

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
Salcaproizat 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
Salcaproizat 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
Salcaproizat 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)
: 12/15/2025

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>	
<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 Novo Nordisk Inc. 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 Inc. 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 Inc.

END OF DOCUMENT

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Rybelsus® (semaglutide) tablets - 3mg, 7mg**

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 # : No information available.

**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) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015).

Classification:

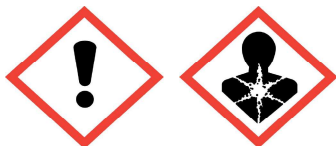
Eye damage/irritation -Category 2A

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

Specific target organ toxicity, repeated exposure - Category 2

Label elements

Hazard pictogram(s)



Signal Word

WARNING!

Hazard statement(s)

Causes serious eye irritation.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure if swallowed.

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Precautionary statement(s)

Wash thoroughly after handling.
Avoid breathing dust.
Use only outdoors or in a well-ventilated area.
Wear protective gloves and eye/face protection.

Get medical attention if irritation develops and persists.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Call a POISON CENTER or doctor/physician if you feel unwell.
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/attention.

Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Dispose of contents/container in accordance with local regulation.

Other hazards

Other hazards which do not result in classification: This product contains teratogenic substances, which may cause long-term adverse effects to the unborn fetus.

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

<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* : Flush eyes with water for at least 15 minutes. Remove contact lenses, if present and easy to do. If irritation or symptoms develop, seek medical attention.

Most important symptoms and effects, both acute and delayed

- : Causes serious eye irritation. Symptoms may include redness, pain, tearing and conjunctivitis. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure. An overdose of inhaled substance may lead to a state of hypoglycemia, especially in diabetic individuals. Hypoglycemia is, in severe cases, lethal if untreated.

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

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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

- : Carbon oxides and other irritating fumes and smoke.

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

- : Avoid breathing dust. Avoid contact with skin, eyes and clothing. Keep away from heat and flame. Keep away from incompatibles. Label containers appropriately. Wash thoroughly after handling. Keep containers closed when not in use.

Conditions for safe storage : Store in a cool, dry, well-ventilated area. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Store in original containers. Inspect periodically for damage or leaks. Store between: 15°C (59°F)-25°C (77°F).

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

SAFETY DATA SHEET

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	N/Av	N/Av	N/Av	N/Av
Semaglutide	N/Av	N/Av	N/Av	N/Av

Exposure controls

Ventilation and engineering measures

: Provide sufficient mechanical ventilation (general and/or local exhaust) to keep the airborne concentrations of vapors, mists, aerosols or dust below their respective occupational exposure limits

Respiratory protection

: Respiratory protection is required if the concentrations exceed the TLV. Use a NIOSH approved dust respirator if dust levels exceed exposure limits. Seek advice from respiratory protection specialists.

Skin protection

: Wear protective gloves. 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

: An eyewash station and safety shower should be made available in the immediate working area. Other equipment may be required depending on workplace standards.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Solid

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 (solid, gas) : The product is not flammable.

Lower flammable limit (% by vol.)

: No data available.

Upper flammable limit (% by vol.)

: No data available.

Oxidizing properties : None known.

Explosive properties : Not explosive

Vapour pressure : No data available.

Vapour density : No data available.

Relative density / Specific gravity

: No data available.

Solubility in water : Soluble

Other solubility(ies) : No data available.

SAFETY DATA SHEET

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.

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

: Carbon oxides and other irritating fumes and smoke.

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.

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.

Reproductive effects & Teratogenicity

: Not classifiable as a reproductive toxin. This product contains teratogenic substances, which may cause long-term adverse effects to the unborn fetus

Sensitization to material : Not expected to be a skin or respiratory sensitizer.

SAFETY DATA SHEET

Specific target organ effects : This material is classified as hazardous under U.S. OSHA regulations (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015). Classification:
Specific target organ toxicity, single exposure - Category 3 (respiratory) May cause respiratory irritation.

Specific Target Organ Toxicity, Repeated Exposure - Category 2. May cause damage to organs through prolonged or repeated exposure.

Medical conditions aggravated by overexposure

: Pre-existing skin, eye and respiratory disorders.

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.

