

## SAFETY DATA SHEET

### SECTION 1. IDENTIFICATION

**Product identifier used on the label**

: **Xultophy® 100/3.6 (insulin degludec and liraglutide injection)**

**Other means of identification** : Not available.

**Recommended use of the chemical and restrictions on use**

: Drug product  
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 #** : +1-800-727-6500

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

Refer to supplier

### SECTION 2. HAZARDS IDENTIFICATION

**Classification of the chemical**

Cloudy, aqueous suspension with a smell of phenol/cresol

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).

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:

The substance is a pharmacologically active substance. If the substance is absorbed systemically by inhalation, it has blood-sugar lowering properties. An overdose of inhaled substance may lead to a state of hypoglycaemia, especially in diabetic individuals. Hypoglycaemia is in severe cases lethal if untreated.

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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> |
|----------------------|---------------------------------|--------------|------------------------------------|
| Liraglutide          | Not available.                  | 204656-20-2  | 0.1 - 1.0                          |
| Insulin degludec     | Not available.                  | 844439-96-9  | 0.1 - 1.0                          |

Aqueous solution for injection. Contains insulin degludec (100 U/mL) and liraglutide (3.6 mg/mL)

Inactive ingredients include: glycerol, metacresol, zinc, hydrochloric acid, and sodium hydroxide ( for pH adjustment) and water for injection.

### 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 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

- : May cause an allergic skin reaction (e.g. hives, rash) in some hypersensitive individuals.

#### 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.

### 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.

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**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 breathing mist, vapors or spray. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Do not freeze.

**Conditions for safe storage** : Keep only in original packaging. Before opening, store in tightly closed original container in a well ventilated place, no more than 25°C or a refrigerator (2°C - 8°C). Do not freeze.

**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>     |
| Liraglutide             | N/Av             | N/Av        | 0.15mg/m <sup>3</sup> N/Av |
| Insulin degludec        | N/Av             | N/Av        | N/Av 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** : Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust and/or fumes). Advice should be sought from respiratory protection specialists.

**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** : Wear sufficient clothing to prevent skin contact. Depending on conditions of use, an impervious apron should be worn. An eyewash station and safety shower should be made available in the immediate working area.

**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

**Appearance** : Cloudy aqueous suspension with a smell of phenol/cresol  
**Odour** : Mild odor.  
**Odour threshold** : Not available.  
**pH** : Not available.  
**Melting Point/Freezing point** : Not available.

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### Initial boiling point and boiling range

: Not available.

**Flash point** : Not available.

**Flashpoint (Method)** : Not available.

**Evaporation rate (BuAe = 1)** : Not available.

**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**  
: 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. Do not freeze. Direct sunlight.

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

**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

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### 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

: 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

: May cause an allergic skin reaction (e.g. hives, rash) in some hypersensitive individuals.

#### 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

: 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>LC<sub>50</sub>(4hr)</u> | <u>LD<sub>50</sub></u> |                         |
|----------------------|-----------------------------|------------------------|-------------------------|
|                      | <u>inh, rat</u>             | <u>(Oral, rat)</u>     | <u>(Rabbit, dermal)</u> |
| Liraglutide          | N/Av                        | N/Av                   | N/Av                    |
| Insulin degludec     | 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 #</u> | <u>Toxicity to Fish</u> |                      |                 |
|--------------------|--------------|-------------------------|----------------------|-----------------|
|                    |              | <u>LC50 / 96h</u>       | <u>NOEC / 21 day</u> | <u>M Factor</u> |
| Liraglutide        | 204656-20-2  | N/Av                    | N/Av                 | None.           |
| Insulin degludec   | 844439-96-9  | N/Av                    | N/Av                 | None.           |

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| <u>Ingredients</u> | CAS #       | Toxicity to Daphnia |               |          |
|--------------------|-------------|---------------------|---------------|----------|
|                    |             | EC50 / 48h          | NOEC / 21 day | M Factor |
| Liraglutide        | 204656-20-2 | N/Av                | N/Av          | None.    |
| Insulin degludec   | 844439-96-9 | N/Av                | N/Av          | None.    |

| <u>Ingredients</u> | CAS #       | Toxicity to Algae |                   |          |
|--------------------|-------------|-------------------|-------------------|----------|
|                    |             | EC50 / 96h or 72h | NOEC / 96h or 72h | M Factor |
| Liraglutide        | 204656-20-2 | N/Av              | N/Av              | None.    |
| Insulin degludec   | 844439-96-9 | 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> |
|-------------------------------|--------------------------------------------------------|--------------------------------------|
| Liraglutide (CAS 204656-20-2) | 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.

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### 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          |    |
| <b>49CFR/DOT Additional information</b> | None.     |                         |                            |               |                                                                                       |
| IMDG                                    | None.     | Not regulated.          | not regulated              | none          |    |
| <b>IMDG Additional information</b>      | None.     |                         |                            |               |                                                                                       |
| ICAO/IATA                               | None.     | Not regulated.          | not regulated              | none          |    |
| <b>ICAO/IATA Additional information</b> | None.     |                         |                            |               |                                                                                       |
| TDG                                     | None.     | Not regulated.          | not regulated              | none          |  |
| <b>TDG Additional information</b>       | 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.

**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 |
| Liraglutide        | 204656-20-2 | NL             | None.                                            | None.                                                                | No                                                            | N/Ap                     |
| Insulin degludec   | 844439-96-9 | 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.

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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 |
| Liraglutide        | 204656-20-2 | No                        | N/Ap             | No                          | No | No | No | No | No |
| Insulin degludec   | 844439-96-9 | 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 |
|--------------------|-------------|-----------------|----------------|-------------------|------------|-----------------|-------------|----------------|
| Liraglutide        | 204656-20-2 | 810-818-7       | N/Av           | N/Av              | N/Av       | N/Av            | N/Av        | N/Av           |
| Insulin degludec   | 844439-96-9 | 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  
HSDB: Hazardous Substances Data Bank  
IARC: International Agency for Research on Cancer  
Inh: Inhalation  
LC: Lethal Concentration  
LD: Lethal Dose  
N/Ap: Not Applicable  
N/Av: Not Available  
NTP: National Toxicology Program  
OECD: Organisation for Economic Co-operation and Development  
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  
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, 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)**

: 03/17/2021

**Other special considerations for handling**

: Provide adequate information, instruction and training for operators.

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