1. Identification

1.1. Product identifier
Product Identity Kcentra
Alternate Names Kcentra

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 LLC
PO Box 511
Kankakee, IL 60901

Emergency
24 hour Emergency Telephone No. Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring LLC (815) 932-6771

2. Hazard(s) identification

2.1. Classification of the substance or mixture
No applicable GHS categories.

2.2. Label elements
Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:
No GHS prevention statements

[Response]:
No GHS response statements

[Storage]:
No GHS storage statements

[Disposal]:
No GHS disposal statements

3. Composition/information on ingredients

Page 1 of 8
There are no ingredients in this product which are classified as hazardous.

Non-Hazardous Ingredients:
Material: Medicinal product derived from human plasma.
Active ingredient: Concentrate of human Coagulation Factors II, VII, IX, X, Protein C and Protein S (non hazardous component).
Other components: Human Albumin, Antithrombin III and Heparin (non hazardous components).

Packaging units: 500 units Kcentra® in a single-use vial, 20mL vial of Sterile Water for Injection, USP, Mix2Vial® filter transfer set, Alcohol swab 1000 units Kcentra® in a single-use vial, 40mL vial of Sterile Water for Injection, USP, Mix2Vial® filter transfer set, Alcohol swab.

### 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.

**Eyes**
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**
If the person is conscious, have them drink water. Contact a physician immediately. Do not induce vomiting.

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

**Overview**
No hazardous product according to guideline 67/548/EWG.

Kcentra® is made from human plasma. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in such products. The risk that such products could transmit viruses has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses during manufacture. Despite these measures, such products may still potentially transmit disease.

See section 2 for further details.

### 5. Fire-fighting measures

**5.1. Extinguishing media**
Water or any media appropriate for extinguishing.

**5.2. Special hazards arising from the substance or mixture**
5.3. Advice for fire-fighters
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
Personal Measures: General precautions for handling of pharmaceuticals are to be considered. Avoid the formation of dust.
Environmental Measures: No environmental hazard known.
Purification / Absorption: Collect/adsorb 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.

7.2. Conditions for safe storage, including any incompatibilities
Handle containers carefully to prevent damage and spillage.
Incompatible materials: No data available.
Store Kcentra® between 2 - 25°C (36 - 77°F), do not exceed 25°C (77°F). Do not freeze. Store locked up or accessible for 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.

8.2. Exposure controls
Respiratory Avoid dust formation
Eyes
Skin
Engineering Controls

Eyes
Skin
Engineering Controls

Not Applicable
Not Applicable
Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

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>White Solid</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>Not Measured</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></td>
<td>Upper Explosive Limit: Not Measured</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>
<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
Store Kcentra between 2 - 25°C (36 - 77°F), this includes room temperature, not to exceed 25°C (77°F). Keep away from light. Do not freeze.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
None

11. Toxicological information

Acute toxicity

There are no ingredients in this product which are classified as hazardous.

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>
<tr>
<td>Aspiration hazard</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.

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 Applicable</td>
<td>Not Regulated</td>
<td>Not Regulated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>14.2. UN proper shipping name</th>
<th>DOT Hazard Class</th>
<th>IMDG:</th>
<th>Air Class:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Regulated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>14.4. Packing group</th>
<th>DOT</th>
<th>IMDG</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>14.6. Special precautions for user</th>
<th>DOT</th>
<th>IMDG:</th>
<th>ICAO/IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>No further information</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Regulatory information

Regulatory Overview
The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA)
All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification: Not Regulated

US EPA Tier II Hazards:
- **Fire**: No
- **Sudden Release of Pressure**: No
- **Reactive**: No
- **Immediate (Acute)**: No
- **Delayed (Chronic)**: No

**EPCRA 311/312 Chemicals and RQs:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 302 Extremely Hazardous:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**EPCRA 313 Toxic Chemicals:**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Carcinogens (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Developmental Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Female Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Proposition 65 - Male Repro Toxins (>0.0%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**New Jersey RTK Substances (>1%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

**Pennsylvania RTK Substances (>1%):**
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.
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.

The information contained herein is based on data considered true and accurate. CSL Behring makes no warranties, express or invalid, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

End of Document