

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

1.1. Product identifier

Product Source : Solution
 Product name : Tresiba® 100 U/ml, 200 U/ml
 Formula : $C_{274}H_{411}N_{65}O_{81}S_6$
 Other mean of identification : Tresiba® FlexTouch®, insulin degludec

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

Use of the substance/mixture : Drug Product. Tresiba® is a long-acting basal insulin called insulin degludec. It is used to treat diabetes mellitus in patients one year of age or older.

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
 STOT SE 1 H370

Full text of H-phrases: see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS07

GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H317 - May cause an allergic skin reaction
 H370 - Causes damage to organs (circulatory system, circulatory organs)

Precautionary statements (GHS-US) :

P260 - Do not breathe mist
 P261 - Avoid breathing mist
 P264 - Wash hands thoroughly after handling
 P270 - Do not eat, drink or smoke when using this product
 P272 - Contaminated work clothing must not be allowed out of the workplace
 P280 - Wear appropriate PPE
 P302 + P352 - If on skin: Wash with plenty of soap and water
 P307 + P311 - If exposed: Call a poison center/doctor
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
 P362+P364 - Take off contaminated clothing and wash it before reuse
 P405 - Store locked up
 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: glycerol, metacresol, phenol, zinc, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections. Inadvertent needle sticks may pose the risk of blood borne pathogens.

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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	%	GHS-US classification
Aqueous solution for injection, contains: B29 N(ε)-hexadecandioyl-γ-L-Glu desB30 Insulin degludec [rDNA origin]	(CAS No) 844439-96-9	100	Skin Sens. 1, H317 STOT (SE) 1, H370

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. Do NOT induce vomiting. Not expected to be active orally (hypoglycemia).

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
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.
Symptoms/injuries upon injection.	: Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension. May result in severe hypoglycemia.

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.

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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 with non-combustible material and transfer to containers.

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. Prevent contact with needles used to administer Tresiba®. Use personal protective equipment as required. Tresiba® is for subcutaneous use only.
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 : After first opening: Tresiba® FlexTouch® (pre-filled pen) should be kept at room temperature (below 86°F [30°C]) or stored in the refrigerator (36 - 46°F [2 - 8°C]) away from direct heat and light. The opened (in-use) Tresiba® FlexTouch® pen may be used for up to 56 days (8 weeks) after being opened, if it is kept at room temperature or refrigerated (as indicated above). Tresiba® should not be used after the expiration date on the pens.
Incompatible products : Heat sources.
Maximum storage period : 56 days (8 weeks) opened at room temperature or in the refrigerator. 30 months unopened and refrigerated.
Storage temperature : Unopened: Keep refrigerated between 2 - 8°C (36 - 46° F). Do not freeze.

7.3. Specific end use(s)

Drug Product. Tresiba® is a long-acting basal insulin called insulin degludec. It is used to treat diabetes mellitus in patients one year of age or older.

SECTION 8: Exposure controls/personal protection

Phenol (108-95-2)		
USA ACGIH	ACGIH TWA (ppm)	5 ppm
USA ACGIH	Remark (ACGIH)	URT irr; lung dam; CNS impair
USA OSHA	OSHA PEL (TWA) (mg/m ³)	19 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm
Metacresol (108-39-4)		
USA ACGIH	ACGIH TWA (mg/m ³)	22 mg/m ³
USA ACGIH	ACGIH TWA (ppm)	5 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	22 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm
USA OSHA	Remark (US OSHA)	Skin Irrt.

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 (e.g. local extractor fan). 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. Avoid contact with sharps used to administer Tresiba®.
Respiratory protection : Not normally required.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear/colorless aqueous solution.
Molecular mass	: 6103.972 g/mol
Color	: Clear/Colorless
Odor	: No special smell.
Odor threshold	: No data available
pH	: No data available
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
Vapor pressure	: No data available
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Relative vapor 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
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.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
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 (Proteins are not expected to have any genotoxic potential. None of the excipients in Tresiba® posses any genotoxic potential.)
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified (The effect of insulin degludec was consistent with those observed with human insulin as both caused pre- and post-implantation losses and visceral/skeletal abnormalities in rats at an insulin degludec dose of 21 U/kg/day (approximately 5 times the human exposure (AUC) at a human subcutaneous dose of 0.75 U/kg/day) and in rabbits at a dose of 3.3 U/kg/day (approximately 10 times the human exposure (AUC) at a human subcutaneous dose of 0.75 U/kg/day). The effects are probably secondary to maternal hypoglycemia.)
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
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.
Symptoms/injuries upon Injection	: Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension. May result in severe hypoglycemia.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

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. Do not throw sharps in the garbage, the toilet or in recycling containers. Refer to <http://www.epa.gov/wastes/nonhaz/industrial/medical/med-home.pdf> for more information regarding the safe disposal of sharps.

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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

Aqueous solution for injection, contains: B29 N(ε)-hexadecandioyl-γ-L-Glu desB30 Insulin degludec [rDNA origin] (844439-96-9)

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

Phenol (108-95-2)

U.S. – Idaho – Non-Carcinogenic Toxic Air Pollutants – Acceptable Ambient Concentrations

U.S. – Maine – Air pollutants – Hazardous Air Pollutants

U.S. – Massachusetts – Right To Know List

U.S. – New Jersey – Right to Know Hazardous Substance List

U.S. – New York – Reporting of Releases Part 597 – List of Hazardous Substances

U.S. – Pennsylvania – RTK (Right to Know) List

Metacresol (108-39-4)

U.S. – Idaho – Non-Carcinogenic Toxic Air Pollutants – Acceptable Ambient Concentrations

U.S. – Maine – Air pollutants – Hazardous Air Pollutants

U.S. – Massachusetts – Right To Know List

U.S. – New Jersey – Right to Know Hazardous Substance List

U.S. – New York – Reporting of Releases Part 597 – List of Hazardous Substances

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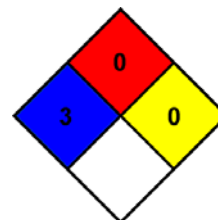
SECTION 16: Other information

- Data sources : ChemIDplus [<http://chem.sis.nlm.nih.gov/chemidplus/rn/844439-96-9>]
Environmental Health & Toxicology – National Library of Medicine [<http://sis.nlm.nih.gov/enviro.htm>].
Novo Nordisk 2015. Tresiba® prescribing information Retrieved from www.novo-pi.com/tresiba.pdf.
- Training advice : No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

Full text of H-phrases:

Skin Sens. 1	Skin sensitization Category 1
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
H317	May cause an allergic skin reaction
H370	Causes damage to organs

- NFPA health hazard : 3 - Short exposure could cause serious temporary or residual injury even though prompt medical attention was 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