFETY DATA SHEET

Product name: Biolon® 1.0 mL



SDS Version: Version 1.0

Revision date: 7/9/2018

Print date: 8/15/2018

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY

Product name: Biolon ® 1mL
(10mg/mL Sodium Hyaluronate)
Intraocular Injection Solution - Disposable prefilled sterile syringe and cannula

Finished Form: Liquid

Trade Name: N/A

Synonyms: N/A

Intended Use:

Intended Use: Biolon® is indicated for use as a surgical aid to protect corneal endothelium during cataract extraction (extra-capsular) procedures, intraocular lens (IOL) implantation and anterior segment surgery. When introduced in the anterior segment of the eye during these surgical procedures, Biolon® serves to maintain a deep anterior chamber. In addition, Biolon® helps to push back the vitreous face and prevent formation of a post-operative flat chamber.

Manufacturer's name:

Bio-Technology General (Israel) Ltd.

Manufacturer's address:

Be'er Tuvia Industrial Zone

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Kiryat Malachi 83104

Israel

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Emergency telephone number:

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2. HAZARDS IDENTIFICATION

2.1 Substance or mixture classification

GHS Classification in accordance with 29 CFR 1910.1200(d)

Not a hazardous substance or mixture

2.2 GHS Label Elements

Not a hazardous substance or mixture

2.3 Hazards not otherwise classified - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Amount per 1 ml
Sodium hyaluronate	10 mg
Sodium chloride	8.5 mg
Disodium hydrogen phosphate dodecahydrate	0.56 mg
Sodium dihydrogen phosphate dihydrate	0.05 mg
Water for injections	q.s.

Hazardous Components - none

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4. FIRST-AID MEASURES

- Inhalation: As a precaution, move injured person into fresh air and keep person calm under observation.
- Skin contact: Remove contaminated clothes and rinse skin thoroughly with water as a precaution.
- Eye contact: Do not rub eye. Flush eyes with water as a precaution.
- Ingestion: Rinse mouth and drink plenty of water as a precaution.

5. FIRE-FIGHTING MEASURES

- Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.
- Special hazards: During fire, gases hazardous to health may be formed.
Wear a self-contained breathing apparatus in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

- Under normal handling conditions an accidental release is highly unlikely.
- Personal precautions: For personal protection, see section 8. Follow precautions for safe handling described in this safety data sheet.
- Environmental precautions: Avoid discharge into drains, water courses or onto the ground.
- Methods for cleaning up: Collect spillage with a moist cloth. For waste disposal, see Section 13.

7. HANDLING AND STORAGE

- Safe handling advice: Observe good laboratory hygiene practices.
If liquid is spilled avoid contact with eyes, skin, and clothing.
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Wash hands and any exposed skin after removal of PPE, as a precaution.
- Technical measures: Work practice should minimize contact. Keep the workplace clean. Do not eat, drink or smoke when using the product. Do not store tobacco, food or beverage in work rooms or areas where the product is used.
- Technical measures for safe storage: Store as directed by product packaging.
- Storage conditions: Store as directed by product packaging.
- Specific end use: None other than those listed in Section 1.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Occupational exposure limit values: Contains no substances with Occupational Exposure Limits

During normal handling operations of the liquid

- Exposure controls: None needed during normal handling operations.
- Respiratory protection: None needed during normal handling operations or spill.
- Hand protection: None needed during normal handling operations.
In the event of a spill, chemical resistant gloves should be worn for clean-up (disposable nitrile gloves).
- Eye protection: None needed during normal handling operations.

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Skin protection: None needed during normal handling operations.

Hygiene measures: Wash hands after handling. When using do not eat, drink or smoke. In the event of contact with the product. Remove contaminated clothing and wash the skin thoroughly with soap and water after work, as a precaution.

Environmental Exposure Controls: None needed during normal handling operations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Liquid

Odor: No data available

Odor threshold: No data available

pH: No data available

Melting point: No data available

Boiling point: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability: No data available

Explosion limits: No data available

Relative density: No data available

Solubility: Soluble in water

Partition coefficient: No data available
(n-octanol/water)

Auto-ignition temperature: No data available

Decomposition temperature: No data available

Other information: None

10. STABILITY AND REACTIVITY

Reactivity and Chemical Stability: Stable under normal conditions of use.

Conditions/materials to avoid: No data available

Hazardous decomposition products: No data available

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Inhalation: No data available

Skin contact: No data available

Eye contact: No data available

Ingestion: No data available

Specific effects: No information available

Carcinogenicity: No component of this product is present at levels greater than or equal to 0.1% is identified as a probable, possible or confirmed human carcinogen by IARC; or a known or

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anticipated carcinogen by NTP; or a carcinogen or potential carcinogen by ACGIH or OSHA.

12. ECOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the hazardous components listed in Section 2.

Toxicity: No information available.

Persistence and degradability: No information available.

Bioaccumulative potential: No information available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose of waste and residues in accordance with local authority requirements.

14. TRANSPORT INFORMATION

Transported as a pharmaceutical finished product.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

NONE

16. OTHER INFORMATION

Date of SDS Preparation: 7/9/18

Current Version Preparation: 5/4/15

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions. The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.