

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

1.1. Product identifier

Product form : Mixture
Product name : Novoeight®
Other means of identification : Novoeight®, Antihemophilic Factor (Recombinant)
For Intravenous Injection. Lyophilized Powder for Solution available in 250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU vial sizes

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

Use of the substance/mixture : Drug Product. Novoeight® temporarily replaces the missing clotting factor VIII that is needed for effective hemostasis.

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Skin Sens. 1 H317

2.2. Label elements

GHS-US labeling

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: sodium chloride, L-histidine, sucrose, polysorbate 80, L-methionine and calcium chloride dihydrate. The product contains no preservative.

2.4. Unknown acute toxicity (GHS-US)

No data available

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	%	Classification (GHS-US)
Human coagulation factor VIII (rDNA)		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 dust containing protein may cause sensitization. Other symptoms: wheezing, urticaria, and pruritus.
- Symptoms/injuries after skin contact : Not investigated. May cause slight irritation.
- Symptoms/injuries after eye contact : Not investigated. May cause irritation. Avoid contact with the eyes.
- Symptoms/injuries after ingestion : Not investigated. Ingestion of dust containing protein may cause sensitization. Other symptoms: wheezing, urticaria, and pruritus.
- Symptoms/injuries upon inadvertent injection : Hypersensitivity reactions, including anaphylaxis, are possible. Novoeight® contains trace amounts of hamster proteins. Early signs of hypersensitivity reactions that can progress to anaphylaxis include angioedema, chest tightness, dyspnea. Other symptoms: wheezing, urticaria, and pruritus.

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 dust - 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 : Vacuum or sweep up material and place in a disposal container.

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 original packaging
- Incompatible products : Direct sunlight. Light.
- Storage temperature : Keep refrigerated 2 to 8 °C (36 to 46 °F) for up to 30 months from the date of manufacture until the expiration date stated on the label. Do not freeze. If you choose to store Novoeight® at room temperature, clearly record the date when the product was removed from the refrigerator in the space provided on the outer carton. The total time of storage at room temperature should not exceed 12 months. Do not return the product to the refrigerator. Do not use Novoeight® after the end of the 12-month period at room temperature storage, or after the expiration date stated on the vial, whichever occurs earlier. Use Novoeight® within 4 hours after reconstitution when stored at room temperature. Store the reconstituted product in the vial. Discard any unused reconstituted product stored at room temperature for more than 4 hours.

7.3. Specific end use(s)

No indications

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 : Lyophilized powder/solution
- Appearance : White powder / clear solution
- Molecular mass : 166 kDa
- Color : White.
- Odor : No special smell.
- Odor threshold : No data available
- pH : No data available
- Relative evaporation rate (butyl acetate=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 : Water: Highly Soluble.
- 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
Oxidizing 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

Novoeight®	
Additional information	Hypersensitivity reactions, including anaphylaxis, are possible with Novoeight®. Novoeight® contains trace amounts of hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins. Early signs of hypersensitivity reactions that can progress to anaphylaxis include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus.

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Long-term studies in animals have not been performed.)
Carcinogenicity	: Not classified (No indication of carcinogenic potential for Novoeight®.)

Novoeight®	
Additional information	No chronic carcinogenicity studies have been performed.

Reproductive toxicity : Not classified
(Long-term studies in animals have not been performed.)

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Novoeight®	
Additional information	1250 IU/kg in rats and 5000 IU/kg in monkeys.

Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Not investigated. Inhalation of dust or mist containing protein may cause sensitization. Other symptoms: wheezing, urticaria, and pruritus.
Symptoms/injuries after skin contact	: Not investigated. May cause slight irritation.
Symptoms/injuries after eye contact	: Not investigated. May cause irritation. Avoid contact with the eyes.

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- Symptoms/injuries after ingestion : Not investigated. Ingestion of dust or liquid containing protein may cause sensitization. Other symptoms: wheezing, urticaria, and pruritus
- Symptoms/injuries upon inadvertent injection : Hypersensitivity reactions, including anaphylaxis, are possible. Novoeight® contains trace amounts of hamster proteins. Early signs of hypersensitivity reactions that can progress to anaphylaxis include angioedema, chest tightness, dyspnea. Other symptoms: wheezing, urticaria, and pruritus.

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

Novoeight®	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

- Other information : No other effects known.

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

Additional information

- Other information : No supplementary information available.

ADR

- Transport document description :

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Human coagulation factor VIII (rDNA)	
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). Novoeight® Prescribing Information. Retrieved from
<http://www.novonordiskmedicalinformation.com/products.aspx>

Training advice

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

Full text of H-phrases: see section 16:

Skin Sens. 1	Skin sensitization Category 1
H317	May cause an allergic skin reaction

NFPA health hazard

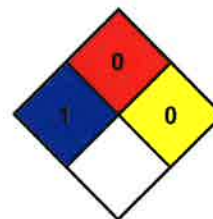
- 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

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