

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Ozempic® (semaglutide) injection**

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:

Novo Nordisk Inc.

800 Scudders Mill Road
Plainsboro, NJ, USA
08536

Supplier's Telephone # : 1-800-727-6500

24 Hr. Emergency Tel # : +1-800-727-6500

Name, address, and telephone number of the manufacturer:

Refer to supplier

SECTION 2. HAZARDS IDENTIFICATION

Classification of the chemical

Cloudy, aqueous suspension with a smell of phenol.

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:

The substance is a pharmacologically active substance. If the substance is absorbed systemically by inhalation, it has blood-sugar lowering properties. An overdose of inhaled substance may lead to a state of hypoglycaemia, especially in diabetic individuals. Hypoglycaemia is in severe cases lethal if untreated.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

<u>Chemical name</u>	<u>Common name and synonyms</u>	<u>CAS #</u>	<u>Concentration (% by weight)</u>
Phenol	Hydroxybenzene Phenyl Alcohol	108-95-2	0.1 - 1.0

Solution for injection containing Semaglutide and small amount of phenol

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

- : May cause an allergic skin reaction (e.g. hives, rash) in some hypersensitive individuals.

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.

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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).
US CERCLA Reportable quantity (RQ): See section 15.

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

<u>Exposure Limits:</u>				
<u>Chemical Name</u>	<u>ACGIH TLV</u>		<u>OSHA PEL</u>	
	<u>TWA</u>	<u>STEL</u>	<u>PEL</u>	<u>STEL</u>
Phenol	5 ppm (skin)	N/Av	5 ppm (19 mg/m ³) (skin)	N/Av

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** : Cloudy aqueous suspension with a smell of phenol
- Odour** : Mild odor.
- Odour threshold** : Not available.
- pH** : 7.4
- 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.**Volatiles (% 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. Direct sunlight.**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:****Routes of entry inhalation** : YES**Routes of entry skin & eye** : YES**Routes of entry Ingestion** : YES**Routes of exposure skin absorption**
: NO

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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.

Potential Chronic Health Effects

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

Mutagenicity

: 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.

Sensitization to material

: May cause an allergic skin reaction (e.g. hives, rash) in some hypersensitive individuals.

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.

<u>Chemical name</u>	<u>LC₅₀(4hr)</u>	<u>LD₅₀</u>	
	<u>inh, rat</u>	<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Phenol	> 1.8 mg/L (aerosol)	320 mg/kg (rat) The estimated human lethal dose is: 140 - 290 mg/kg	660 - 707 mg/kg

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:

<u>Ingredients</u>	<u>CAS #</u>	<u>Toxicity to Fish</u>		
		<u>LC50 / 96h</u>	<u>NOEC / 21 day</u>	<u>M Factor</u>
Phenol	108-95-2	5.02 mg/L (Rainbow trout)	N/Av	None.

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<u>Ingredients</u>	CAS #	Toxicity to Daphnia		
		EC50 / 48h	NOEC / 21 day	M Factor
Phenol	108-95-2	3.1 mg/L Ceriodaphnia (water flea)	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Algae		
		EC50 / 96h or 72h	NOEC / 96h or 72h	M Factor
Phenol	108-95-2	61.1 mg/L/96hr (Green algae)	N/Av	None.

Persistence and degradability

: No data is available on the product itself.

Bioaccumulation potential

: No data is available on the product itself.

<u>Components</u>	<u>Partition coefficient n-octanol/water (log Kow)</u>	<u>Bioconcentration factor (BCF)</u>
Phenol (CAS 108-95-2)	1.47	no significant bioaccumulation

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.

