



# MATERIAL SAFETY DATA SHEET

**BAYER HEALTHCARE LLC**  
Biological Products Division  
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**TRANSPORTATION EMERGENCY**  
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**NON-TRANSPORTATION**  
BAYER EMERGENCY PHONE : (800) 288-8371  
BAYER INFORMATION PHONE: (800) 662-2927

## Section 1: Product and Company Identification

**Product Name:** GAMIMUNE N 10% 20GM 200ML SD  
**Material Number:** 8613640  
**Common/Generic Name:** Immune Globulin Intravenous (Human), 10%  
**Chemical Family:** Aqueous solution of human plasma proteins  
**Chemical Name:** Immune Gamma Globulins  
**NDC Number:** None.

## 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:** White to 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:, Skin Contact, Eye Contact, Ingestion, Appropriate route of entry:, Intravenous

### 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. Immediately remove contaminated clothing and shoes. Wash clothing and shoes before reuse. Contact a physician if irritation develops.

**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 1-800-288-8371.

**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:**

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

**Section 8: Exposure Controls/Personal Protection**

**Personal Protection Equipment**

**Eye Protection Requirements:**

Chemical safety goggles or glasses.

**Skin Protection Requirements:**

Lab coat., Gloves, long sleeved shirts and pants., 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

|                                    |                 |
|------------------------------------|-----------------|
| <b>Physical Form:</b>              | Liquid          |
| <b>Color:</b>                      | White to yellow |
| <b>Odor:</b>                       | Odorless        |
| <b>pH:</b>                         | Not Applicable  |
| <b>Boiling Point:</b>              | Not Established |
| <b>Melting/Freezing Point:</b>     | Not Established |
| <b>Viscosity:</b>                  | Not Established |
| <b>Solubility in Water:</b>        | Soluble         |
| <b>Specific Gravity:</b>           | 1.05            |
| <b>Bulk Density:</b>               | Not Established |
| <b>Percent Volatile by Volume:</b> | 83 - 95         |
| <b>Vapor Pressure:</b>             | Not Established |

### Section 10: Stability and Reactivity

|                                  |  |
|----------------------------------|--|
| <b>Stability:</b>                | Stable   |
| <b>Hazardous Polymerization:</b> | Will not occur                                     |
| <b>Substances to Avoid:</b>      | Oxidizing agents, Reducing agents, Water reactives |
| <b>Conditions to Avoid:</b>      | None known.  |
| <b>Decomposition Products:</b>   | None known.  |

### Section 11: Toxicological Information

#### Toxicity Data for IGIV 10% 200ML FROM PRECISION

### Section 12: Ecological Information

#### Ecological Data for IGIV 10% 200ML FROM PRECISION

**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:** Pharmaceutical

**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 Rating:** Not subject to OSHA

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

**CERCLA Hazardous Substance:**

Component(s)

None

Reportable Quantity

**SARA Title III**

**SARA Section 302 Extremely Hazardous Substances:**

Component(s)/

CAS Number

Exempt

Concentration

Min.

Max.

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

**SARA Section 313 Toxic Chemicals:**

Component(s)/

CAS Number

Exempt

Reporting

Threshold

Concentration

Min.

Max.

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**

|                     |  |   |
|---------------------|--|---|
| <b>Health</b>       |  | 0 |
| <b>Flammability</b> |  | 0 |
| <b>Reactivity</b>   |  | 0 |

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe  
\*=Chronic Health Hazard

BAYER HEALTHCARE LLC's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS and NFPA ratings are provided by BAYER HEALTHCARE LLC as a customer service.

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MSDS Number: R26812  
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