

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Esperoct® [antihemophilic factor
(recombinant), glycopegylated-exei]**

Other means of identification : None reported.

Recommended use of the chemical and restrictions on use

: Pharmaceutical
Restriction on use: None known

Chemical family : Pure substance

**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 (29CFR 1910.1200) (Hazcom 2012) and Canadian WHMIS regulations (Hazardous Products Regulations) (WHMIS 2015).

Label elements

Hazard pictogram(s)

None required under U.S. OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations.

Signal Word

None required under U.S. OSHA HazCom 2012 and Canadian WHMIS 2015 regulations.

Hazard statement(s)

None required under OSHA HazCom2012 and 2015 Canadian WHMIS regulations.

Precautionary statement(s)

None required under U.S. OSHA HazCom 2012 and Canadian WHMIS 2015 regulations.

Other hazards

Other hazards which do not result in classification:

Contact with eyes may cause irritation. Prolonged or repeated contact with skin may cause irritation in some cases.

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 Lyophilized N8-GP and excipients 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>
Lyophilized N8-GP and excipients	Not available.	N/Av	100.00

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SECTION 4. FIRST-AID MEASURES

Description of first aid measures

- Ingestion* : Rinse mouth thoroughly and then drink plenty of water. Do NOT induce vomiting. Seek medical advice in case of persistent discomfort.
- Inhalation* : Seek fresh air. Seek medical advice in case of persistent discomfort.
- Skin contact* : Remove contaminated clothes immediately. Wash skin with soap and water. Seek medical advice in case of persistent discomfort.
- Eye contact* : Flush immediately with water (preferably using eye wash equipment) for at least 5 minutes. Open eye wide. Remove any contact lenses. Seek medical advice if irritation continues.

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

- : None reported by the manufacturer.

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

- : Carbon oxides and other irritating fumes and smoke.

Special protective equipment and precautions for firefighters

Protective equipment for fire-fighters

- : None known or reported by the manufacturer.

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

- : None known or reported by the manufacturer.

Environmental precautions

- : None known or reported by the manufacturer.

Methods and material for containment and cleaning up

- : Use sand, sawdust, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in container for disposal, according to local regulations. To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.

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

- : Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms. See section on 'Exposure controls/personal protection' for information on personal protection.

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- 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: 2 and 8 °C (36 and 46°F)
- Incompatible materials** : Strong oxidizing agents Strong reducing agents strong acids and bases.

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>
Lyophilized N8-GP and excipients	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

- : Wear appropriate protective clothing to prevent skin contact, such as coveralls or long sleeved shirt, long pants, and shoes and socks. Wear protective gloves. 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** : granular
- 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.

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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.
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 : Frost
Incompatible materials : Avoid contact with incompatible materials. Incompatible materials (see Section 7).
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

: May cause mild skin irritation on prolonged contact.

Sign and symptoms eyes

: Direct eye contact may cause slight redness.

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.

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Reproductive effects & Teratogenicity

: Not expected to have other reproductive effects.

Sensitization to material

: Not expected to be a skin or respiratory sensitizer.

Specific target organ effects

: The substance or mixture is not classified as specific target organ toxicant, single exposure.

The substance or mixture is not classified as specific target organ toxicant, 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>	LC₅₀(4hr) <u>inh, rat</u>	LD₅₀	
		<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Lyophilized N8-GP and excipients	N/Av	N/Av	N/Av

Other important toxicological hazards

: See Section 3 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
Lyophilized N8-GP and excipients	N/Av	N/Av	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Daphnia		
		EC₅₀ / 48h	NOEC / 21 day	M Factor
Lyophilized N8-GP and excipients	N/Av	N/Av	N/Av	None.

<u>Ingredients</u>	CAS #	Toxicity to Algae		
		EC₅₀ / 96h or 72h	NOEC / 96h or 72h	M Factor
Lyophilized N8-GP and excipients	N/Av	N/Av	N/Av	None.

Persistence and degradability

: No data is available on the product itself.

Bioaccumulation potential

: No data is available on the product itself.

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<u>Components</u>	<u>Partition coefficient n-octanol/water (log Kow)</u>	<u>Bioconcentration factor (BCF)</u>
Lyophilized N8-GP and excipients (CAS N/Av)	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.

SECTION 15 - REGULATORY INFORMATION

US Federal Information:

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

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<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
Lyophilized N8-GP and excipients	N/Av	NL	None.	None.	No	N/Av

SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: None.

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
Lyophilized N8-GP and excipients	N/Av	No	N/Av	Yes	Yes	Yes	Yes	Yes	Yes

Canadian Information:

WHMIS information: Refer to Section 2 for a WHMIS Classification for this product.

International Information:

Components listed below are present on the following International Inventory list:

<u>Ingredients</u>	CAS #	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	Korea KECI/KECL	China IECSC	NewZealand IOC
Lyophilized N8-GP and excipients	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
- IARC: International Agency for Research on Cancer
- IMDG: International Maritime Dangerous Goods
- Inh: Inhalation
- LC: Lethal Concentration
- LD: Lethal Dose
- N/Av: Not Applicable
- N/Av: Not Available
- 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
- WHMIS: Workplace Hazardous Materials Identification System

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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, CCHInfoWeb 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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Other special considerations for handling
: Provide adequate information, instruction and training for operators.

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