Norditropin®

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 1/23/2015 Version: 1.0

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

1.1. Product identifier

Product form : Liquid

Product name : Norditropin®

Formula : $C_{990}H_{1528}N_{262}O_{300}S_7$

Other means of identification : Norditropin® FlexPro® 5 mg/1.5 mL
Norditropin® FlexPro® 10 mg/1.5 mL
Norditropin® FlexPro® 15 mg/1.5 mL
Norditropin® FlexPro® 30mg/3mL
Norditropin® NordiFlex® 30 mg/3.0 mL

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: histidine, poloxamer 188, phenol, mannitol, hydrogen chloride/sodium hydroxide, and water for injection.

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 containing somatropin	12629-01-5	100	Skin Sens. 1, H317
Phenol	(CAS No) 108-95-2	≤0.03	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Muta. 2, H341 STOT RE 2, H373 Aquatic Acute 3, H402

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 an anticipated route of entry. If inhaled, remove person to fresh air.

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 mist 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 inadvertant injection : Local Allergic Reaction: Injection site reactions may occur and include pain, redness, itching, hives, swelling, bruising and inflammation. May cause intracranial hypertension, significant diabetic retinopathy, slipped capital femoral epiphysis in pediatric patients, Progression of preexisting scoliosis in pediatric patients, fluid retention manifested by edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paraesthesias, unmasking of latent central hypothyroidism, and pancreatitis

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.

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.

Storage temperature : Keep refrigerated 2 to 8 °C (36 to 46 °F) but not in the freezer. Do not freeze. After the initial injection, a Norditropin® FlexPro® or NordiFlex® prefilled pen may be EITHER stored in the refrigerator (2°C–8°C/36°F–46°F) and used within 4 weeks OR stored for up to 3 weeks at room temperature not more than 25°C (77°F).

7.3. Specific end use(s)

Drug product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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/m³)	19 mg/m³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm

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, 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 : Liquid

Appearance : Clear, colorless liquid.

Molecular mass : 22125 Dalton

Colour : Colorless. clear.

Odour : Light phenol smell.

Odour threshold : No data available

pH : No data available

pH solution : No data available

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : 100 °C

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	:	1.01 g/ml (at 25 °C)
Solubility	:	No data available
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
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

Victoza should be protected from excessive heat and sunlight.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Phenol (108-95-2)	
LD50 oral rat	270 mg/kg Gigiena i Sanitariya. For English translation, see HYSAAV. Vol. 38(8), Pg. 6, 1973.
LD50 dermal rabbit	630 mg/kg Union Carbide Data Sheet. Vol. 1/6/1966.
LC50 inhalation rat (ppm)	81 ppm Nagoznyi 1976
ATE CLP (oral)	100.000 mg/kg body weight
ATE CLP (dermal)	300.000 mg/kg body weight
ATE CLP (gases)	700.000 ppmV/4h
ATE CLP (vapors)	3.000 mg/l/4h
ATE CLP (dust, mist)	0.500 mg/l/4h
Norditropin®	
Additional information	Hypersensitivity to the active substance or to any of the excipients.

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 (Studies have not been conducted.)

Carcinogenicity : Not classified
(Studies have not been conducted.)

Phenol (108-95-2)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified
(Studies have not been conducted.)

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Phenol (108-95-2)	
LOAEL (oral,rat,90 days)	1.8 mg/kg bodyweight/day

Norditropin®	
Additional information	Rarely causes pancreatitis at therapeutic doses delivered by injection..

Aspiration hazard : Not classified

Symptoms/injuries after inhalation : Not investigated. Inhalation of mist 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 inadvertant injection : Local Allergic Reaction: Injection site reactions may occur and include pain, redness, itching, hives, swelling, bruising and inflammation. May cause intracranial hypertension, significant diabetic retinopathy, slipped capital femoral epiphysis in pediatric patients, Progression of preexisting scoliosis in pediatric patients, fluid retention manifested by edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paraesthesias, unmasking of latent central hypothyroidism, and pancreatitis.

SECTION 12: Ecological information

12.1. Toxicity

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

Phenol (108-95-2)	
LC50 fish	20.5 mg/l Cairns, J.Jr., and A. Scheier 1959. The Relationship of Bluegill Sunfish Body Size to Tolerance for Some Common Chemicals. Proc.13th Ind.Waste Conf., Purdue Univ.Eng.Bull 96:243-252; Smith, S., V.J. Furay, P.J. Layiwola, and J.A. Menezes-Filho 1994. Ev
EC50 Daphnia	20 mg/l Kamshilov, M.M., and B.A. Flerov 1976. Experimental Research on Phenol intoxication of Aquatic Organisms and Destruction of Phenol in Model Communities. In: D.I.Mount, W.R.Swain, N.K.Ivanikiw (Eds.), Proc.1st and 2nd USA-USSR Symp.on Effects of Pollutants upon Aquatic Ecosystems, Duluth, MN :181-192 (U.S.NTIS PB-287-219) (Author Communication Used); Cowgill, U.M., and D.P. Milazzo 1991. The Sensitivity of Ceriodaphnia dubia and Daphnia magna to Seven Chemicals Utilizing the Three-Brood Test. Arch.Environ.Contam.Toxicol. 20(2):211-217
EC50 Daphnia	12.6 mg/l Holcombe, G.W., G.L. Phipps, A.H. Sulaiman, and A.D. Hoffman 1987. Simultaneous Multiple Species Testing: Acute Toxicity of 13 Chemicals to 12 Diverse Freshwater Amphibian, Fish, and Invertebrate Families. Arch.Environ.Contam.Toxicol. 16:697-710 (OECDG Data File)
ErC50 (algae)	229 mg/l (72 hours) Tisler, T., and J. Zagorc-Koncan 1995. Relative Sensitivity of Some Selected Aquatic Organisms to Phenol. Bull.Environ.Contam.Toxicol. 54(5):717-723
ErC50 (other aquatic plants)	84.5 mg/l (96 hours) Thellen, C., C. Blaise, Y. Roy, and C. Hickey 1989. Round Robin Testing with the Selenastrum capricornutum Microplate Toxicity Assay. Hydrobiologia 188/189:259-268

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Phenol (108-95-2)	
Log Pow	1.5

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

Phenol (108-95-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on United States SARA Section 313	
RQ (Reportable quantity, section 304 of EPA's List of Lists) :	1000 lb

Aqueous solution for injection containing somatropin
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

Phenol (108-95-2)
U.S. - Pennsylvania - RTK (Right to Know) List

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). *Norditroprin® somatropin (rDNA origin) injection.* Retrieved from www.novo-pi.com/**norditropin**.pd.

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

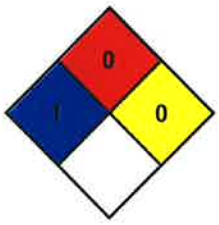
Full text of **H-phrases**: see section 16:

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