

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>
Salcaprozat 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.

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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	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.

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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.

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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.

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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.

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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

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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

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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.

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