

# Safety data sheet

## Xultophy ®, Insulin Degludec + Liraglutide

### 1. Identification of the substance/preparation and of the company/undertaking

Prepared on: 12-11-2014/ TBEM	Distributor: <b>Novo Nordisk A/S</b> <b>External Environment</b> <b>Novo Allé DK-2880 Bagsværd</b>
	<b>Tel:+45 44 44 88 88 Fax:+45 44 49 05 55</b> <b>Emergency telephone +45 44 42 00 00</b> <b>Email adresse: compliance-team@novonordisk.com</b>

### 2. Hazards identification

The product shall not be classified as hazardous according to (EC) No. 1272 / 2008, EU GHS/ CLP.
<b>Additional information</b> No special risk if used in accordance with the instructions of the supplier.

### 3. Composition/information on ingredients

REACH registration number	CAS No./ Eines no.	Substances	Classification/ CLP-classification	w/w%
-	844439-96-9/2 04656-20-2	Aqueous solution for injection. Contains insulin degludec (100 U/mL) and liraglutide (3.6 mg/mL)	Not classified	-
<i>Please see section 16 for the full text of R-phrases and H-phrases.</i>				

### 4. First aid measures

<b>Inhalation</b> Seek fresh air. Seek medical advice in case of persistent discomfort.
<b>Ingestion</b> Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.
<b>Skin</b> Remove contaminated clothing. Wash the skin thoroughly with water and continue washing for a long time.
<b>Eyes</b> Open eye wide, remove any contact lenses and flush immediately with water (preferably using eye wash equipment). Seek medical advice immediately. Continue flushing until medical attention is obtained.
<b>Other information</b> When obtaining medical advice, show the safety data sheet or label.

### 5. Fire-fighting measures

The product is not readily flammable. Avoid breathing vapors and flue gases - seek fresh air. Fire Fighting Extinguishing Media: In case of fire use foam, waterspray, dry chemical or CO2.
--

### 6. Accidental release measures

Mop up spillage with a cloth. Dam spill and collect with sand or other absorbent material and place in suitable waste containers. For information on disposal please see item 13.
---

## 7. Handling and storage

### Handling

See section 8 for information about precautions for use and personal protective equipment.

### Storage

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.

## 8. Exposure controls/ personal protection

### Precautions for use

There must be access to running water and eye wash.

### Respiratory protection

Not normally required.

### Gloves and protective clothing

Use disposable gloves made of PVC or use gloves made of nitrile rubber.

### Eye protection

Wear safety goggles if there is a risk of eye splash.

### Occupational exposure limits

Contains no substances subject to reporting requirements.

## 9. Physical and chemical properties

Appearance: Liquid

Odour: Smell of phenol and m-cresol (sweetish, sickening odour)

## 10. Stability and reactivity

The product is stable when used in accordance with the supplier's directions.

## 11. Toxicological information

### Acute

#### Inhalation

Not investigated. Inhalation of spray mist may cause irritation to the upper airways.

#### Ingestion

Not expected to be active orally. May irritate mucous membranes in mouth and gastrointestinal tract.

#### Skin contact

May cause irritation by the active substance or any of the excipients.

#### Eye contact

May cause irritation. Avoid contact with the eyes.

#### Risk of sensitization

Hypersensitivity to the active substance or to any of the excipients.

#### Long-term effects

None known.

## 12. Ecological information

Do not discharge large quantities of concentrated spills and residue into drains.

## 13. Disposal considerations

The product is not hazardous waste .  
It is recommended that large quantities of waste and waste disposed of through the local receiving station.

## 14. Transport information

The product is not covered by the rules for transport of dangerous goods by road and sea according to ADR and IMDG.

## 15. Regulatory information

**Hazard designation:** It has been assessed that the product shall not be classified according to (EC) No. 1272 / 2008, EU GHS/ CLP.

### Contains

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

### Supplemental information

None.

### Chemical safety assessment

Chemical safety assessment has not been performed.

## 16. Other information

### Restrictions on use

### Training requirement

No special training is necessary but a thorough knowledge of this safety data sheet is assumed.

### Line of business

Industry

### Sources used

### Other information

The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

### Full text of the R-phrases that are stated in section 3.

No R-phrases.

### Full text of the H-phrases that are stated in section 3.

No H-phrases.