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SECTION 14. TRANSPORT INFORMATION

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

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:

<u>Ingredients</u>	CAS #	TSCA Inventory	CERCLA Reportable Quantity(RQ) (40 CFR 117.302):	SARA TITLE III: Sec. 302, Extremely Hazardous Substance, 40 CFR 355:	SARA TITLE III: Sec. 313, 40 CFR 372, Specific Toxic Chemical	
					Toxic Chemical	de minimus Concentration
Phenol	108-95-2	Yes	1000 lb/ 454 kg	500 lb lower TPQ; 10000 lb upper TPQ	Yes	1%

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:

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<u>Ingredients</u>	CAS #	California Proposition 65		State "Right to Know" Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Phenol	108-95-2	No	N/Ap	Yes	Yes	Yes	Yes	Yes	Yes

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:

<u>Ingredients</u>	CAS #	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	Korea KECI/KECL	China IECSC	NewZealand IOC
Phenol	108-95-2	203-632-7	Present	Present	(3)-481	KE-28209	Present	HSR006982

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
- 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
- 7. OECD - The Global Portal to Information on Chemical Substances - eChemPortal

Preparation Date (mm/dd/yyyy)

: 03/15/2021

Other special considerations for handling

: Provide adequate information, instruction and training for operators.

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<p><u>Prepared for:</u> Novo Nordisk 800 Scudders Mill Road Plainsboro, NJ 08536 1-800-727-6500 www.novonordisk-us.com</p>	
<p><u>Prepared by:</u> ICC The Compliance Center Inc. Telephone: (888) 442-9628 (U.S.); (888) 977-4834 (Canada) http://www.thecompliancecenter.com</p>	

DISCLAIMER

This Safety Data Sheet was prepared by ICC The Compliance Center Inc using information provided by / obtained from Novo Nordisk and CCOHS' Web Information Service. The information in the Safety Data Sheet is offered for your consideration and guidance when exposed to this product. ICC The Compliance Center Inc and Novo Nordisk expressly disclaim all expressed or implied warranties and assume no responsibilities for the accuracy or completeness of the data contained herein. The data in this SDS does not apply to use with any other product or in any other process.

This Safety Data Sheet may not be changed, or altered in any way without the expressed knowledge and permission of ICC The Compliance Center Inc and Novo Nordisk.

END OF DOCUMENT

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Ozempic (semaglutide) tablets - 1.5 mg, 4 mg, 9 mg**

Other means of identification : None reported.

Recommended use of the chemical and restrictions on use

: Pharmaceutical drug, use according to package insert.
Restriction on use: None known

Chemical family

: Mixture

Name, address, and telephone number of the supplier:

Novo Nordisk Inc.

800 Scudders Mill Road
Plainsboro, NJ, USA
08536

Supplier's Telephone # : 1-800-727-6500

24 Hr. Emergency Tel # : 24-hour emergency (Poison Help Line): 1-800-222-1222

Name, address, and telephone number of the manufacturer:

Refer to supplier

SECTION 2. HAZARDS IDENTIFICATION

Classification of the chemical

This material is classified as hazardous under U.S. OSHA regulations (29CFR 1910.1200) and Canadian WHMIS regulations (Hazardous Products Regulations) .

Classification :

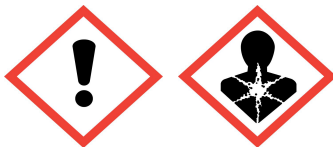
Eye Damage/Irritation - Category 2;H319

Specific target organ toxicity, single exposure - Category 3 (respiratory);H335

Reproductive toxicity - Category 2;H361

Label elements

Hazard pictogram(s)



Signal Word

Warning

Hazard statement(s)

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

H361d - Suspected of damaging the unborn child.

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Precautionary statement(s)

- P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands thoroughly after handling.
P261 - Avoid breathing dust.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear protective gloves, clothing and eye, face protection.
- P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor/physician.
P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 - Call a POISON CENTER or doctor/physician if you feel unwell.
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation persists: get medical advice/attention.
- P403 + P233 - Store in a well-ventilated area. Keep container tightly closed.
P405 - Store locked up.
- P501 - Dispose of contents or container in accordance with local regulation.