<u>Chemical name</u>	LC ₅₀ (4hr)	LD ₅₀	
	<u>inh, rat</u>	<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Salcaproizat sodium	N/Av	N/Av	N/Av
Semaglutide	N/Av	N/Av	N/Av

Other important toxicological hazards

: See Section 2 for additional information.

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:

<u>Ingredients</u>	CAS #	Toxicity to Fish		
		LC50 / 96h	NOEC / 21 day	M Factor
Salcaproizat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Daphnia		
		EC50 / 48h	NOEC / 21 day	M Factor
Salcaproizat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Algae		
		EC50 / 96h or 72h	NOEC / 96h or 72h	M Factor
Salcaproizat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

SAFETY DATA SHEET

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>
Salcaproizat sodium (CAS 203787-91-1)	N/Av	N/Av
Semaglutide (CAS 910463-68-2)	N/Av	N/Av

Mobility in soil

: No data is available on the product itself.

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.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: This information is not available.

SAFETY DATA SHEET

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
Salcaprozat sodium	203787-91-1	NL	None.	None.	No	N/Ap
Semaglutide	910463-68-2	NL	None.	None.	No	N/Ap

SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: Eye irritation ; Specific target organ toxicity, single exposure; Specific target organ toxicity, repeated exposure. 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	N/Ap	No	No	No	No	No	No
Semaglutide	910463-68-2	No	N/Ap	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	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av
Semaglutide	910463-68-2	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av

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

SAFETY DATA SHEET

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
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
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
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 for
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)

: 01/14/2020

Reviewed Date SDS (dd/mm/yyyy)

: 28/07/2020

Revision No.

: 2

Revision Information

: (M)SDS sections updated :Ingredient classification

Other special considerations for handling

: Provide adequate information, instruction and training for operators.

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

END OF DOCUMENT

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Rybelsus® (semaglutide) tablets -14 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 # : No information available.

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) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015).

Classification:

Eye damage/irritation -Category 2A

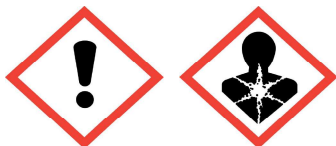
Reproductive toxicity - Category 2

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

Specific target organ toxicity, repeated exposure - Category 2

Label elements

Hazard pictogram(s)



Signal Word

WARNING!

Hazard statement(s)

Causes serious eye irritation.

Suspected of damaging the unborn child.

May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure if swallowed.

SAFETY DATA SHEET

Precautionary statement(s)

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wash thoroughly after handling.
Avoid breathing dust.
Use only outdoors or in a well-ventilated area.
Wear protective gloves and eye/face protection.

Get medical attention if irritation develops and persists.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Call a POISON CENTER or doctor/physician if you feel unwell.
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/attention.

Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Dispose of contents/container in accordance with local regulation.

Other hazards

Other hazards which do not result in classification: This product contains teratogenic substances, which may cause long-term adverse effects to the unborn fetus.

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

<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* : Flush eyes with water for at least 15 minutes. Remove contact lenses, if present and easy to do. If irritation or symptoms develop, seek medical attention.

Most important symptoms and effects, both acute and delayed

- : Causes serious eye irritation. Symptoms may include redness, pain, tearing and conjunctivitis. May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure. Suspected of damaging the unborn child. An overdose of inhaled substance may lead to a state of hypoglycemia, especially in diabetic individuals. Hypoglycemia is, in severe cases, lethal if untreated.

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

SAFETY DATA SHEET

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

- : Carbon oxides and other irritating fumes and smoke.

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

- : Avoid breathing dust. Avoid contact with skin, eyes and clothing. Keep away from heat and flame. Keep away from incompatibles. Label containers appropriately. Wash thoroughly after handling. Keep containers closed when not in use.

Conditions for safe storage

- : Store in a cool, dry, well-ventilated area. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Store in original containers. Inspect periodically for damage or leaks. Store between: 15°C (59°F)-25°C (77°F).

Incompatible materials

- : Strong oxidizing agents ;Strong reducing agents ;strong acids and bases.

