

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form	: Mixture
Product name	: NovoSeven® RT
Other means of identification	: NovoSeven® RT 1.0 mg NovoSeven® RT 2.0 mg NovoSeven® RT 5.0 mg NovoSeven® RT 8.0 mg

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture	: Drug Product. NovoSeven RT is recombinant coagulation factor VIIa (rFVIIa) and is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia
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1.3. Details of the supplier of the safety data sheet

Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
T 800-727-6500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number	: 800-727-6500
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Sens. 1 H317

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



GHS07

Signal word (GHS-US)	: Warning
Hazard statements (GHS-US)	: H317 - May cause an allergic skin reaction
Precautionary statements (GHS-US)	: P261 - Avoid breathing dust P272 - Contaminated work clothing should not be allowed out of the workplace P280 - Wear appropriate PPE P302+P352 - IF ON SKIN: Wash with plenty of soap and water P321 - Specific treatment (see Section 4 on this label) P333+P313 - If skin irritation or rash occurs: Get medical advice/attention P362+P364 - Take off contaminated clothing and wash it before reuse P501 - Dispose of contents/container to comply with local/regional/national/international regulations

2.3. Other hazards

Other hazards not contributing to the classification	: Inactive ingredients include: histidine diluent (supplied separately, histidine in water 10 mmol), sodium chloride, calcium chloride dihydrate, glycylglycine, polysorbate 80, mannitol, methionine, and sucrose.
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2.4. Unknown acute toxicity (GHS-US)

Not applicable

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Eptacog alpha (activated) Powder and solvent for injection	(CAS No) 102786-61-8	100	Skin Sens. 1, H317

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

First-aid measures after inhalation

: Remove person to fresh air. If signs/symptoms continue, get medical attention.

First-aid measures after skin contact

: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse.

First-aid measures after eye contact

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.

First-aid measures after ingestion

: Rinse mouth. Drink plenty of water. Seek medical advice in case of persistent discomfort.

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

Symptoms/injuries after inhalation

: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.

Symptoms/injuries after skin contact

: May cause irritation by the active substance or any of the excipients.

Symptoms/injuries after eye contact

: May cause irritation. Avoid contact with the eyes.

Symptoms/injuries after ingestion

: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.

Chronic symptoms

: Systemic exposure to the product may cause increase in the risk of thrombosis.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

: Any. Use media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard

: The product is not readily flammable.

Reactivity

: Not reactive under normal use and conditions.

5.3. Advice for firefighters

Protection during firefighting

: Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

: -Do not inhale dusts or mists. Seek fresh air.

6.1.1. For non-emergency personnel

Emergency procedures

: Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment

: Equip cleanup crew with proper protection.

6.2. Environmental precautions

Under normal use, this product is not expected to impact the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment

: Do not touch or walk through spilled material.

Methods for cleaning up

: Absorb with non-combustible material and transfer to containers.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.
Hygiene measures	: Do not eat, drink or smoke when using this product. Practice good housekeeping. Wash thoroughly after handling. Change contaminated clothing. Do not reuse until laundered.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Must be kept in tightly original packings and store according to product instruction and to prevent degradation. Store protected from light.
Incompatible products	: Light.
Storage temperature	: Prior to reconstitution, store NovoSeven RT powder and histidine diluent between 2-25 degrees C (36-77 degrees F). After reconstitution, store NovoSeven RT either at room temperature or refrigerated for up to 3 hours. Do not freeze.

7.3. Specific end use(s)

Drug Product. NovoSeven RT is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX. Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets. Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances subject to reporting requirements.

8.2. Exposure controls

Appropriate engineering controls	: Work must be done with effective mechanical ventilation. There must be access to running water and eye wash.
Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Polyvinylchloride (PVC) /Nitrile rubber gloves.
Eye protection	: Eye protection such as chemical splash goggles and/or face shield must be worn when possibility exists for eye contact due to splashing or spraying liquid. Contact lenses should not be worn.
Skin and body protection	: PVC gloves, nitrile rubber or similar protection are recommended for waste clear-up and manufacturing operations.
Respiratory protection	: Not normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid or Liquid
Appearance	: Freeze-dried white powder/ aqueous solution.
Color	: White.
Odor	: No special smell.
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available

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Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal use and conditions.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No known incompatibilities.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

NovoSeven® RT	
Additional information	Not investigated. NovoSeven® RT may contain trace amount of immunogenic proteins. Systemic exposure to the product may cause hypersensitivity to these proteins.
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified (No indication of carcinogenic potential for NovoSeven® RT. No chronic carcinogenicity studies have been performed.)
Reproductive toxicity	: Not classified (No teratogenic or development effects was observed in animals.)
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist containing protein may cause sensitization.
Symptoms/injuries after skin contact	: May cause irritation by the active substance or any of the excipients.
Symptoms/injuries after eye contact	: May cause irritation. Avoid contact with the eyes.
Symptoms/injuries after ingestion	: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.
Chronic symptoms	: Systemic exposure to the product may cause increase in the risk of thrombosis.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Avoid discharge to drain or surface water.

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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : The product is not hazardous waste. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with DOT

Not regulated for transport

SECTION 15: Regulatory information

15.1. US Federal regulations

Eptacog alpha (activated)

Powder and solvent for injection (102786-61-8)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

15.2.2. National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources

: ChemIDplus [<http://chem.sis.nlm.nih.gov/chemidplus/rn/116094-23-6>],
Environmental Health & Toxicology - National Library of Medicine [<http://sis.nlm.nih.gov/enviro.html>].
Novo Nordisk. (2014). NovoSeven® RT Coagulation Factor VIIa (Recombinant). Retrieved from www.novo-pi.com/novosevenrt.pdf.

Training advice

: No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

NFPA health hazard

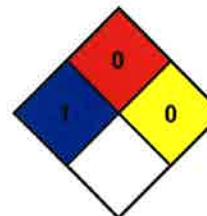
: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

: 0 - Materials that will not burn.

NFPA reactivity

: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product