Other hazards

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 containing semaglutide tablets with regard to special storage, handling and administration requirements in the clinical setting.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

<u>Chemical name</u>	<u>Common name and synonyms</u>	<u>CAS #</u>	<u>Concentration (% by weight)</u>
Salcaproizat sodium	Salcaprozoic acid, sodium salt	203787-91-1	60.0 - 80.0
Semaglutide	Not available.	910463-68-2	0.1 - 1.0

The exact concentrations of the above listed chemicals are being withheld as a trade secret.

SECTION 4. FIRST-AID MEASURES

Description of first aid measures

- Ingestion* : Do not induce vomiting. Rinse mouth thoroughly. Never give anything by mouth to an unconscious person. Get medical attention if symptoms persist.
- Inhalation* : Immediately remove person to fresh air. If breathing is difficult, give oxygen by qualified medical personnel only. If breathing has stopped, give artificial respiration. Get medical attention if symptoms persist.
- Skin contact* : IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
- Eye contact* : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice.

Most important symptoms and effects, both acute and delayed

- : Irritation effects: This product contains substances, which may cause irritation upon exposure to skin, eyes or lungs. Exposure may result in an increased absorption potential of other hazardous substances at the area of exposure.

IF exposed or concerned: Get medical attention.

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.

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SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media

: Recommended: alcohol-resistant foam, carbonic acid, powder, water mist.

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

: May include and are not limited to: Carbon oxides. Metallic oxides.

Special protective equipment and precautions for firefighters

Protective equipment for fire-fighters

: Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. 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

: Evacuate personnel to safe areas. Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame. Dike for water control. Avoid release to the environment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

: All persons dealing with clean-up should wear the appropriate protective equipment including self-contained breathing apparatus. Keep all other personnel upwind and away from the spill/release. Restrict access to area until completion of clean-up. Refer to Section 8, EXPOSURE CONTROLS AND PERSONAL PROTECTION, for additional information on acceptable personal protective equipment.

Environmental precautions : Ensure spilled product does not enter drains, sewers, waterways, or confined spaces. For large spills, dike the area to prevent spreading.

Methods and material for containment and cleaning up

: Ventilate the area. Prevent further leakage or spillage if safe to do so. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Contact the proper local authorities.

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).
US CERCLA Reportable quantity (RQ): None reportable.

SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

: Keep away from heat and sunlight. Avoid breathing dust. Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms. Good standard of personal hygiene according to local procedures. As a minimum, in between use of the product and at the end of the working day, all potentially exposed areas of the body must be washed thoroughly. Pay special attention to hands, forearms and face. Remove contaminated clothing and protective equipment before entering eating areas.

Conditions for safe storage : Store at 68°F to 77°F (20°C to 25°C); excursions permitted to 59°F to 86°F (15°C to 30°C) {see USP Controlled Room Temperature}. Store and dispense in the original bottle. Store tablet in the original bottle until use to protect tablet from moisture. Store product in a dry place away from moisture.
Store in accordance with information listed on the product insert.

Incompatible materials : Strong oxidizing agents ;Strong reducing agents ;Strong acids and bases.

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SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<u>Exposure Limits:</u>				
<u>Chemical Name</u>	<u>ACGIH TLV</u>		<u>OSHA PEL</u>	
	<u>TWA</u>	<u>STEL</u>	<u>PEL</u>	<u>STEL</u>
Salcaprozat sodium	Not available	Not available	Not available	Not available
Semaglutide	Not available	Not available	Not available	Not available

Active pharmaceutical ingredient: OEL of 17ug/m3

Salcaprozate Sodium (SNAC)

Long-term exposure limit (8-hour TWA reference period): - ppm | 0.53 mg/m³

Short-term exposure limit (15-minute reference period): - ppm | - mg/m³

Comments: Systemic toxicity

Semaglutide

Long-term exposure limit (8-hour TWA reference period): - ppm | 0,017 mg/m³

Short-term exposure limit (15-minute reference period): - ppm | - mg/m³

Exposure controls

Ventilation and engineering measures

: Professional users are subjected to the legally set maximum concentrations for occupational exposure. See occupational hygiene limit values above.

