

1. Identification

Product identifier	Coagulation Factor VIIa		
Other means of identification			
Catalog number	1311500		
Chemical name	Eptacog Alfa (Activated)		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2A
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements



Signal word	Warning
Hazard statement	Causes serious eye irritation.
Precautionary statement	
Prevention	Wash thoroughly after handling. Wear eye protection/face protection.
Response	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	Does not contain material of human origin. As with all materials of biological origin, this material should be regarded as potentially hazardous to health.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Mannitol	1,2,3,4,5,6-Hexanehexol Mannite	69-65-8	60
Sucrose	Sugar	57-50-1	24
Sodium Chloride		7647-14-5	6
Calcium Chloride		10035-04-8	4

Chemical name	Common name and synonyms	CAS number	%
Diglycine		556-50-3	3
Recombinant Coagulation Factor VIIa		102786-61-8	2
Racemethionine	dl-Methionine	59-51-8	1
Polysorbate 80	Polyoxyethylene 20 sorbitan monooleate Glycol	9005-65-6	< 0.1

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Severe eye irritation.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	REL	5 mg/m3 10 mg/m3	Respirable. Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	For laboratory operations, use good technique and limit open handling. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Chose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Solid. (Lyophilized).
Color	White.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.

Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Glycoprotein.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	None known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, Cl-, SOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes serious eye irritation.
Ingestion	Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics	Fever. Gastrointestinal disturbances.

Information on toxicological effects

Acute toxicity	Not known.
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Components	Species	Test Results
Calcium Chloride (CAS 10035-04-8)		
<u>Acute</u>		
Oral		
LD50	Rabbit	755 mg/kg
Polysorbate 80 (CAS 9005-65-6)		
Oral		
LD50	Mouse	25 g/kg
	Rat	> 5000 mg/kg
		34500 µliters/kg
Racemethionine (CAS 59-51-8)		
Inhalation		
LC50	Rat	> 5.25 mg/l/4h
Oral		
LD50	Rat	> 10000 mg/kg
Sodium Chloride (CAS 7647-14-5)		
<u>Acute</u>		
Oral		
LD50	Mouse	4000 mg/kg
	Rat	3000 mg/kg
Other		
LD50	Mouse	2602 mg/kg

Components	Species	Test Results
Sucrose (CAS 57-50-1)		
Acute		
Oral		
LD50	Rat	29700 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Causes serious eye irritation. Knowledge about health hazard is incomplete.	
Local effects		
Polysorbate 80		150 mg Draize test Result: Irritant. Species: Rabbit Organ: Eye Severity: Mild.
Calcium Chloride		Eye irritancy (OECD 405) Result: Severe. Species: Rabbit
Polysorbate 80		Irritancy Result: Irritant. Species: Rabbit Organ: Skin Severity: Mild.
Sodium Chloride		Irritancy Result: Moderate; mild Species: Rabbit Organ: Eye Irritancy Result: Moderate; mild Species: Rabbit Organ: Skin
Polysorbate 80		Irritancy Result: Negative. Species: Human Organ: Skin Irritancy Result: Negative. Species: Rabbit Organ: Eye
Racemethionine		Irritancy test (100 mg) Result: Negative. Species: Rabbit Organ: Eye. Test Duration: 72 hours Irritancy test (500 mg) Result: Negative. Species: Rabbit Organ: Skin. Test Duration: 4 hours
Calcium Chloride		Skin irritancy (OECD 404) Result: Slight to none. Species: Rabbit
Respiratory or skin sensitization		
Respiratory sensitization	Anaphylactic reactions following therapeutic use have been reported. Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Polysorbate 80		Maximisation Assay (Magnusson and Kligman) Result: Negative. Species: Guinea pig Organ: Skin
Racemethionine		Sensitization study Result: Negative. Species: Guinea pig Organ: Skin.
Germ cell mutagenicity	Data from germ cell mutagenicity tests were not found. Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Coagulation Factor VIIa		In vitro clastogenicity assay in human lymphocytes. Result: Negative.

Mutagenicity

Coagulation Factor VIIa

In vivo micronucleus test.

Result: Negative.

