

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Alhemo® (concizumab-mtci) injection**

Other means of identification : Not available.

Recommended use of the chemical and restrictions on use

: Pharmaceutical drug, use according to package insert
Recommended restrictions: Keep out of reach of children.

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

This material is not classified as hazardous under U.S. OSHA regulations (29 CFR 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: May cause skin and respiratory irritation.

This is a drug product and should be used in accordance with the instructions for use. The product is tested according to applicable regulations for pharmaceutical products.

Contains a pharmacologically active substance
Consult the package insert

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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>
Concizumab	Not available.	N/Ap	1.0 - 10.0
May be added to adjust pH			
Sodium Hydroxide	Caustic soda	1310-73-2	Not known.
Hydrochloric acid	Hydrochloric acid ; Muriatic acid	7647-01-0	Not known.
Preservative			
Phenol	Hydroxybenzene Phenyl Alcohol	108-95-2	<1

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. 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 5 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

- : None known or reported by the manufacturer.

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.

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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.

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 contact with eyes, skin and clothing. Wash thoroughly after handling.

Conditions for safe storage : Before first use: Store in refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do not freeze.
After first use: Store in refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature below 86°F (30°C) for up to 28 days. Write the date of first use in the space provided on the carton. Discard the unused portion of the pen 28 days after first opening.
Store Alhemo® with the cap on and in the original carton to protect from light. Alhemo® should not be stored in direct sunlight, and the Alhemo® pen should be kept away from direct heat. Do not freeze or store it close to a cooling element in a refrigerator (the part that cools the refrigerator).
Do not use Alhemo® if it has been frozen or stored at temperatures above 86°F (30°C).

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>
Concizumab	N/Av	N/Av	N/Av	N/Av
Sodium Hydroxide	2 mg/m ³ (Ceiling)	N/Av	2 mg/m ³	N/Av
Hydrochloric acid	2ppm	N/Av	5ppm; 7mg/m ³	N/Av
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 : None required when used as intended.

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 : None required when used as intended.

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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

- Physical State** : Liquid
- Colour** : Clear
- Odour** : Not available.
- Odour threshold** : Not available.
- pH** : 6
- Melting Point/Freezing point** : Not available.
- Initial boiling point and boiling range**
 - : Not available
- Flash point** : Not available.
- Flashpoint (Method)** : Not available.
- Evaporation rate (BuAe = 1)** : Not available.
- Flammability** : Not applicable.
- Lower explosion or flammability limit (% by vol.)**
 - : Not applicable.
- Upper explosion or flammability limit (% by vol.)**
 - : Not applicable.
- Oxidizing properties** : None.
- Explosive properties** : Not explosive
- Vapour pressure** : Not available.
- Relative 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.
- Particle characteristics** : Not applicable.
- 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. Keep from freezing.
- Incompatible materials** : Acids: Strong oxidizing agents; Bases; Reducing agents.

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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

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

: None known or reported by the manufacturer.

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. swelling, rash and eczema). Not expected to be a respiratory sensitizer.

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

: Not available.

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>
Concizumab	N/Av	N/Av	N/Av
May be added to adjust pH			
Sodium Hydroxide	N/Av	N/Av	N/Av
Hydrochloric acid	1.05- 1.175 mg/L	238-277 mg/kg	5010 mg/kg
Preservative			
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

: Not applicable

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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>	CAS #	Toxicity to Fish		
		LC50 / 96h	NOEC / 21 day	M Factor
Concizumab	N/Ap	N/Av	N/Av	None.
Sodium Hydroxide	1310-73-2	125 mg/L (Mosquito fish)	N/Av	None.
Hydrochloric acid	7647-01-0	4.92 mg/L (Cyprinus carpio)	n/av	None.
Phenol	108-95-2	5.02 mg/L (Rainbow trout)	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Daphnia		
		EC50 / 48h	NOEC / 21 day	M Factor
Concizumab	N/Ap	N/Av	N/Av	None.
Sodium Hydroxide	1310-73-2	40.4 mg/L (Daphnia magna)	N/Av	None.
Hydrochloric acid	7647-01-0	n/av	n/av	None.
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
Concizumab	N/Ap	N/Av	N/Av	None.
Sodium Hydroxide	1310-73-2	N/Av	N/Av	None.
Hydrochloric acid	7647-01-0	0.492 mg/L/72 hours (Green alga)	n/av	None.
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>
Hydrochloric acid (CAS 7647-01-0)	N/Ap	N/Ap
Phenol (CAS 108-95-2)	1.47	17.5 dimensionless BCF met

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.

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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.

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.				

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.

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	de Minimis Concentration
Concizumab	N/Ap	NL	None.	None.	No	N/Ap
Sodium Hydroxide	1310-73-2	Yes	1000 lb/ 454 kg	N/Av	No	NS
Hydrochloric acid	7647-01-0	Yes	5000 lb/ 2270 kg	500 lb TPQ (gas only)	Yes	1%
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.

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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
Concizumab	N/Ap	No		NS	NS	NS	NS	NS	NS
Sodium Hydroxide	1310-73-2	No	N/Ap	Yes	Yes	Yes	Yes	Yes	Yes
Hydrochloric acid	7647-01-0	No	N/Ap	Yes	Yes	Yes	Yes	Yes	Yes
Phenol	108-95-2	No	N/Ap	Yes	Yes	Yes	Yes	Yes	Yes

Canadian Information:

All ingredients are listed on the DSL, or are exempted materials.

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
Concizumab	N/Ap		N/Av	N/Av	N/Av	N/Av	N/Av	N/Av
Sodium Hydroxide	1310-73-2	215-185-5	Present	Present	(2)-1972; (1)-410	KE-31487	Present	HSR001547
Hydrochloric acid	7647-01-0	231-595-7	Present	Present	(1)-215	KE-20189	Present	HSR004090
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
- CFR: Code of Federal Regulations
- DOT: Department of Transportation
- EPA: Environmental Protection Agency
- IARC: International Agency for Research on Cancer
- 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
- OECD: Organisation for Economic Co-operation and Development
- OSHA: Occupational Safety and Health Administration
- PEL: Permissible exposure limit
- SARA: Superfund Amendments and Reauthorization Act
- STEL: Short Term Exposure Limit
- TLV: Threshold Limit Values
- TWA: Time Weighted Average

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

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Preparation Date (mm/dd/yyyy)

: 01/21/2025

Other special considerations for handling

: Provide adequate information, instruction and training for operators.

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