

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Insulin Aspart Protamine and Insulin Aspart Injectable
Suspension Mix 70/30**

Other means of identification : None reported.

Recommended use of the chemical and restrictions on use

: Pharmaceutical drug, use according to package insert.
Recommended restrictions: None known.

Chemical family

: Mixture.

**Name, address, and telephone number
of the supplier:**

Novo Nordisk Inc.

800 Scudders Mill Road
Plainsboro, NJ, USA
08536

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

24 Hr. Emergency Tel # : No information available.

**Name, address, and telephone number of
the manufacturer:**

Refer to supplier

SECTION 2. HAZARDS IDENTIFICATION

Classification of the chemical

This material, Insulin Aspart Injection 100 units/mL is not considered hazardous by OSHA Hazcom 2012 or WHMIS 2015 regulations.

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 mild skin irritation.
May result in severe hypoglycemia.

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.

SAFETY DATA SHEET

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>
Insulin Aspart	Insulin Aspart EP/USP	116094-23-6	Proprietary

Contains < 1 % Phenol (Preservative)
Contains < 1 % m-Cresol (Preservative)

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* : IF ON SKIN: Wash with plenty of soap and water. If irritation or symptoms develop, seek medical attention.
- Eye contact* : If in eyes, rinse with water for 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. If irritation persists, seek prompt medical attention.

Most important symptoms and effects, both acute and delayed

- : 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

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

- : Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

SAFETY DATA SHEET

: 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 : Ecological injuries are not known or expected under normal use.

Methods and material for containment and cleaning up

: 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

: Use personal protective equipment as required. Avoid breathing mist, vapors or spray. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Conditions for safe storage : Containers which are opened must be carefully resealed and kept upright to prevent leakage. Store at temperatures between 2°C (35.6°F) and 8°C (46.4°F).

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

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:				
Chemical Name	ACGIH TLV		OSHA PEL	
	TWA	STEL	PEL	STEL
Insulin Aspart	N/Av	N/Av	N/Av	N/Av

Exposure controls

Ventilation and engineering measures

: Not required under normal conditions of handling.

Respiratory protection : not required under normal use

Skin protection : not required under normal use

Eye / face protection : not required under normal use

Other protective equipment : not required under normal use

General hygiene considerations

: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Liquid

Odour : Not available.

Odour threshold : Not available.

pH : 7.1

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.

SAFETY DATA SHEET

Flammability (solid, gas) : Not applicable.
Lower flammable limit (% by vol.)
: Not applicable.
Upper flammable limit (% by vol.)
: Not applicable.
Oxidizing properties : Not applicable
Explosive properties : Not explosive
Vapour pressure : Not available.
Vapour density : Not available.
Relative density / Specific gravity
: Not available.
Solubility in water : Soluble
Other solubility(ies) : Not available.
Partition coefficient: n-octanol/water or Coefficient of water/oil distribution
: Not available.
Auto-ignition temperature : Not applicable.
Decomposition temperature : Not available.
Viscosity : Not available.
Volatiles (% by weight) : Not available.
Volatile organic Compounds (VOC's)
: Not available.
Absolute pressure of container
: Not applicable.
Flame projection length : Not applicable.
Other physical/chemical comments
: No additional information.

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.
Incompatible materials : See Section 7 (Handling and Storage) for further details.
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 minor respiratory irritation. Symptoms may include coughing and sneezing.

SAFETY DATA SHEET

Sign and symptoms ingestion

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

Sign and symptoms skin

: Direct skin contact may cause slight or mild, transient irritation.

Sign and symptoms eyes

: Direct eye contact may cause slight or mild, transient irritation.

Potential Chronic Health Effects

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

Mutagenicity

: Not expected to be mutagenic in humans.

Carcinogenicity

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

Reproductive effects & Teratogenicity

: Not expected to cause reproductive effects.

Sensitization to material

: Not expected to be a skin or respiratory sensitizer.

Specific target organ effects

: Not classified as a specific target organ toxicity-single exposure.

Not classified as specific target organ toxicity-repeated exposure.

Medical conditions aggravated by overexposure

: None known.

Synergistic materials

: Not available.

Toxicological data

: There is no available data for the product itself, only for the ingredients. See below for individual ingredient acute toxicity data.

<u>Chemical name</u>	<u>LC₅₀(4hr)</u> <u>inh. rat</u>	<u>LD₅₀</u>	
		<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Insulin Aspart	N/Av	N/Av	N/Av

Other important toxicological hazards

: None known or reported by the manufacturer.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

: Not classified for hazards to the environment. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Ecotoxicity data:

<u>Ingredients</u>	<u>CAS No</u>	<u>Toxicity to Fish</u>		
		<u>LC50 / 96h</u>	<u>NOEC / 21 day</u>	<u>M Factor</u>
Insulin Aspart	116094-23-6	N/Av	N/Av	None.

