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SECTION 1. IDENTIFICATION

Product identifier used on the label

: Tretten®, Coagulation Factor XIII A-Subunit (Recombinant)

Other means of identification

: Not available.

Recommended use of the chemical and restrictions on use

: Drug product
  Recommended restrictions: None known.

Chemical family

: Mixture

Name, address, and telephone number of the supplier:

Nodo Nordisk Inc.
800 Scudders Mill Road
Plainboro, NJ, USA
08536
Supplier's Telephone # : 1-800-727-6500
24 Hr. Emergency Tel # : No information available.

SECTION 2. HAZARDS IDENTIFICATION

Classification of the chemical

The powder is white (lyophilized powder) and the solvent is clear and colorless.

This material is not classified as hazardous under U.S. OSHA regulations (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015).

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. Your needs may vary depending upon the potential for exposure in your workplace. The precautionary statements, warnings and hazards included herein may not apply in all cases, such as when the product or device is in its final form and being used to treat the approved medical condition(s) while under the care of a licensed medical professional and in accordance with the FDA-approved Prescribing Information. Refer to FDA-approved Prescribing Information for final marketed products with regard to special storage, handling and administration requirements in the clinical setting.

Label elements

Hazard pictogram(s)

None required under U.S. OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations.

Signal Word

Not required

Hazard statement(s)

Not required

Precautionary statement(s)

Not required

Other hazards

Other hazards which do not result in classification:

No special risk if used in accordance with the instructions of the supplier. Tretten is used for the long-term prevention of bleeding in adults and children aged six and over. Tretten is a recombinant coagulation factor XIII A-subunit produced in yeast cells (Saccharomyces cerevisiae) by recombinant DNA technology.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS #</th>
<th>Concentration (% by weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No hazardous ingredients</td>
<td>Not available.</td>
<td>N/Av</td>
<td>N/Ap</td>
</tr>
</tbody>
</table>

Recmbinant Human Coagulation Factor XIII (Protein)

SECTION 4. FIRST-AID MEASURES

Description of first aid measures

Ingestion: Do NOT induce vomiting. Have victim rinse mouth with water, then give one to two glasses of water to drink. Never give anything by mouth to an unconscious person. Seek medical attention if discomfort occurs.

Inhalation: If inhaled, move to fresh air. If breathing is difficult, give oxygen by qualified medical personnel only. If breathing has stopped, give artificial respiration. Obtain medical attention if symptoms develop and persist.

Skin contact: Wash with water and soap as a precaution. If irritation or symptoms develop, seek medical attention.

Eye contact: If in eyes, rinse with water for 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. If irritation persists, seek prompt medical attention.

Most important symptoms and effects, both acute and delayed

Hypersensitivity to the active substance or to any of the excipients. As Tretten contains a recombinant protein it may cause allergic reactions including anaphylactic reactions. Patients should be informed of the early signs of hypersensitivity reactions (including hives, generalised urticaria, tightness of the chest, wheezing, hypotension).

Indication of any immediate medical attention and special treatment needed

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

SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media

Use media suitable to the surrounding fire such as water fog or fine spray, alcohol foams, carbon dioxide and dry chemical.

Unsuitable extinguishing media

Do not use a solid water stream as it may scatter and spread fire.

Special hazards arising from the substance or mixture / Conditions of flammability

None known or reported by the manufacturer.

Flammability classification (OSHA 29 CFR 1910.106)

Not flammable.

Hazardous combustion products

Irritating fumes and smoke

Special protective equipment and precautions for firefighters

Protective equipment for fire-fighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

Special fire-fighting procedures

Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Restrict access to area until completion of clean-up. Ensure clean-up is conducted by trained personnel only. Wear suitable protective equipment. Refer to protective measures listed in sections 7 and 8. Restrict access to area until completion of clean-up.

Environmental precautions

Ensure spilled product does not enter drains, sewers, waterways, or confined spaces.
SAFETY DATA SHEET

Methods and material for containment and cleaning up

Ventilate area of release. Stop spill or leak at source if safely possible. Dike for water control. Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g. sand), then place absorbent material into a container for later disposal (see Section 13).

Special spill response procedures

If a spill/release in excess of the EPA reportable quantity is made into the environment, immediately notify the national response center in the United States (phone: 1-800-424-8802).


SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

Avoid breathing mist, vapors or spray. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Keep refrigerated until use.

Maximum storage period: 24 months
Storage temperature: 2°C to 8°C

Conditions for safe storage

Keep only in original packaging. Before use: store in a refrigerator (2°C - 8°C). Do not store them in or too near the freezer section or cooling element. During use: do not refrigerate. Do not store above 25°C. Keep the vial in the outer carton in order to protect from light. Protect from excessive heat and sunlight.

Incompatible materials

Strong acids, bases and oxidizing or reducing agents.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TWA</td>
<td>STEL</td>
</tr>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>N/Av</td>
</tr>
</tbody>
</table>

Exposure controls

Ventilation and engineering measures

Use in a well-ventilated area. Use general or local exhaust ventilation to maintain air concentrations below recommended exposure limits.

