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 2C and not exceed 8C.

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

Appearance	Colorless to Pale-Yellow Up to Light Brown Liquid
Odor	None
Odor threshold	Not Measured
pH	6.4-7.2
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	**Lower Explosive Limit:** Not Measured **Upper Explosive Limit:** Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Readily Soluble
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured

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 2C and not exceed 8C.

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).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

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

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	**DOT Hazard Class:** Not Applicable	**IMDG:** Not Applicable **Sub Class:** Not Applicable	**Air class:** Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	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

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

National Legislation

None noted.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

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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