<u>Ingredients</u>	<u>CAS No</u>	<u>Toxicity to Daphnia</u>		
		<u>EC50 / 48h</u>	<u>NOEC / 21 day</u>	<u>M Factor</u>
Insulin Aspart	116094-23-6	N/Av	N/Av	None.

SAFETY DATA SHEET

<u>Ingredients</u>	CAS No	<u>Toxicity to Algae</u>		
		<u>EC50 / 96h or 72h</u>	<u>NOEC / 96h or 72h</u>	<u>M Factor</u>
Insulin Aspart	116094-23-6	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.

<u>Components</u>	<u>Partition coefficient n-octanol/water (log Kow)</u>	<u>Bioconcentration factor (BCF)</u>
Insulin Aspart (CAS 116094-23-6)	N/Av	N/Av

Mobility in soil

: No data is available on the product itself.

Other Adverse Environmental effects

: No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13. DISPOSAL CONSIDERATIONS

Handling for Disposal

: Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.




Methods of Disposal

: Dispose in accordance with all applicable federal, state, provincial and local regulations.

RCRA

: If this product, as supplied, becomes a waste in the United States, it may meet the criteria of a hazardous waste as defined under RCRA, Title 40 CFR 261. It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies.

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.				

SAFETY DATA SHEET

Special precautions for user : None known or reported by the manufacturer.

Environmental hazards : This substance does not meet the criteria for an environmentally hazardous substance according to the IMDG Code. See ECOLOGICAL INFORMATION, Section 12.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
: Not available.

SECTION 15 - REGULATORY INFORMATION

US Federal Information:

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

<u>Ingredients</u>	CAS #	TSCA Inventory	CERCLA Reportable Quantity(RQ) (40 CFR 117.302):	SARA TITLE III: Sec. 302, Extremely Hazardous Substance, 40 CFR 355:	SARA TITLE III: Sec. 313, 40 CFR 372, Specific Toxic Chemical	
					Toxic Chemical	de minimus Concentration
Insulin Aspart	116094-23-6	NL	None.	None.	No	N/Ap

SARA TITLE III: Sec. 311 and 312, SDS Requirements, 40 CFR 370 Hazard Classes: None. Under SARA Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds or the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

US State Right to Know Laws:

The following chemicals are specifically listed by individual States:

<u>Ingredients</u>	CAS #	California Proposition 65		State "Right to Know" Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Insulin Aspart	116094-23-6	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
Insulin Aspart	116094-23-6	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
- CSA: Canadian Standards Association
- DOT: Department of Transportation
- EPA: Environmental Protection Agency
- HMIS: Hazardous Materials Identification System
- HSDB: Hazardous Substances Data Bank
- IARC: International Agency for Research on Cancer

SAFETY DATA SHEET

Inh: Inhalation
LC: Lethal Concentration
LD: Lethal Dose
MN: Minnesota
N/Ap: Not Applicable
N/Av: Not Available
NFPA: National Fire Protection Association
NIOSH: National Institute of Occupational Safety and Health
NJ: New Jersey
NTP: National Toxicology Program
OECD: Organisation for Economic Co-operation and Development
OSHA: Occupational Safety and Health Administration
PA: Pennsylvania
PEL: Permissible exposure limit
RCRA: Resource Conservation and Recovery Act
RI: Rhode Island
RTECS: Registry of Toxic Effects of Chemical Substances
SARA: Superfund Amendments and Reauthorization Act
STEL: Short Term Exposure Limit
TLV: Threshold Limit Values
TWA: Time Weighted Average
WHMIS: Workplace Hazardous Materials Identification System

References

- : 1. ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices for 2018.
- 2. International Agency for Research on Cancer Monographs, searched 2019.
- 3. Canadian Centre for Occupational Health and Safety, CCInfoWeb databases, 2019 (Chempendium, HSDB and RTECs).
- 4. Safety Data Sheets from manufacturer.
- 5. US EPA Title III List of Lists - June 2019 version.
- 6. California Proposition 65 List - September 2019 version.
- 7. OECD - The Global Portal to Information on Chemical Substances - eChemPortal, 2019.

Preparation Date (mm/dd/yyyy)

: 01/14/2020

Other special considerations for handling

: Provide adequate information, instruction and training for operators.

<p>Prepared for: Novo Nordisk Pharma Inc. 800 Scudders Mill Road Plainsboro, NJ 08536 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 / obtained from Novo Nordisk Pharma 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 Pharma 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 Pharma Inc.

SAFETY DATA SHEET

END OF DOCUMENT