Respiratory protection

: Use suitable protective breathing equipment, if the ventilation is not sufficient. The choice depends on the specific work situation. At oxygen deficient atmospheres or usage more than 3 hours (turbofilter excluded) self-contained respirator must be used: Using mask with filter, use NIOSH approved P100 filter.
 Use respirator at dust producing work.

Skin protection

: Wear protective gloves. Nitrile rubber gloves recommended. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye / face protection

: Wear as appropriate: Safety glasses with side shields

Other protective equipment

: Handling of dry substance in large scale (amounts in kilo):

Minimize dust generation. Whenever possible use closed processes when handling dry substance, for example by using a powder weighing hood or equivalent ventilated containment system. If not available, a non-ventilated hood should be used with Local Exhaust Ventilation covering breaches. Use a shield or cover when transferring the substance. If closed handling is not possible use a filtering respirator.

Handling of dry substance in small scale (amounts in grams):

Minimize dust generation. When handling in the laboratory preferably use fume hood or as a minimum use local exhaust ventilation with a closed hood. If closed handling is not possible use a filtering respirator.

Handling of substance in solution:

Processing tanks are to be kept covered. Avoid aerosol-generating processes.

For aerosol-generating processes with small amounts (< 1 liter) of substances in solution, use at least local exhaust ventilation close to the source, or enclosure at aerosol generating points.

For aerosol generating processes with large amounts (>1 litres) of substance in solution, handle in containment system e.g. safety cabinet. If the above this is not possible, use filtering respirator.

General hygiene considerations

: Avoid breathing dust. Avoid contact with skin, eyes and clothing. Do not eat, drink, smoke or use cosmetics while working with this product. Upon completion of work, wash hands before eating, drinking, smoking or use of toilet facilities. Remove soiled clothing and wash it thoroughly before reuse.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State	: Solid
Colour	: No data available.
Odour	: No data available.
Odour threshold	: No data available.
pH	: No data available.
Melting Point/Freezing point	: No data available.
Initial boiling point and boiling range	: No data available.
Flash point	: No data available.
Flashpoint (Method)	: No data available.
Evaporation rate (BuAe = 1)	: No data available.
Flammability	: The product is not flammable.
Lower explosion or flammability limit (% by vol.)	: No data available.
Upper explosion or flammability limit (% by vol.)	: No data available.
Oxidizing properties	: Not applicable
Explosive properties	: Not explosive
Vapour pressure	: No data available.
Relative vapour density	: No data available.
Relative density / Specific gravity	: No data available.
Solubility in water	: Soluble
Other solubility(ies)	: No data available.
Partition coefficient: n-octanol/water or Coefficient of water/oil distribution	: No data available.
Auto-ignition temperature	: No data available.
Decomposition temperature	: No data available.
Viscosity	: No data available.
Particle characteristics	: Not available
Volatiles (% by weight)	: No data available.
Volatile organic Compounds (VOC's)	: No data available.
Absolute pressure of container	: No data available.
Flame projection length	: No data available.
Other physical/chemical comments	: No additional information.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not normally reactive.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Hazardous polymerization does not occur.
Conditions to avoid	: Direct sunlight. ;Moisture.
Incompatible materials	: Strong acids, bases and oxidizing or reducing agents.
Hazardous decomposition products	: May include and are not limited to: Carbon oxides. Metallic oxides.

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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:

Routes of entry inhalation : YES

Routes of entry skin & eye : YES

Routes of entry Ingestion : YES

Routes of exposure skin absorption
: NO

Potential Health Effects:

Signs and symptoms of short-term (acute) exposure

Sign and symptoms Inhalation

: May cause respiratory irritation. Symptoms may include upper respiratory irritation, coughing and breathing difficulties.

