

Novo Nordisk A/S	<b>DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET</b> according to 91/155/EEC		
	<b>NovoSeven<sup>®</sup> RT 1.0 mg, NovoSeven<sup>®</sup> RT 2.0 mg, NovoSeven<sup>®</sup> RT 5.0 mg</b> [Coagulation Factor VIIa (Recombinant), rFVIIa Room Temperature Stable]		

Trade name	NovoSeven <sup>®</sup> RT 1.0 mg NovoSeven <sup>®</sup> RT 2.0 mg NovoSeven <sup>®</sup> RT 5.0 mg	CAS-no.	102786-61-8
Chemical name	Eptacog alpha (activated)	EU-no.	-
Synonyms	-	INDEX-no.	-
Novo Nordisk item no	-		

<b>COMPOSITION / INFORMATION ON CONTENTS</b>	<b>2</b>
--	----------

Class of risks	Not classified	Hazard symbols			
Risk-phrases	No R-phrases.				
Safety-phrases	No S-phrases.				

<b>HAZARDS IDENTIFICATIONS</b>	<b>3</b>
--------------------------------	----------

HAZARDOUS PROPERTIES	Swallowing: Ingestion of the material is not known to result in significant adverse health effect.
Acute effects	Inhalation: May cause possible mild irritation Skin contact: May cause possible mild skin irritation. Eye contact: May cause possible mild irritation.
Chronicle effects	Upon repeated or prolonged exposure, inhalation of the material may cause hypersensitivity-like reactions in very sensitive persons.
FLAMMABLE PROPERTIES	NovoSeven <sup>®</sup> is not combustible.

<b>FIRST AID MEASURES</b>	<b>4</b>
---------------------------	----------

Consumption	Rinse out mouth thoroughly with water and give plenty of water. Do NOT provoke vomiting. If symptoms persist, seek medical attention.
Inhalation	Go out into fresh air. Seek medical attention if allergic symptoms occur.
Skin contact	Remove contaminated clothes immediately and rinse contaminated skin for at least 15 minutes with water and soap. If symptoms persist, seek medical attention.
Eye contact	Rinse the eyes immediately with water for at least 15 minutes. Seek medical attention if symptoms persist.

Novo Nordisk A/S	<b>DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET</b> according to 91/155/EEC
	<b>NovoSeven<sup>®</sup> RT 1.0 mg, NovoSeven<sup>®</sup> RT 2.0 mg, NovoSeven<sup>®</sup> RT 5.0 mg</b> [Coagulation Factor VIIa (Recombinant), rFVIIa Room Temperature Stable]

<b>PRECAUTIONS IN CASE OF FIRE</b>	<b>5</b>
------------------------------------	----------

No special precautions.

<b>ACCIDENTIAL RELEASE MEASURES</b>	<b>6</b>
-------------------------------------	----------

Collect powder spill into a suitable container. Clean contaminated surfaces with excess of water. Use personal protection during the clean-up.

<b>HANDLING AND STORAGE</b>	<b>7</b>
-----------------------------	----------

Freeze-dried powder must be kept in a refrigerated place in original packing. NovoSeven<sup>®</sup> -solution must be kept in a deep freezer (< ±80°C).

<b>EXPOSURE CONTROLS / PERSONAL PROTECTION</b>	<b>8</b>
--	----------

Limit value	none	Smell limit value	none
-------------	------	-------------------	------

Avoid inhalation of dust/aerosols.  
In case of spillage, use breathing protection (P2-particle filter, authorized for aerosols).  
Avoid contact with the skin. Wear gloves (e.g. PVC-disposable gloves).  
There must be easy access to running water, emergency water spray/eye-wash bottle on the spot.

<b>PHYSICAL AND CHEMICAL PROPERTIES</b>	<b>9</b>
---	----------

Chemical formula	Eptacog alpha is a glycoprotein consisting of 406 amino acid residues	Water-solubility	Soluble
Appearance	Freeze-dried white powder/ aqueous solution	Molecular weight	50 K Dalton
Density	Not determined	Melting point	Not applicable
Boiling point	No data	Flash point	Not applicable
Viscosity	No data	Vapour pressure	Not applicable
Explosion limits	Not applicable	Auto-ignition point	Not applicable
pH-value	Not applicable	Octanol/water coefficient (Log P)	Not applicable

Novo Nordisk A/S	DIRECTIONS FOR USE / MATERIAL SAFETY DATA SHEET according to 91/155/EEC	
	<b>NovoSeven<sup>®</sup> RT 1.0 mg, NovoSeven<sup>®</sup> RT 2.0 mg, NovoSeven<sup>®</sup> RT 5.0 mg</b> [Coagulation Factor VIIa (Recombinant), rFVIIa Room Temperature Stable]	

STABILITY AND REACTIVITY	10
--------------------------	----

NovoSeven<sup>®</sup> is normally stable under normal storage.

TOXICOLOGICAL DATA	11
--------------------	----

LD <sub>50</sub> -value, oral (rat)	-		LD <sub>50</sub> -value, dermatological (rat)	-	
Long-term adverse effects:	No	Under suspicion	Yes	Contradictory information	No information
Carcinogenic					X
Allergy (contact allergy)					X
Allergy (inhalation allergy)		X			
Teratogenic					X
Nerve-damaging					X

ENVIRONMENT INFORMATION	12
-------------------------	----

NovoSeven<sup>®</sup> does no harm to the environment.

WASTE DISPOSAL CONSIDERATIONS	13
-------------------------------	----

Spillage and waste are to be collected in proper receptacles. Dispose at an approved site according local regulations regarding disposal.

Chemical waste group	Z	Chemical waste card	-
----------------------	---	---------------------	---

TRANSPORT INFORMATION	14
-----------------------	----

ADR	Not dangerous goods	IMDG	Not dangerous goods
RID	Not dangerous goods	IATA	Not dangerous goods

REGULATORY INFORMATION	15
------------------------	----

No special regulations.

OTHER INFORMATION	16
-------------------	----

There are no special demands for education, but persons handling NovoSeven<sup>®</sup> should be familiar with the instructions mentioned in these directions for use.