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

1.1. Product identifier
Product Identity: Humate-P®
Alternate Names: Humate-P®

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.

Composition/Information on Ingredients
Upon reconstitution with the volume of diluent provided (Sterile Diluent for Humate-P®), each mL of Humate-P® contains:
- 20-40 IU Factor VIII, Active Ingredient
- 50-100 IU VWF:RCo, Active Ingredient
- Albumin (Human)
- Other proteins
- Sodium Chloride, USP, (7647-14-5),
- Glycine, USP (56-40-6)
- Sodium Citrate, USP (68-04-2)
- Water For Injection, USP (7732-18-5)

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, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

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 Rinse from mouth and seek medical guidance. Induce vomiting only as directed by medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed

Overview Potential Health Effects:
This product has been prepared from the pooled plasma of healthy adult donors. Each plasma donation has been tested for the absence of antibodies against HIV-1, HIV-2 and Hepatitis C, as well as Hepatitis B surface antigens. In addition, the product underwent a minimum of two different virus reduction procedures. The final fractionation pool used in the manufacture of this product has also been tested for antibodies against HIV-1/HIV-2 and Hepatitis B surface antigen. Furthermore, only fractionation pools which are nonreactive for HCV RNA, HIV RNA, HAV RNA, and negative for HBV DNA, and high titer Parvovirus B19 DNA by Polymerase Chain Reaction (PCR) Technology are utilized. However, the risk of infectivity due to known or as yet unknown pathogens cannot be totally eliminated from this product.

No adverse health effects anticipated with normal handling and use in appropriate medical setting. Medical implications of therapeutic use are described in product package insert or may be found in the Physicians’ Desk Reference.

Emergency Overview:
This product is a sterile prescription pharmaceutical. It is to be administered only at the order of a licensed physician. This product is safe when used for its intended purpose and
administered as directed by a physician. In addition, no adverse health effects are anticipated as a result of incidental contact or exposure to this product by those handling it or administering it in a therapeutic setting. More detailed information is available in the product package insert. Please report adverse events in patients using this product to the manufacturer at the telephone number listed above.

Eye Contact: No data. No adverse health effects reported nor anticipated.
Skin Contact: No data. No adverse health effects reported nor anticipated.
Skin Absorption: This product is not absorbed through the skin.
Ingestion: Not intended for oral use. See section 2 for further details.

5. Fire-fighting measures

5.1. Extinguishing media
As appropriate for packaging material.

5.2. Special hazards arising from the substance or mixture
Hazardous decomposition: Packaging material fire may produce carbon monoxide and other gaseous asphyxiants, plus airborne particulate matter.

5.3. Advice for fire-fighters
This product is neither flammable nor explosive. The only fire hazard would involve packaging material. Firefighting personnel should respond with appropriate protective clothing, firefighting gear and breathing equipment, as trained. All other personnel should exit the area and proceed to a gathering point in an area unaffected by fire and smoke.

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
Large Spill: Absorb spills with material suitable for aqueous solutions and dispose in solid waste container, or mop spilled material with detergent/water or bleach/water solution and dispose in sanitary sewer. Ventilate area, if desired.
Small Spill: Clean area of spill with wetted toweling and dispose in solid waste container, or follow procedure for large spills.

7. Handling and storage

7.1. Precautions for safe handling
Wear suitable protective clothing (may include gloves, gowns, plastic aprons, masks, caps, safety eye glasses, face shields or respirators) and prevent physical damage to package to avoid breakage and spilling.
7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Incompatible materials: No data available.
Store in accordance with the conditions specified in the product package insert.

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

8. Exposure controls and personal protection

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 Required
Eyes: None required to provide protection against the product. Eye protection may be required by procedure of administration.
Skin: None required for protection against the product. Medical-grade examination or surgical gloves may be required by procedure of administration.
Engineering Controls: Not Applicable
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 Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>Unspecified</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not Measured</td>
</tr>
<tr>
<td>pH</td>
<td>6.9 +/- 0.5</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></td>
</tr>
<tr>
<td>Lower 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>Complete</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>
<tr>
<td>Decomposition temperature</td>
<td>Not Measured</td>
</tr>
<tr>
<td>Viscosity (cSt)</td>
<td>Not Measured</td>
</tr>
</tbody>
</table>

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
No data available.

#### 10.5. Incompatible materials
No data available.

#### 10.6. Hazardous decomposition products
Packaging material fire may produce carbon monoxide and other gaseous asphyxiants, plus airborne particulate matter.

### 11. Toxicological information

#### Acute toxicity

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).

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
<th>Hazard Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity (oral)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (dermal)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Acute toxicity (inhalation)</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>---</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>14.1. UN number</th>
<th>DOT (Domestic Surface Transportation)</th>
<th>IMO / IMDG (Ocean Transportation)</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.2. UN proper shipping name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.3. Transport hazard class(es)</th>
<th>DOT Hazard Class</th>
<th>IMDG</th>
<th>Sub Class</th>
<th>Air class</th>
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</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.4. Packing group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.5. Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDG Marine Pollutant: No</td>
</tr>
</tbody>
</table>

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

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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End of Document