Sign and symptoms ingestion

: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Sign and symptoms skin

: Harmful effects are not expected under normal usage. Injection site may have temporary redness and bruising.

Sign and symptoms eyes

: Causes serious eye irritation. Symptoms may include redness, pain, tearing and conjunctivitis.

Potential Chronic Health Effects

: Prolonged exposure can cause redness, swelling, itching, cracking of the skin, dermatitis and sensitization.

Mutagenicity

: Not expected to be mutagenic in humans.

Carcinogenicity

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

Data on substance: Semaglutide

Test: ICH Guidelines on nonclinical safety studies for pharmaceuticals

Result: GLP-1 RA are known to cause thyroid C-cell tumours in rodents exposed by subcutaneous injection. The mechanism of action is a nongenotoxic, specific GLP-1 receptor-mediated mechanism, to which rats and mice are particularly sensitive and monkeys and humans are not. This is supported by comprehensive human data on GLP-1 RA. No classification of semaglutide for carcinogenicity based on conclusive data.

Data on substance: Salcaprozate Sodium (SNAC)

Test: ICH Guidelines on nonclinical safety studies for pharmaceuticals

Result: 26-Week oral (gavage) carcinogenicity study in transgenic mouse, 104-week oral (gavage) carcinogenicity study in rat. No indication of a carcinogenicity potential.

Reproductive effects & Teratogenicity

: Suspected of damaging the unborn child. A classification of semaglutide as Repr Cat 2 H361d: Suspected of damaging the unborn child is chosen to mitigate a potential risk for humans.

Sensitization to material

: Not expected to be a skin or respiratory sensitizer.

Specific target organ effects

: Classification:
Specific target organ toxicity, single exposure - Category 3 (respiratory) May cause respiratory irritation.

Medical conditions aggravated by overexposure

: Not applicable

Synergistic materials

: No information available.

Toxicological data

: There is no available data for the product itself, only for the ingredients. See below for individual ingredient acute toxicity data. ATE oral = 571,432-857,148 mg/kg

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Chemical name	LC₅₀(4hr) inh, rat	LD₅₀	
		(Oral, rat)	(Rabbit, dermal)
Salcaproizat sodium	>3028 mg/m ³ , rat (Max. Attainable Concentration)	1500-2000 mg/kg, rat	>2000 mg/kg, rat
Semaglutide	Not available	Not available	Not available

Other important toxicological hazards

: Clinical effects may include nausea, vomiting, dizziness and tiredness.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity : Discharge into the environment must be avoided. The product should not be allowed to enter drains or water courses, or be deposited where it can affect ground or surface waters.

See the following tables for individual ingredient ecotoxicity data.

Ecotoxicity data:

Ingredients	CAS #	Toxicity to Fish		
		LC₅₀ / 96h	NOEC / 21 day	M Factor
Salcaproizat sodium	203787-91-1	Not available	Not available	None.
Semaglutide	910463-68-2	>100 mg/L	Not available	None.

Ingredients	CAS #	Toxicity to Daphnia		
		EC₅₀ / 48h	NOEC / 21 day	M Factor
Salcaproizat sodium	203787-91-1	Not available	Not available	None.
Semaglutide	910463-68-2	>100 mg/L	Not available	None.

Ingredients	CAS #	Toxicity to Algae		
		EC₅₀ / 96h or 72h	NOEC / 96h or 72h	M Factor
Salcaproizat sodium	203787-91-1	Not available	Not available	None.
Semaglutide	910463-68-2	>96 mg/L (72 hr)	Not available	None.

Persistence and degradability

: No data is available on the product itself.

Semaglutide is biodegradable - Manometric Respirometry Test (TG 301 F): Result: 100%

Bioaccumulation potential

: No data is available on the product itself.

Semaglutide is not accumulative - Log Pow: 2.39, BCF: No data available.

