

Safety data sheet

NovoEight® 250, 500, 1000, 1500, 2000 and 3000 IU

1. Identification of the substance/preparation and of the company/undertaking

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2. Hazards identification

The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.
Additional information No special risk if used in accordance with the instructions of the supplier. NovoEight is indicated for the treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VII or Factor IX.

3. Composition/information on ingredients

REACH registration number	CAS No./ Eines no.	Substances	Classification/ CLP-classification	w/w%
	1192451-26-5	Turoctocog alfa Solvent for injection	Not classified	-
<i>Please see section 16 for the full text of R-phrases and H-phrases.</i>				

4. First aid measures

Inhalation Seek fresh air. Seek medical advice if symptoms persist.
Ingestion Rinse mouth thoroughly and then drink plenty of water. Seek medical advice if symptoms persist.
Skin Remove contaminated clothes. Wash skin with water and soap.
Eyes Rinse immediately with water (preferably using eye wash) for at least 5 minutes. Open eyes wide. Remove any contact lenses. Seek medical advice if irritation persists.
Other information When obtaining medical advice, show the safety data sheet or label.

5. Fire-fighting measures

The product is not readily flammable. Avoid breathing vapors and flue gases - seek fresh air. Fire Fighting Extinguishing Media: In case of fire use foam, waterspray, dry chemical or CO2.
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6. Accidental release measures

Use the same personal protection as for item 8. Mop up spillage with a cloth. Contain and absorb spill with sand or other absorbent material and transfer to suitable waste containers. See section 13 for instructions on disposal.

7. Handling and storage

Handling

Please see item 8 for information on personal protection.

Storage

Keep refrigerated (2 - 8°C /36 - 46°F). Avoid exposure to direct sunlight.. Do not use past the expiration date.

8. Exposure controls/ personal protection

Precautions for use

There must be access to running water and eye wash.

Respiratory protection

Not required.

Gloves and protective clothing

Gloves, nitril rubber or similar protection are recommended for waste clear-up and manufacturing operations.

Eye protection

Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a risk of splashing.

Occupational exposure limits

Contains no substances subject to reporting requirements.

9. Physical and chemical properties

Appearance: Aqueous solution

Odor: No special smell

10. Stability and reactivity

The product is stable if used in accordance with supplier's instructions. No known incompatibilities. No known hazardous decomposition products.

11. Toxicological information

Acute

Inhalation

Inhalation of spray mist containing protein may cause sensitization.

Ingestion

May irritate mucous membranes in mouth and gastrointestinal tract.

Skin contact

May be slightly irritating.

Eye contact

May be temporary irritating.

Risk of sensitization

NovoEight may contain trace amount of immunogenic proteins. Systemic exposure to the product may cause hypersensitivity to these proteins.

Long-term effects

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

Cancer

No indication of carcinogenic potential for NovoEight.

May cause damage to the reproductive system

No teratogenic or development effects was observed in animals.

12. Ecological information

Do not discharge large quantities of concentrated spills and residue into drains.

13. Disposal considerations

The product is not hazardous waste. It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

14. Transport information

The product is not covered by the rules for transport of dangerous goods by road and sea according to ADR and IMDG.

15. Regulatory information

Hazard designation: It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

Contains

Turoctocog alfa.

Supplemental information

Chemical safety assessment

16. Other information

Restrictions on use

None.

Training requirement

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

Sources used

Other information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

Full text of the R-phrases that are stated in section 3.

No R-phrases.

Full text of the H-phrases that are stated in section 3.

No H-phrases.