

**Product:** Human anti-D immunoglobulin  
**Trade Name:** Rhophylac® 200, Rhophylac® 300,

Date of issue: 22. January 2010  
Replaces Version: 19. March 2007

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## 1. Identification of the product and of the company

Product:

Human anti-D immunoglobulin

Company name:

CSL Behring AG

Wankdorfstr. 10

3000 Bern 22

Switzerland

Phone: +41 31 344 44 44

Fax: +41 31 344 55 55

U.S. CSL Behring (610) 878-4000

U.S. Emergency Response: (800) 424-9300

U.S. Emergency Product Information: (800) 504-5434

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## 2. Composition / Information on ingredients

Trade names:

Rhophylac® 200, Rhophylac® 300

Chemical characterization of the substance / preparation:

Proteins, glycine, sodium chloride, water for injection

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## 3. Hazards identification

According to the present state of knowledge, provided that this product is handled correctly, there is no known danger to humans.

No hazardous product as specified in Directive 67 / 548 / EEC.

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## 4. First aid measures

After contact with the eyes:

Rinse eyes with running water.

After contact with the skin:

Rinse contaminated skin.

After inhalation:

Consult a physician if irritating symptoms develop and persist.

After ingestion or accident:

If feeling sick consult a physician.

Notes to physician:

Only effective when administered parenterally.

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## 5. Fire fighting measures

Extinguishing media, suitable:  
all, suit to surrounding area  
Extinguishing media, not to be used:  
no restrictions  
Special advice in case of fire:  
Not combustible. Cool container with a water spray jet  
Hazardous products of combustion:  
Nitrogen oxide

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## 6. Accidental release measures

After spillage, leakage, large amounts:  
Must not be released into sewers, drains or wells.  
Take up by mechanical means and dispose  
After spillage, leakage, small amounts:  
Wash away remnants with water and detergents  
Cleaning of equipment:  
Wash with water

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## 7. Handling and storage

Protect from (while storing)  
Light  
Max. storage temperature  
2-8°C or 36.6-46.4°F (storage temperature for product quality reasons)  
2-30°C or 36.6-86°F (storage temperature for workplace safety reasons only)  
Protective measures, storage and handling:  
Store protected from light, do not freeze

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## 8. Exposure controls / personal protection

Personal protection for open handling:  
Respiratory protection: mask, dust filter in case of aerosol generation  
Eye protection: safety glasses  
Hand protection: required  
Others: change contaminated working clothes. Wash hands after finishing work.

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## 9. Physical and chemical properties

Form:	liquid
Color:	colorless, slightly opaque liquid
Odour:	no
pH-value	approx. 5 (20°C)
Melting point:	not applicable
Boiling point:	not applicable
Ignition temperature:	not applicable
Flash point:	not applicable
Explosion limit:	not applicable
Density:	1.0 g/mL

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## 10. Stability and reactivity

Conditions to be avoided (for safety reason only):  
No information available.  
Substances to be avoided (for safety reason only):  
Commonly known reactants for water.  
Hazardous decomposition products  
No information available

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## 11. Toxicological information

No toxic effects are expected, when the product is handled appropriately

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## 12. Ecological information

Biological degradation:  
Based on results of similar compounds rapid and complete biodegradation can be expected.  
Further ecological data:  
No ecological impact is expected when the product is handled and used with due care and attention.

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### 13. Disposal considerations

**Product:**

Must be disposed of in compliance with country-specific regulations; e.g. Incineration in controlled furnaces.

Please contact your local authorities.

**Packaging:**

Must be disposed of in compliance with country-specific regulations. Handle contaminated packaging material as product.

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### 14. Transport information

Not subject to transport regulation

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### 15. Regulatory information

Labeling according to EC Directives

Symbol: none

R-phrases: none

S-phrases: none

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### 16. Other information

Product should be stored, handled and used in accordance with good industrial hygiene practice and in conformity with the product labeling and applicable regulations. The information contained herein is based on the present state of knowledge and is intended to describe this product from the point of view of safety requirements; it should therefore not be construed as guaranteeing specific properties.

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### Revision Summary

1/22/10

U.S. telephone contacts added.