Respiratory protection

Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust and/or fumes). Advice should be sought from respiratory protection specialists.

Skin protection

Wear protective gloves. Advice should be sought from glove suppliers.

Eye / face protection

Wear eye/face protection. Wear safety glasses with side shields (or goggles).

Other protective equipment

Wear sufficient clothing to prevent skin contact. Depending on conditions of use, an impervious apron should be worn. An eyewash station and safety shower should be made available in the immediate working area.

General hygiene considerations

Avoid contact with skin, eyes and clothing. Upon completion of work, wash hands before eating, drinking, smoking or use of toilet facilities. Handle in accordance with good industrial hygiene and safety practice. Contaminated work clothing must not be allowed out of the workplace.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

The powder is white (lyophilized powder) and the solvent is clear and colorless.

Odour

Not available.

Odour threshold

Not available.

pH

8.0

Melting Point/Freezing point

Not available.
### SAFETY DATA SHEET

**Initial boiling point and boiling range**
- Not available.

**Flash point**
- Not available.

**Flashpoint (Method)**
- Not available.

**Evaporation rate (BuAe = 1)**
- Not available.

**Flammability (solid, gas)**
- Not applicable.

**Lower flammable limit (% by vol.)**
- Not applicable.

**Upper flammable limit (% by vol.)**
- Not applicable.

**Oxidizing properties**
- Not applicable.

**Explosive properties**
- Not explosive.

**Vapour pressure**
- Not available.

**Vapour density**
- Not available.

**Relative density / Specific gravity**
- Not available.

**Solubility in water**
- Soluble

**Other solubility(ies)**
- Not available.

**Partition coefficient: n-octanol/water or Coefficient of water/oil distribution**
- Not available.

**Auto-ignition temperature**
- Not applicable.

**Decomposition temperature**
- Not available.

**Viscosity**
- Not available.

**Volatile (% by weight)**
- Not available.

**Volatile organic Compounds (VOC's)**
- Not available.

**Absolute pressure of container**
- Not applicable.

**Flame projection length**
- Not applicable.

**Other physical/chemical comments**
- None reported by the manufacturer.

### SECTION 10. STABILITY AND REACTIVITY

**Reactivity**
- This product is not reactive.

**Chemical stability**
- Material is stable under normal conditions.

**Possibility of hazardous reactions**
- Under normal conditions of handling and storage, hazardous reactions will not occur.

**Conditions to avoid**
- Avoid contact with incompatible materials. Do not freeze.

**Incompatible materials**
- Strong acids, bases and oxidizing or reducing agents.

**Hazardous decomposition products**
- None known, refer to hazardous combustion products in Section 5.

### SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure:**

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>YES (\times)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of entry inhalation</td>
<td>YES (\times)</td>
</tr>
<tr>
<td>Routes of entry skin &amp; eye</td>
<td>YES (\times)</td>
</tr>
<tr>
<td>Routes of entry Ingestion</td>
<td>YES (\times)</td>
</tr>
<tr>
<td>Routes of exposure skin absorption</td>
<td>NO (\times)</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Potential Health Effects:

Signs and symptoms of short-term (acute) exposure

**Sign and symptoms Inhalation**
- May cause mild transient irritation.

**Sign and symptoms ingestion**
- Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

**Sign and symptoms skin**
- Direct skin contact may cause slight or mild, transient irritation.

**Sign and symptoms eyes**
- Direct eye contact may cause slight or mild, transient irritation.

Frequent or prolonged contact may dry the skin, leading to discomfort and dermatitis.

Potential Chronic Health Effects

- Not expected to be mutagenic in humans.

Carcinogenicity
- No components are listed as carcinogens by ACGIH, IARC, OSHA or NTP.

Reproductive effects & Teratogenicity
- Not expected to cause reproductive effects. There are no clinical data on the use of Tretten in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. No effects on reproductive organs have been seen in non-clinical studies.

Sensitization to material
- Hypersensitivity to the active substance or to any of the excipients. As Tretten contains a recombinant protein it may cause allergic reactions including anaphylactic reactions. Patients should be informed of the early signs of hypersensitivity reactions (including hives, generalised urticaria, tightness of the chest, wheezing, hypotension).

Specific target organ effects
- According to the classification criteria of U.S. OSHA regulations (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015), this product is not expected to cause target organ toxicity through single or repeated exposures.

Medical conditions aggravated by overexposure
- None known.

Synergistic materials
- Not available.

Toxicological data
- There is no available data for the product itself, only for the ingredients. See below for individual ingredient acute toxicity data.

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>LC₅₀ (4hr, inh, rat)</th>
<th>LD₅₀ (oral, rat)</th>
<th>LD₅₀ (rabbit, dermal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
</tr>
</tbody>
</table>

Other important toxicological hazards
- None known or reported by the manufacturer.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
- Not classified for hazards to the environment. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Ecotoxicity data:**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Toxicity to Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>LC₅₀ / 96h</td>
</tr>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>N/Av</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

### Ingredients

<table>
<thead>
<tr>
<th>CAS #</th>
<th>Toxicity to Daphnia</th>
<th>Toxicity to Algae</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 / 48h</td>
<td>NOEC / 21 day</td>
</tr>
<tr>
<td></td>
<td>EC50 / 96h or 72h</td>
<td>NOEC / 96h or 72h</td>
</tr>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>N/Av</td>
</tr>
</tbody>
</table>

### Persistence and degradability

- No data is available on the product itself.

