

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

1.1. Product identifier

Product form : Lyophilized powder for injection
Product name : Tretten
Formula : $C_{3708}H_{5735}N_{1013}O_{1111}S_{28}$

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

Use of the substance/mixture : Drug Product

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

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 mist
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 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: L-histidine, polysorbate 20, sodium chloride, and sucrose.

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

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3.2. Mixture

Name	Product identifier	%	GHS-US classification
Recombinant Human Coagulation Factor XIII (Protein)	(CAS No) 9013-54-3	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 : Not anticipated. If large amounts of dusts are inhaled, remove to fresh air. If breathing problems occur, a certified professional should administer oxygen or CPR if indicated. Seek immediate 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 : When swallowed, seek medical attention if symptoms persist and show the physician the package insert. Do NOT induce vomiting. Not expected to be active orally.

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. Tretten® may cause allergic reactions including anaphylactic reaction.
- 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 : Increased levels of activated rFXIII may increase 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 : Not 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 : 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 spillage to prevent material damage.

6.4. Reference to other sections

No additional information available

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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.
- Incompatible products : Light.
- Storage temperature : Keep refrigerated 2 to 8 °C (36 to 46 °F) but not in the freezer. Do not freeze.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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, nitril 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/solution
- Appearance : White powder for solution for injection. The reconstituted preparation is a clear, colorless solution.
- Molecular mass : 83.2 kDa
- Colour : White in powder form. Colorless/clear upon reconstitution.
- Odour : No data available
- Odour threshold : No data available
- pH : No data available
- pH solution : 8 (at 20 °C)
- 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
- Vapour pressure : No data available
- Relative vapour density at 20 °C : No data available
- Relative density : No data available
- Solubility : Soluble in water.
- Log Pow : No data available
- Log Kow : No data available
- Viscosity, kinematic : No data available
- Viscosity, dynamic : No data available

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Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information 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

Light. Extreme heat or cold.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Tretten	
Additional information	Hypersensitivity to the active substance or to any of the excipients. As Tretten® is a protein it may cause allergic reactions including anaphylactic reaction.

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

(Long-term studies in animals have not been performed.)

Carcinogenicity : Not classified

(Long-term studies in animals to evaluate the carcinogenic potential of Tretten® have not been performed. An assessment of the carcinogenic potential of Tretten® was completed and suggests minimal carcinogenic risk from product use.)

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

(Repeated dose studies in animals did not identify any target organ toxicity.)

Recombinant Human Coagulation Factor XIII (Protein) (9013-54-3)	
Additional information	12.5 mg/kg/2 weeks was considered to be the NOAEL (No Observed Adverse Effect Level) of the 4-weeks repeat dose toxicity study in monkey

Aspiration hazard : Not classified

Symptoms/injuries after inhalation : Not investigated. Inhalation of mist containing protein may cause sensitization. Tretten® may cause allergic reactions including anaphylactic reaction.

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 : Increased levels of activated rFXIII may increase the risk of thrombosis.

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SECTION 12: Ecological information

12.1. Toxicity

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

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

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

Recombinant Human Coagulation Factor XIII (Protein) (9013-54-3)

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

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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>].

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	Sensitisation — Skin, category 1
H317	May cause an allergic skin reaction

NFPA health hazard

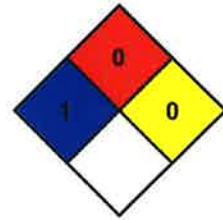
- 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

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