Components	Partition coefficient n-octanol/water (log Kow)	Bioconcentration factor (BCF)
Salcaproizat sodium (CAS 203787-91-1)	Not available.	Not available
Semaglutide (CAS 910463-68-2)	2.39	Not available

Mobility in soil

: No data is available on the product itself.

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Other Adverse Environmental effects

: No data is available on the product itself.




SECTION 13. DISPOSAL CONSIDERATIONS

Handling for Disposal : Handle waste according to recommendations in Section 7. Empty containers may contain hazardous residues.

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.

SECTION 14. TRANSPORT INFORMATION

Regulatory Information	UN Number	UN proper shipping name	Transport hazard class(es)	Packing Group	Label
49CFR/DOT	None.	Not regulated.	not regulated	none	
49CFR/DOT Additional information	None.				
ICAO/IATA	None.	Not regulated.	not regulated	none	
ICAO/IATA Additional information	None.				
IMDG	None.	Not regulated.	not regulated	none	
IMDG Additional information	None.				

Special precautions for user : Appropriate advice on safety must accompany the package.

Environmental hazards : This product does not meet the criteria for an environmentally hazardous mixture, according to the IMDG Code. See Section 12 for more environmental information.

SECTION 15 - REGULATORY INFORMATION

US Federal Information:

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

<u>Ingredients</u>	CAS #	TSCA Inventory	CERCLA Reportable Quantity(RQ) (40 CFR 117.302):	SARA TITLE III: Sec. 302, Extremely Hazardous Substance, 40 CFR 355:	SARA TITLE III: Sec. 313, 40 CFR 372, Specific Toxic Chemical	
					Toxic Chemical	de Minimis Concentration
Salcaprozat sodium	203787-91-1	NL	None.	None.	No	N/Ap
Semaglutide	910463-68-2	NL	None.	None.	No	N/Ap

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SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: Eye irritation ; Specific target organ toxicity, single exposure Reproductive effects

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:

<u>Ingredients</u>	CAS #	California Proposition 65		State "Right to Know" Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Salcaprozat sodium	203787-91-1	No	Not applicable	No	No	No	No	No	No
Semaglutide	910463-68-2	No	Not applicable	No	No	No	No	No	No

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:

<u>Ingredients</u>	CAS #	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	Korea KECI/KECL	China IECSC	NewZealand IOC
Salcaprozat sodium	203787-91-1	Not available	Not available	Not available	Not available	Not available	Not available	Not available
Semaglutide	910463-68-2	Not available.	Not available	Not available	Not available	Not available	Not available	Not available

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
- CNS: Central Nervous System
- DOT: Department of Transportation
- EPA: Environmental Protection Agency
- EINECS: European Inventory of Existing Commercial chemical Substances
- IARC: International Agency for Research on Cancer
- IMDG: International Maritime Dangerous Goods
- Inh: Inhalation
- LC: Lethal Concentration
- LD: Lethal Dose
- N/Ap: Not Applicable
- N/Av: Not Available
- NIOSH: National Institute of Occupational Safety and Health
- NTP: National Toxicology Program
- OSHA: Occupational Safety and Health Administration
- PEL: Permissible exposure limit
- SARA: Superfund Amendments and Reauthorization Act
- STEL: Short Term Exposure Limit
- TDG: Canadian Transportation of Dangerous Goods Act & Regulations
- TLV: Threshold Limit Values
- TWA: Time Weighted Average

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- References** :
1. ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices
 2. ECHA - European Chemical Agency
 3. Canadian Centre for Occupational Health and Safety, CCInfoWeb databases
 4. Safety Data Sheets from manufacturer.
 5. US EPA Title III List of Lists
 6. California Proposition 65 List
 7. OECD - The Global Portal to Information on Chemical Substances - eChemPortal

Preparation Date (mm/dd/yyyy)
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Other special considerations for handling
: Provide adequate information, instruction and training for operators.

<p><u>Prepared for:</u> Novo Nordisk Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 Telephone: 1-800-727-6500 www.novonordisk-us.com</p>	
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