SAFETY DATA SHEET

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	N/Av	N/Av	N/Av	N/Av
Semaglutide	N/Av	N/Av	N/Av	N/Av

Exposure controls

Ventilation and engineering measures

: Provide sufficient mechanical ventilation (general and/or local exhaust) to keep the airborne concentrations of vapors, mists, aerosols or dust below their respective occupational exposure limits

Respiratory protection

: Respiratory protection is required if the concentrations exceed the TLV. Use a NIOSH approved dust respirator if dust levels exceed exposure limits. Seek advice from respiratory protection specialists.

Skin protection

: Wear protective gloves. 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

: An eyewash station and safety shower should be made available in the immediate working area. Other equipment may be required depending on workplace standards.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Solid

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 (solid, gas) : The product is not flammable.

Lower flammable limit (% by vol.) : No data available.

Upper flammable limit (% by vol.) : No data available.

Oxidizing properties : None known.

Explosive properties : Not explosive

Vapour pressure : No data available.

Vapour density : No data available.

Relative density / Specific gravity : No data available.

Solubility in water : Soluble

Other solubility(ies) : No data available.

SAFETY DATA SHEET

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.

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

: Carbon oxides and other irritating fumes and smoke.

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.

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.

Reproductive effects & Teratogenicity

: This material is classified as hazardous under U.S. OSHA regulations (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015). Reproductive toxicity - Category 2. Suspected of damaging the unborn child. This product contains teratogenic substances, which may cause long-term adverse effects to the unborn fetus

SAFETY DATA SHEET

Sensitization to material : Not expected to be a skin or respiratory sensitizer.
Specific target organ effects : This material is classified as hazardous under U.S. OSHA regulations (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015). Classification:
 Specific target organ toxicity, single exposure - Category 3 (respiratory) May cause respiratory irritation.

Specific Target Organ Toxicity, Repeated Exposure - Category 2. May cause damage to organs through prolonged or repeated exposure.

Medical conditions aggravated by overexposure : Pre-existing skin, eye and respiratory disorders.

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.

<u>Chemical name</u>	<u>LC₅₀(4hr)</u>	<u>LD₅₀</u>	
	<u>inh, rat</u>	<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Salcaprozat sodium	N/Av	N/Av	N/Av
Semaglutide	N/Av	N/Av	N/Av

Other important toxicological hazards : See Section 2 for additional information.

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:

<u>Ingredients</u>	<u>CAS #</u>	<u>Toxicity to Fish</u>		
		<u>LC50 / 96h</u>	<u>NOEC / 21 day</u>	<u>M Factor</u>
Salcaprozat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

<u>Ingredients</u>	<u>CAS #</u>	<u>Toxicity to Daphnia</u>		
		<u>EC50 / 48h</u>	<u>NOEC / 21 day</u>	<u>M Factor</u>
Salcaprozat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

<u>Ingredients</u>	<u>CAS #</u>	<u>Toxicity to Algae</u>		
		<u>EC50 / 96h or 72h</u>	<u>NOEC / 96h or 72h</u>	<u>M Factor</u>
Salcaprozat sodium	203787-91-1	N/Av	N/Av	None.
Semaglutide	910463-68-2	N/Av	N/Av	None.

SAFETY DATA SHEET

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>
Salcaproizat sodium (CAS 203787-91-1)	N/Av	N/Av
Semaglutide (CAS 910463-68-2)	N/Av	N/Av

Mobility in soil

: No data is available on the product itself.

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.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: This information is not available.

SAFETY DATA SHEET

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
Salcaprozat sodium	203787-91-1	NL	None.	None.	No	N/Ap
Semaglutide	910463-68-2	NL	None.	None.	No	N/Ap

SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: Eye irritation; Specific target organ toxicity, single exposure; Specific target organ toxicity, repeated exposure. 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	N/Ap	No	No	No	No	No	No
Semaglutide	910463-68-2	No	N/Ap	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	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av
Semaglutide	910463-68-2	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av	N/Av

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

SAFETY DATA SHEET

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
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
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
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 for
 2. ECHA - European Chemical Agency
 3. Canadian Centre for Occupational Health and Safety, CCHInfoWeb 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

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: 2

Revision Information

: (M)SDS sections updated :Ingredient classification

Other special considerations for handling

: Provide adequate information, instruction and training for operators.

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