

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

1.1. Product identifier

Product form : Solution
 Product name : Saxenda®

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

Classification (GHS-US)

Acute Tox. 4 (Oral) H302
 Resp. Sens. 1 H334
 Skin Sens. 1 H317
 Carc. 2 H351

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US)



GHS07

GHS08

Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H302 - Harmful if swallowed
 H317 - May cause an allergic skin reaction
 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
 H351 - Suspected of causing cancer (Injection)

Precautionary statements (GHS-US)

: P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 P261 - Avoid breathing mist, fume, spray, vapors
 P264 - Wash exposed skin thoroughly after handling
 P270 - Do not eat, drink or smoke when using this product
 P272 - Contaminated work clothing should not be allowed out of the workplace
 P280 - Wear appropriate PPE
 P284 - [In case of inadequate ventilation] wear respiratory protection
 P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water
 P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
 P308+P313 - IF exposed or concerned: Get medical advice/attention
 P321 - Specific treatment (see Section 4 on this label)
 P330 - If swallowed, rinse mouth
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
 P342+P311 - If experiencing respiratory symptoms: Call a Poison Center
 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

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2.3. Other hazards

Other hazards not contributing to the classification : Inactive ingredients include: disodium phosphate dihydrate, propylene glycol, phenol 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

SE

Name	Product identifier	%	Classification (GHS-US)
Solution for injection containing liraglutide [rDNA origin] injection	(CAS No) 204656-20-2	100	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317 Carc. 2, H351
Phenol	(CAS No) 108-95-2	≤0.5	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 (hypoglycemia).

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. Saxenda® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of other medications.
- Symptoms/injuries upon inadvertent injection : There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients. May cause hypoglycemia. May cause headache, nausea, diarrhea, constipation, vomiting, decreased appetite, dyspepsia, fatigue, dizziness, and abdominal pain.

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.

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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 initial use of the Saxenda® pen, the pen can be stored for 30 days at controlled room temperature (59°F to 86°F; 15°C to 30°C) or in a refrigerator (36°F to 46°F; 2°C to 8°C).

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/m ³)	19 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	5 ppm

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 : Liquid
- Appearance : Clear, colorless solution
- Molecular mass : 3751.2 Daltons
- Color : Colorless, clear.
- Odor : No particular

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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	: 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

Strong Oxidizers. Saxenda® 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 : Harmful if swallowed.

Saxenda®	
Additional information	Hypersensitivity to the active substance or to any of the excipients..
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 Nagoznyy 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

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Solution for injection containing liraglutide [rDNA origin] (204656-20-2)

LD50 oral rat 980 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Liraglutide was negative with and without metabolic activation in the Ames test for mutagenicity and in a human peripheral blood lymphocyte chromosome aberration test for clastogenicity. Liraglutide was negative in repeat-dose in vivo micronucleus tests in rats.)
Carcinogenicity	: Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. It is unknown whether Saxenda® will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined

Phenol (108-95-2)

IARC group 3 - Not classifiable

Reproductive toxicity	: Not classified (No direct adverse effects on male fertility was observed at doses up to 1.0 mg/kg/day, a high dose yielding an estimated systemic exposure 11- times the human exposure at the MRHD, based on plasma AUC. In female rats, an increase in early embryonic deaths occurred at 1.0 mg/kg/day.)
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

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. Saxenda® causes a delay of gastric emptying, and thereby has the potential to impact the absorption of other medications.
Symptoms/injuries upon inadvertent intravenous administration	: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients. May cause hypoglycemia. May cause headache, nausea, diarrhea, constipation, vomiting, decreased appetite, dyspepsia, fatigue, dizziness, and abdominal pain.

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.Enviro.n.Contam.Toxicol. 20(2):211-217

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Phenol (108-95-2)	
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. It is recommended that large quantities of waste and waste disposed of through the local receiving station with the following specifications. Dispose of any cleanup materials and waste residue according to all applicable laws and 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

Solution for injection containing liraglutide [rDNA origin] (204656-20-2)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

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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

SECTION 16: Other information

Data sources

- ⌚ <http://chem.sis.nlm.nih.gov/chemidplus/rn/204656-20-2>
Environmental Health & Toxicology - National Library of Medicine
[<http://sis.nlm.nih.gov/enviro.html>].
- Novo Nordisk, 2015. Saxenda Prescribing Information, January 2015. Retrieved from
<http://www.novonordiskmedicalinformation.com/>

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:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 2	Carcinogenicity Category 2
Resp. Sens. 1	Respiratory sensitization Category 1
Skin Sens. 1	Skin sensitization Category 1
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H351	Suspected of causing cancer

NFPA health hazard

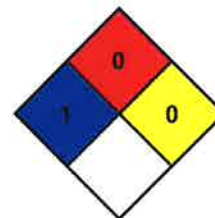
- ⌚ 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

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