



Safety Data Sheet for global[®] total[®] for Fertilization

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY

Product Name: global[®] total[®] for Fertilization
Catalogue Numbers: LGTF-020, LGTF-050, LGTF-100
Manufacturer: LifeGlobal Group, LLC, 393 Soundview Rd, Guilford, CT 06437 US
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2. COMPOSITION/INFORMATION ON INGREDIENTS

Composition:

Component	CAS-code	Approx. %
Water	7732-18-5	>85%
Calcium Chloride	10035-04-8	<1%
Sodium Chloride	7647-14-5	<1%
Potassium Chloride	7447-40-7	<1%
Potassium Phosphate	7778-77-0	<1%
Magnesium Sulfate	10034-99-8	<1%
Sodium Bicarbonate	144-55-8	<1%
Glucose	50-99-7	<1%
Lactate Na Salt	867-56-1	<1%
Sodium Pyruvate	113-24-6	<1%
Amino Acids	N/A	<1%
Glycyl-glutamine	172669-64-6	<1%
EDTA	6381-92-6	<1%
Phenol Red	143-74-8	<1%
Gentamicin Sulfate	1405-41-0	<1%
Albumin (Human) USP 5%	NDC	10%
Human α- and β-globulins	13533-613-25(26)	(1.2%)
Human Serum Albumin		(8.8%)

global[®] total[®] contains a total protein concentration of 5 mg/ml, comprising 4.4 mg/ml human serum albumin and 0.6 mg/ml human α- and β-globulins from therapeutic-grade source material, in a sterile saline solution.

3. HAZARDOUS IDENTIFICATION

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.

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. Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time this product is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

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: +2°C (35.6 F) Maximum: +8°C (46.4 F)

Shelf life: Ten (10) weeks 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

Color: Pink to orange

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.



EC REP



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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: global® total® for Fertilization
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: This information is offered and is accurate to the best knowledge of LifeGlobal Group, LLC. 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.