### Bioaccumulation potential

- No data is available on the product itself.

### Components

<table>
<thead>
<tr>
<th>Partition coefficient n-octanol/water (log Kow)</th>
<th>Bioconcentration factor (BCF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No hazardous ingredients (CAS N/Av)</td>
<td>N/Av</td>
</tr>
</tbody>
</table>

### Mobility in soil

- No data is available on the product itself.

### Other Adverse Environmental effects

- No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Handling for Disposal

- Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Methods of Disposal

- Dispose in accordance with all applicable federal, state, provincial and local regulations.

#### RCRA

- If this product, as supplied, becomes a waste in the United States, it may meet the criteria of a hazardous waste as defined under RCRA, Title 40 CFR 261. It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies.
SAFETY DATA SHEET

SECTION 14. TRANSPORT INFORMATION

<table>
<thead>
<tr>
<th>Regulatory Information</th>
<th>UN Number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing Group</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>49CFR/DOT</td>
<td>None.</td>
<td>Not regulated.</td>
<td>not regulated</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>49CFR/DOT (Additional information)</td>
<td>None.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>None.</td>
<td>Not regulated.</td>
<td>not regulated</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>IMDG (Additional information)</td>
<td>None.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICAO/IATA</td>
<td>None.</td>
<td>Not regulated.</td>
<td>not regulated</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>ICAO/IATA (Additional information)</td>
<td>None.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TDG</td>
<td>None.</td>
<td>Not regulated.</td>
<td>not regulated</td>
<td>none</td>
<td></td>
</tr>
<tr>
<td>TDG (Additional information)</td>
<td>None.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Special precautions for user: None known or reported by the manufacturer.

Environmental hazards: This substance does not meet the criteria for an environmentally hazardous substance according to the IMDG Code. See ECOLOGICAL INFORMATION, Section 12.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not available.

SECTION 15 - REGULATORY INFORMATION

US Federal Information:
Components listed below are present on the following U.S. Federal chemical lists:

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>NS</td>
<td>None.</td>
<td>None.</td>
<td>None.</td>
</tr>
</tbody>
</table>

SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: None. Under SARA Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds or the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

US State Right to Know Laws:
The following chemicals are specifically listed by individual States:
SAFETY DATA SHEET

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>California Proposition 65</th>
<th>State “Right to Know” Lists</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Listed</td>
<td>Type of Toxicity</td>
</tr>
<tr>
<td>No hazardous ingredients</td>
<td>N/Av</td>
<td>No</td>
<td>N/Ap</td>
</tr>
</tbody>
</table>

Canadian Information:

WHMIS information: Refer to Section 2 for a WHMIS Classification for this product.

International Information:

Components listed below are present on the following International Inventory list:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>European EINECs</th>
<th>Australia AICS</th>
<th>Philippines PICCS</th>
<th>Japan ENCS</th>
<th>Korea KECI/KECL</th>
<th>China IECSC</th>
<th>NewZealand IOC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
<td>N/Av</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Legend:

ACGIH: American Conference of Governmental Industrial Hygienists
CAS: Chemical Abstract Services
CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR: Code of Federal Regulations
CSA: Canadian Standards Association
DOT: Department of Transportation
EPA: Environmental Protection Agency
HSDB: Hazardous Substances Data Bank
IARC: International Agency for Research on Cancer
Inh: Inhalation
LC: Lethal Concentration
LD: Lethal Dose
N/Ap: Not Applicable
N/Av: Not Available
NTP: National Toxicology Program
OECD: Organisation for Economic Co-operation and Development
OSHA: Occupational Safety and Health Administration
PEL: Permissible exposure limit
RCRA: Resource Conservation and Recovery Act
RTECS: Registry of Toxic Effects of Chemical Substances
SARA: Superfund Amendments and Reauthorization Act
STEL: Short Term Exposure Limit
TLV: Threshold Limit Values
TWA: Time Weighted Average
WHMIS: Workplace Hazardous Materials Identification System

References:

1. ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices for
2. ECHA - European Chemical Agency
3. Canadian Centre for Occupational Health and Safety, CCInfoWeb databases, (Chempendium, HSDB and RTECs).
4. Safety Data Sheets from manufacturer.
5. US EPA Title III List of Lists
6. California Proposition 65 List

Preparation Date (mm/dd/yyyy):

12/02/2020

Other special considerations for handling:

Provide adequate information, instruction and training for operators.
SAFETY DATA SHEET

Prepared for:
Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
1-800-727-6500
www.novonordisk-us.com

Prepared by:
ICC The Compliance Center Inc.
Telephone: (888) 442-9628 (U.S.); (888) 977-4834 (Canada)
http://www.thecompliancecenter.com

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END OF DOCUMENT