BAYER HEALTHCARE LLC
Biological Products Division
8368 US 70 West
Clayton, NC  27520

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

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : (800) 288-8371
BAYER INFORMATION PHONE: (800) 662-2927

Section 1: Product and Company Identification

Product Name: Immune Globulin Intravenous (Human), Chromatography (IGIV-C) 10%
Material Number: 8613055
Common/Generic Name: Immune Globulin Intravenous (Human), 10%
Chemical Family: Aqueous solution of human plasma proteins
Chemical Name: Immune Gamma Globulins
Synonyms: IGIV-C 10%
NDC Number: None.

Section 2: Composition/Information on Ingredients

Hazardous Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name/ CAS Number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 Aggravated by Exposure: None known.

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

Material Name: Immune Globulin Intravenous (Human), Chromatography (IGIV-C) 10%
Article Number: 8613055
**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.

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**Section 6: Accidental Release Measures**

**Spill or Leak Procedures:** 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. Use appropriate personal protective equipment during clean up.

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**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:** 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(). Avoid contact with skin or clothing. Avoid contact with eyes. Wash thoroughly after handling.

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**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.
accessible to employees. Educate and train employees in the safe use and handling of this product.

**Section 9: Physical and Chemical Properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Form</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>White to yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>pH</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Not Established</td>
</tr>
<tr>
<td>Melting/Freezing Point</td>
<td>Not Established</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not Established</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Soluble</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.05</td>
</tr>
<tr>
<td>Bulk Density</td>
<td>Not Established</td>
</tr>
<tr>
<td>Percent Volatile by Volume</td>
<td>83 - 95</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

**Section 10: Stability and Reactivity**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</td>
</tr>
<tr>
<td>Substances to Avoid</td>
<td>Oxidizing agents, Reducing agents, Water reactives</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Decomposition Products</td>
<td>None known.</td>
</tr>
</tbody>
</table>

**Section 11: Toxicological Information**

**Toxicity Data for** Immune Globulin Intravenous (Human), Chromatography (IGIV-C) 10%

**Section 12: Ecological Information**

**Ecological Data for** Immune Globulin Intravenous (Human), Chromatography (IGIV-C) 10%

**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

Air Transportation (ICAO / IATA)
Hazard Class Division: Non-Regulated

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 Concentration Threshold Min. Max.

RCRA Status: If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)
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**

<table>
<thead>
<tr>
<th>Component(s)/CAS Number</th>
<th>State Code</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Min.</td>
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</table>

State Code Translation Table

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**Section 16: Other Information**

**HMIS Rating**

<table>
<thead>
<tr>
<th>Health</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>0</td>
</tr>
<tr>
<td>Reactivity</td>
<td>0</td>
</tr>
</tbody>
</table>

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.

Contact: John Parrish
Phone: (919) 359-4592
MSDS Number: R36534
Version Date: 06/11/2004
MSDS Version: 1.4

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Indicates Relevant Change Made.