**Section 1: Product and Company Identification**

| Product Name: | BayRho-D |
| Material Number: | 8612636 |
| Common/Generic Name: | Rho(D) Immune Globulin (Human), USP |
| Chemical Family: | Aqueous solution of human plasma proteins |
| Chemical Name: | Immune Gamma Globulins |
| Synonyms: | HyperRho-D |
| NDC Number: | None. |

**Section 2: Composition/Information on Ingredients**

**HAZARDOUS INGREDIENTS**

<table>
<thead>
<tr>
<th>Ingredient Name/ CAS Number</th>
<th>Exposure Limits</th>
<th>Concentration Min.</th>
<th>Max.</th>
</tr>
</thead>
</table>

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

---

**Material Name:** BayRho-D  
**Article Number:** 8612636
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. 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 1-919-553-5011.

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: 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 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.


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

<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>Colorless to light 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>Water reactives, Reducing agents, Oxidizing agents</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 BayRho-D
Toxicity Note: No data available for this product.

Section 12: Ecological Information

Ecological Data for BayRho-D
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 Rating: Non-Hazardous

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) Reportable Quantity
None

SARA Title III
SARA Section 302 Extremely Hazardous Substances:
Component(s)/ Concentration
CAS Number Min. Max.
Exempt

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

SARA Section 313 Toxic Chemicals:
Component(s)/ Reporting Concentration
CAS Number Threshold Min. Max.
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)/ Concentration
CAS Number State Code Min. Max.
State Code Translation Table

Section 16: Other Information

<table>
<thead>
<tr>
<th>HMIS Rating</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Health</td>
<td>0</td>
</tr>
<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

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: R21945
Version Date: 11/02/2005
MSDS Version: 2.0

This information is furnished without warranty, expressed or implied, except that it is accurate to the best knowledge of Talecris Biotherapeutics, Inc. The data on this sheet relates only to the specific material designated herein. Talecris Biotherapeutics, Inc. assumes no legal responsibility for use or reliance upon these data.

Indicates Relevant Change Made.