

Ozempic® (semaglutide) for Injection

Safety Data Sheet

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

Revision date: 08/06/2018

SECTION 1: Identification

1.1. Identification

Product name : Ozempic® (semaglutide) for Injection
 Other means of identification : Injection: 2 mg/1.5 mL (1.34 mg/mL) available in:
 • Single-patient-use pen that delivers 0.25 mg or 0.5 mg per injection
 • Single-patient-use pen that delivers 1 mg per injection

1.2. Recommended use and restrictions on use

Recommended use : Ozempic® is a glucagon-like peptide 1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

1.3. Supplier

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

1.4. Emergency telephone number

Manufacturer Number : 1-800-727-6500

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS-US labeling

No labeling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Solution for injection containing semaglutide	(CAS No) 910463-68-2	95 - 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Repr. 2, H361
Phenol	(CAS No) 108-95-2	< 1	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

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Not an anticipated route of entry. Remove person to fresh air and keep comfortable for breathing.
 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.

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- 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.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects : The most common adverse reactions when taking Ozempic® subcutaneous injections are: nausea, vomiting, diarrhea, abdominal pain and constipation.
- Symptoms/effects after inhalation : None under normal conditions.
- Symptoms/effects after skin contact : None anticipated under normal conditions and use. As with other GLP-1 therapy, patients may experience rash, redness, inflammation, bruising or itching at the site of Ozempic® injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of Ozempic®.
- Symptoms/effects after eye contact : None under normal conditions
- Symptoms/effects after ingestion : None under normal conditions.
- Symptoms/effects upon intramuscular travenous administration : Serious hypersensitivity reactions (e.g. anaphylaxis, angioedema) have been reported with GLP-1 receptor agonists. If hypersensitivity reactions occur, discontinue Ozempic and treat promptly per standard of care.

4.3. Immediate medical attention and special treatment, if necessary

No additional information available.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

- Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Special protective equipment and precautions for fire-fighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
- Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Good housekeeping should be employed.
- Hygiene measures : Wash contaminated clothing before reuse. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Refrigerator (59°F to 86°F; 15°C to 30°C) Store locked up. Store in a well-ventilated place. Keep cool.
- Information on mixed storage : After first use, or when first reaching room temperature, the Ozempic® pen can be stored for 56 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). Do not freeze. When not in use, keep the pen cap on with no needle attached. Ozempic® should be protected from excessive heat and sunlight.

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Storage area : Do not freeze Ozempic® and do not use Ozempic® if it has been frozen.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Phenol (108-95-2)		
ACGIH	ACGIH TWA (ppm)	5 ppm
ACGIH	Remark (ACGIH)	URT irr; lung dam; CNS impair
OSHA	OSHA PEL (TWA) (mg/m ³)	19 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	5 ppm
NIOSH	US IDLH (ppm)	250 ppm

Solution for injection containing semaglutide (910463-68-2)		
Not applicable		

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Personal protective equipment:

Use only CE marked protective equipment.

Hand protection:

Protective gloves

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear respiratory protection

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Color : Colorless
Odor : Odorless.
Odor threshold : No data available
pH : 7.4
Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : Not applicable.
Vapor pressure : No data available
Relative vapor density at 20 °C : No data available
Relative density : No data available
Solubility : No data available
Log Pow : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available

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Explosion limits : No data available
Explosive properties : No data available
Oxidizing properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Phenol (108-95-2)	
LD50 oral rat	270 mg/kg Gigena 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 US (oral)	270.000 mg/kg body weight
ATE US (dermal)	630.000 mg/kg body weight
ATE US (gases)	700.000 ppmV/4h
ATE US (vapors)	3.000 mg/l/4h
ATE US (dust, mist)	0.500 mg/l/4h

Skin corrosion/irritation : Causes skin irritation.
pH: 7.4
Serious eye damage/irritation : Causes serious eye irritation.
pH: 7.4
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

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

Reproductive toxicity : Suspected of damaging fertility or the unborn child.
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

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

Aspiration hazard : Not classified
Symptoms/effects after inhalation : None under normal use.
Symptoms/effects after skin contact : Irritation.
Symptoms/effects after eye contact : May cause severe irritation.

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Symptoms/effects after ingestion : Abdominal pain, nausea.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

Phenol (108-95-2)	
LC50 fish 1	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 1	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 2	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

Effect on the global warming : No known effects from this product.
GWPmix comment : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT
Not regulated

TDG

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

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Phenol (108-95-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	1000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	10000 lb 500lb if the substance is solid in powder form with particle size less than 100 microns, or is in solution or molten form
Solution for injection containing semaglutide (910463-68-2)	
Not listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. International regulations

CANADA

Phenol (108-95-2)	
Listed on the Canadian DSL (Domestic Substances List)	
Solution for injection containing semaglutide (910463-68-2)	
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)	

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

Phenol (108-95-2)	
U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities	
U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations	
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

Revision date	: 08/06/2018
Data sources	: http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~OKqi2W:3 . National Library of Medicine [http://sis.nlm.nih.gov/enviro.html]. Novo Nordisk Medical Information for Health Care Professionals. [http://www.novonordiskmedicalinformation.com/products.aspx].

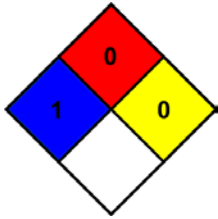
Full text of H-phrases:

H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H341	Suspected of causing genetic defects
H361	Suspected of damaging fertility or the unborn child
H373	May cause damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life

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NFPA health hazard	: 1 - Materials that, under emergency conditions, can cause significant irritation.	
NFPA fire hazard	: 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.	
NFPA reactivity	: 0 - Material that in themselves are normally stable, even under fire conditions.	
HMIS III Rating		
Health	: 2 Moderate Hazard - Temporary or minor injury may occur	
Flammability	: 0 Minimal Hazard - Materials that will not burn	
Physical	: 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.	

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