1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier
Product Identity
Hepatitis B Immunoglobulin P Behring
Alternate Names
Hepatitis B Immunoglobulin P Behring

1.2. Relevant identified uses of the substance or mixture and uses advised against
Intended use
See Technical Data Sheet.
Application Method
See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet
Company Name
CSL Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia, PA

Emergency
24 hour Emergency Telephone No.
Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C.
(610) 878-4000

2. Hazard identification of the product

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
No applicable CLP categories.
Classification according to 67/548/EEC or 1999/45/EC.
No applicable DPD categories.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.
According to Regulation (EC) No 1272/2008
[Prevention]:
No CLP prevention statements
[Response]:
No CLP response statements
[Storage]:
No CLP storage statements
[Disposal]:
No CLP disposal statements
See Technical Data Sheet.

2.3. Other hazards
This product contains no PBT/vPvB chemicals.

3. Composition/information on ingredients
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Material: Medicinal product derived from human plasma
Active ingredient: Human hepatitis B immunoglobulin (non hazardous component)
Other components: Amino acetic acid, sodium chloride, (non hazardous components)
Packaging units: Pack with 1 ampoule of 1 or 5 ml or pre-filled syringe of 1 ml or 5 ml solution (ready-for-use) for intramuscular administration

4. First aid measures

4.1. Description of first aid measures
General
In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation
Remove to fresh air.

Eye
Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin
Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.

Ingestion
Drink water. Obtain medical attention if feeling ill.

4.2. Most important symptoms and effects, both acute and delayed
Overview
No specific symptom data available.

5. Fire-fighting measures

5.1. Extinguishing media
As suitable for surrounding fire.

5.2. Special hazards arising from the substance or mixture
Hazardous decomposition: No hazardous decomposition data available.

5.3. Advice for fire-fighters
None
ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions
Do not allow spills to enter drains or waterways.
Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up
Collect/absorb spilled material and dispose of properly.
7. Handling and storage

7.1. Precautions for safe handling
General precautions for handling of pharmaceuticals are to be considered. Protect from light when handling.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Storage and transportation temperatures should not fall below 2°C and not exceed 8°C.
Incompatible materials: No data available.
Keep container closed tightly.
Store locked up or accessible to authorized persons or their representatives only.

7.3. Specific end use(s)
No data available.

8. Exposure controls and personal protection

8.1. Control parameters
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls
Respiratory Not Applicable
Eyes Not Applicable
Skin Not Applicable
Engineering Controls Provide adequate ventilation.
Other Work Practices Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Colorless to Pale-Yellow Up to Light Brown Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>None</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not Measured</td>
</tr>
<tr>
<td>pH</td>
<td>6.4-7.2</td>
</tr>
<tr>
<td>Melting point / freezing point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flash Point</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Evaporation rate (Ether = 1)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Lower Explosive Limit: Not Measured</td>
</tr>
<tr>
<td>Upper Explosive Limit: Not Measured</td>
<td></td>
</tr>
<tr>
<td>Upper Explosive Limit: Not Measured</td>
<td></td>
</tr>
<tr>
<td>Vapor pressure (Pa)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Solubility in Water</td>
<td>Readily Soluble</td>
</tr>
<tr>
<td>Partition coefficient n-octanol/water (Log Kow)</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not Measured</td>
</tr>
</tbody>
</table>
Decomposition temperature  Not Measured
Viscosity (cSt)  Not Measured
Molecular Weight  about 150 KD

9.2. Other information
No other relevant information.

10. Stability and reactivity

10.1. Reactivity
Hazardous Polymerization will not occur.

10.2. Chemical stability
Stable under normal circumstances.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
Storage and transportation temperatures should not fall below 2°C and not exceed 8°C.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No hazardous decomposition data available.

11. Toxicological information

Acute toxicity

All product components are considered to be non-hazardous. Hepatitis B Immunoglobulin P Behring is manufactured according to the same procedure as Beriglobin P. Therefore, toxicological studies performed with Beriglobin P are also applicable for Hepatitis B Immunoglobulin P Behring. The product is intended for intramuscular application only, therefore no oral, dermal or inhalation toxicity studies have been performed.

Single dose toxicity studies:
Acute toxicity studies were performed in rodents (mice, rats) with single i.m. injection. In the i.m. studies mice were administered with a dose up to 8 g/kg and rats with a dose up to 1.6 g/kg b.w. No relevant toxic findings were observed in these studies.

Local tolerance:
Rabbits were injected with 0.5 mL (80 mg/rabbit) i.m. The substance was regarded as local tolerable after i.m. injection.

Safety Pharmacology:
Dogs were injected i.m. at a maximal dose of 480 mg/kg (3 mL/kg) b.w. No relevant adverse effect was observed. There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).
12. Ecological information

12.1. Toxicity
No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity
There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

12.2. Persistence and degradability
There is no data available on the preparation itself.

12.3. Bioaccumulative potential
Not Measured

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects
No data available.

13. Disposal considerations

13.1. Waste treatment methods
Observe all federal, state and local regulations when disposing of this substance.

14. Transport information
14.1. UN number
Not Applicable

14.2. UN proper shipping name
Not Regulated

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable
IMDG: Not Applicable

14.4. Packing group
Not Applicable

14.5. Environmental hazards
IMDG Marine Pollutant: No

14.6. Special precautions for user
No further information

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
EU Legislation


National Legislation
None noted.

16. Other information

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The full text of the phrases appearing in section 3 is:
Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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