

MATERIAL SAFETY DATA SHEET



Talecris Biotherapeutics, Inc.
P.O. Box 110526
79 T.W. Alexander Drive
Research Triangle Park, NC 27709

TRANSPORTATION EMERGENCY
CALL CHEMTREC..... : (800) 424-9300
INTERNATIONAL : (703) 527-3887

NON-TRANSPORTATION
EMERGENCY PHONE : (919) 553-5011
INFORMATION PHONE: (919) 553-5011

Section 1: Product and Company Identification

Product Name: GamaSTAN™
Material Number: 8612741
Common/Generic Name: Immune Globulin (Human), USP
Chemical Family: Aqueous solution of human plasma proteins
Chemical Name: Immune Gamma Globulins
NDC Number: 13533-635-02, 13533-635-04, 13533-635-10, 13533-635-12

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

<u>Ingredient Name/</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
<u>CAS Number</u>		<u>Min.</u>	<u>Max.</u>
This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.			

Section 3: Hazards Identification

EMERGENCY OVERVIEW

Color: Colorless to light yellow **Form:** Liquid **Odor:** Odorless
Product poses little or no hazard if spilled and no unusual hazard if involved in a fire.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Accidental:, Eye Contact, Skin Contact, Ingestion, Appropriate route of entry:, Intramuscular

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

General Effects of Exposure

Acute Effects of Exposure: None known.

Chronic Effects of Exposure: None known.

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions None known.

Aggravated by Exposure:

Human Health Effects

Postnote:

This product is prepared from pooled human plasma which may contain the causative agents of hepatitis and other viral diseases. Prescribed manufacturing procedures utilized at the plasma collection centers, testing laboratories, and the fractionation facilities are designed to reduce the risk of transmitting viral infection. The risk of viral infectivity from this product cannot be totally eliminated.

Section 4: First Aid Measures

First Aid for Eye: In case of contact, flush with plenty of water for at least 15 minutes. Call a physician.

First Aid for Skin: In case of skin contact, wash affected areas with soap and water. Contact a physician if irritation develops. Immediately remove contaminated clothing and shoes. Wash clothing and shoes before reuse.

First Aid for Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

First Aid for Ingestion: Contact poison control center or 1-919-553-5011.

Section 5: Fire Fighting Measures

Flash Point: Not Established

Flammable Limits:

Upper Explosion Limit (UEL %): Not Established

Lower Explosion Limit (LEL %): Not Established

Auto-ignition Temperature: Not Established

Extinguishing Media:

Suitable: Water, Dry Chemical, Carbon Dioxide, Foam

Special Fire Fighting Procedures:

Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures:

Use appropriate personal protective equipment during clean up. Spill area can be washed to a sanitary sewer. Absorb material and place in appropriate containers for disposal. Prevent from entering open drains and waterways.

Section 7: Handling and Storage

Storage Temperature:

Minimum: 35 °F (2 °C)
Maximum: 46 °F (8 °C)

Shelf Life:

Do not use after expiration date.

Special Sensitivity:

Avoid freezing as breakage of the container might occur.

Handling/Storage Precautions:

Store in a dry place away from excessive heat. Use normal precautions for storage of a drug. Protect from freezing. Containers should be kept tightly closed to prevent contamination. Follow necessary handling and storage procedures in compliance with the bloodborne pathogen standard under 29CFR1910.1030(). Avoid contact with eyes. Avoid contact with skin or clothing. Wash thoroughly after handling.

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment

Eye Protection Requirements:

Chemical safety goggles or glasses.

Skin Protection Requirements:

Gloves, long sleeved shirts and pants., Lab coat., Employees should wash their hands and face before eating, drinking or using tobacco products.

Ventilation Requirements:

Under normal conditions of use, special ventilation is not required.

Respirator Requirements:

Under normal conditions of use, respiratory protection is not required.

Work Practices:

Normal clinical practice and in compliance with the bloodborne pathogen standard under 29CFR1910.1030.

Additional Protective Measures:

Emergency showers and eye wash stations should be available. Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use

and handling of this product.

Section 9: Physical and Chemical Properties

Physical Form:	Liquid
Color:	Colorless to light yellow
Odor:	Odorless
pH:	Not Applicable
Boiling Point:	Not Established
Melting/Freezing Point:	Not Established
Viscosity:	Not Established
Solubility in Water:	Soluble
Specific Gravity:	1.05
Bulk Density:	Not Established
Vapor Pressure:	Not Established

Section 10: Stability and Reactivity

Stability:	Stable
Hazardous Polymerization:	Will not occur
Substances to Avoid:	Oxidizing agents, Reducing agents, Water reactives
Conditions to Avoid:	None known.
Decomposition Temperature:	Not established
Decomposition Products:	None known.

Section 11: Toxicological Information

Toxicity Data for GamaSTAN™

Toxicity Note: No data available for this product.

Section 12: Ecological Information

Ecological Data for GamaSTAN™

Ecological Note: No data available for this product.

Section 13: Disposal Considerations

Waste Disposal Method: Place in containers and incinerate in accordance with existing federal, state and local environmental regulations.

Section 14: Transportation Information

Technical shipping name: Human plasma proteins

Domestic Surface Transportation (DOT)

Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)

Hazard Class Division Non-Regulated
Number:

Air Transportation (ICAO / IATA)

Hazard Class Division Non-Regulated
Number:

Section 15: Regulatory Information

United States Federal Regulations

OSHA Hazcom Standard Not subject to OSHA
Rating:

TSCA Inventory List: **This product is exempt from TSCA Regulation under Section 3 (2)(B)(vi) when used for pharmaceutical application.**

CERCLA Hazardous Substance:

<u>Component(s)</u>	<u>Reportable Quantity</u>
None	

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

<u>Component(s)/</u>	<u>Concentration</u>	
<u>CAS Number</u>	<u>Min.</u>	<u>Max.</u>
Exempt		

SARA Section 311/312 Hazard Non-hazardous under Section 311/312
Categories:

SARA Section 313 Toxic Chemicals:

<u>Component(s)/</u>	<u>Reporting</u>	<u>Concentration</u>	
<u>CAS Number</u>	<u>Threshold</u>	<u>Min.</u>	<u>Max.</u>
Exempt			

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

Component(s)/
CAS Number

State Code

Concentration
Min. Max.

State Code Translation Table

Section 16: Other Information

HMIS Rating

Health	0
Flammability	0
Reactivity	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

*=Chronic Health Hazard

Talecris Biotherapeutics, Inc.'s method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by Talecris Biotherapeutics, Inc. as a customer service.

Contact: Jim Ball
Phone: (919) 553-5011
MSDS Number: R22085
Version Date: 12/31/2005
MSDS Version: 2.1

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|| Indicates Relevant Change Made.