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Safety Data Sheet for Hyaluronidase

(Catalogue Numbers: LGHY-010)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY

Product Name: Hyaluronidase

Catalogue Numbers: LGHY-010

Manufacturer: LifeGlobal Group, LLC, 393 Soundview Rd, Guilford, CT 06437 US
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2. COMPOSITION/INFORMATION ON INGREDIENTS

Indications for Use: For the removal of the cumulus complex and corona of the oocyte before ICSI.

Composition:

Component	CAS-code	Approx. %
Hyaluronidase (80 IU/ml) in an aqueous solution containing:		
Hyaluronidase	37326-33-3	80 IU/ml
Water	7732-18-5	>90%
Sodium Chloride	7647-14-5	<1%
Potassium Chloride	7447-40-7	<1%
Calcium Chloride	10035-04-8	<1%
Potassium Phosphate	7778-77-0	<1%
Magnesium Sulfate	10034-99-8	<1%
Sodium Bicarbonate	144-55-8	<1%
Glucose	50-99-7	<1%
Sodium Lactate	867-56-1	<1%
Sodium Pyruvate	113-24-6	<1%
HEPES	7365-45-9	<1%
Gentamicin Sulfate	1405-41-0	<1%
Phenol Red	143-74-8	<1%
Human Serum Albumin	70024-90-7	0.4%

3. HAZARDOUS IDENTIFICATION

Contains Human Serum Albumin: This product contains human serum albumin, a derivative of human blood. The human serum albumin used in the preparation of this product has been heated at 60°C for ten hours. All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Contains Gentamicin Sulfate: This product contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

4. FIRST AID MEASURES

Eye contact: Flush with water. Get medical attention if irritation develops or persists.

Skin contact: Wash with soap and water.

Inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

Ingestion: Wash out mouth with water. Contact physician.

5. FIRE FIGHTING MEASURES

Flash point: Not applicable.
Extinguishing media: Not applicable.
Fire & Explosion Hazard: Not applicable.
Special fire fighting procedure: Not applicable.

6. ACCIDENTAL RELEASE MEASURES

Spills: Use absorbent material to mop up spilled liquid.

7. HANDLING AND STORAGE

Recommended storage temperature: Minimum: +2ºC (35.6 F) Maximum: +8ºC (46.4 F)
Shelf life: Six (6) months from the date of manufacture.
Handling (Personnel): Use care in handling and storage. Use aseptic working techniques at all times.
Handling (Physical Aspects): Keep from freezing. Do not store at temperatures above 8°C. Close container after each use.
Storage precautions: Avoid extreme temperatures. Keep away from sunlight. Do not freeze.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering controls: No special ventilation required.
Eye/face protection: When splashing of the material may occur, goggles or a face shield is recommended. If splashing occurs flush immediately and thoroughly with copious quantities of water. Should serious reaction occur, seek medical attention immediately.
Skin protection: Handle with gloves and lab coat. Employees should wash hands after handling product. Avoid contact with skin, eyes and clothing.
Respiratory protection: Under normal use conditions, with adequate ventilation, no special handling equipment is required.
Exposure guidelines: No information available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: Clear Liquid; forms foam after shaking
Color: Colorless
Odor: None
Solubility in water: Complete

10. STABILITY AND REACTIVITY

Stability: Stable
Incompatibility: None known

11. TOXICOLOGY INFORMATION

Toxicity Date: Not established for this product.
Effect of Overexposure: Not established for this product. Contains a human source material, the toxicology properties have not been thoroughly investigated.
Eye: Not expected to be an eye irritant, but can cause temporary discomfort.
Skin: Not expected to be a skin irritant.

Inhalation: Inhalation is not considered a potential route of exposure under normal laboratory use.

Ingestion: Not considered a potential route of exposure under normal laboratory use.

12. ECOLOGICAL INFORMATION

No known ecological damage.

13. DISPOSAL CONSIDERATION

Waste Disposal: Treat or dispose of waste material in accordance with all local state/provincial, and national requirements. Dispose with laboratory waste.

14. TRANSPORTATION INFORMATION

Product Label: Hyaluronidase

D.O.T. Hazard Class: Non-Hazardous

IATA/ICAO Air (54th edition IATA 2013): Non-Hazardous

Miscellaneous: Cool packs are needed for transportation.

15. REGULATORY INFORMATION

This product does not contain any ingredients which have been determined to be health hazards pursuant to U.S. OSHA regulations, and which comprise 1% or more (0.1% for carcinogens) of the mixture.

16. OTHER INFORMATION

Information Sources: LifeGlobal Group supplies Safety Data Sheet for the product you have purchased. OSHA promulgates the regulations for Hazard Communication, 29 CFR 1910.1200.

This information is offered, expressed or implied, except that it is accurate to the best knowledge of LifeGlobal Group. The data on this sheet are related only to the specific material designated herein.

Disclaimer: No claim is made that the information is all-inclusive, and it should be used only as a guide. LifeGlobal Group shall not be held liable for any damage resulting from handling or from contact with the product.

SDS #: **LG-020**

Revision Information:

REV. #	Revision Date yyyy-mm-dd	Description of Change	Authorized By
V1	2007-11-10	Initial release	M.P.
V2	2013-11-22	Reformatted	M.P.
V3	2014-07-17	Change sheet name to SDS	M.P.
V4	2015-02-25	Design update for consistency	D.F.
V5	2015-10-15	Regulatory updates	R.S.
V6	2016-08-08	Regulatory updates	D.G.