

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

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

Hazardous decomposition: None

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.

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

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	Not Applicable
Skin	Not Applicable
Engineering Controls	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

Appearance	White Solid
Odor	None
Odor threshold	Not Measured
pH	Not Measured
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

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).

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.

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 DOT Label: ---	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

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.

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