Polysorbate 80

Ames test (Salmonella typhimurium), with and without activation

Result: Negative.

Calcium Chloride

Bacterial mutation tests

Result: Negative.

Racemethionine

Chromosomal aberrations in CHO cells

Result: Negative.

Sucrose

Chromosomal aberrations in CHO-WBL cells

Result: Positive (with and without activation).

Polysorbate 80

Chromosome aberration

Result: Positive.

Calcium Chloride

In vitro chromosomal aberration assay in Chinese hamster lung cells

Result: Negative.

Sucrose

Mouse lymphoma test

Result: Negative (with and without activation).

Polysorbate 80

Mutagenicity, DNA inhibition test in human lymphocytes and mouse cells

Result: Positive.

Mutagenicity, Human lymphocytes mutagenicity test

Result: Inconclusive.

Mutagenicity, Sister chromatid exchange assay

Result: Negative.

Racemethionine

SCE in CHO cells

Result: Negative.

SCE in human lymphocytes

Result: Negative.

UDS in human lymphocytes

Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

Calcium Chloride

112 g/kg Carcinogenicity study

Result: Thyroid tumors.

Species: Rat

Test Duration: 20 weeks

Polysorbate 80

50000 ppm Carcinogenicity, No evidence of carcinogenicity in female mice. Forestomach ulcers and increased incidence of squamous hyperplasia and inflammation of the forestomach in female mice.

Species: Mouse

Test Duration: 103 weeks

50000 ppm Carcinogenicity, No evidence of carcinogenicity in female rats. Equivocal evidence of pheochromocytomas of the adrenal medulla in male rats.

Species: Rat

Test Duration: 103 weeks

Mannitol

50000 ppm Two-year carcinogenicity study

Result: Negative.

Species: Mouse

50000 ppm Two-year carcinogenicity study

Result: Negative.

Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

Reproductivity

Coagulation Factor VIIa

3 mg/kg/day Fertility and reproductive performance study

Result: No adverse effects observed.

Species: Rat

5 mg/kg Reproductivity and development study

Result: No teratogenicity noted.

Species: Rabbit

Reproductivity

Coagulation Factor VIIa

6 mg/kg Reproductivity and development study

Result: No teratogenicity noted.

Species: Rat

Polysorbate 80

10 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased incidence of developmental defects with intravenous doses.

Species: Rabbit

16 ml/kg Reproductivity, Lower body weight in postnatal offspring but no adverse effects on neurodevelopment with administration in drinking water.

Species: Rat

Calcium Chloride

1600 mg/kg/day Reproductivity study, administered in drinking water

Result: Maternal toxicity and fetal toxicity.

Species: Rat

169 mg/kg/day Developmental toxicity studies, administered during gestation

Result: No toxic effects on dams or fetuses.

Species: Rabbit

176 mg/kg/day Developmental toxicity studies, administered during gestation

Result: No toxic effects on dams or fetuses.

Species: Rat

189 mg/kg/day Developmental toxicity studies, administered during gestation

Result: No toxic effects on dams or fetuses.

Species: Mouse

Polysorbate 80

7000 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased birth defects with oral doses.

Species: Rat

Reproductivity, No evidence of birth defects with injection in chick eggs.

Species: Chick

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Coagulation Factor VIIa

3 mg/kg/day Repeat-dose toxicity test

Result: Well tolerated.

Species: Monkey

Test Duration: 13 weeks

Aspiration hazard

Not classified.

12. Ecological information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
Calcium Chloride (CAS 10035-04-8)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	1062 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	3930 - 5360 mg/l, 96 hours
Chronic			
Crustacea	EC50	Water flea (Daphnia magna)	610 mg/l, 21 days
Sodium Chloride (CAS 7647-14-5)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	340.7 - 469.2 mg/l, 48 hours
Fish	LC50	American eel (Anguilla rostrata)	0 - 27260 mg/l, 96 hours

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential**Octanol/water partition coefficient log Kow**

Mannitol	-3.1
Sucrose	-3.7

Mobility in soil

No data available.

Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.
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13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.
General information	It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No
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SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
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US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.
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International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	08-03-2017
Version #	01
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