SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Solution
Product name : Victoza®, Liraglutide
Formula : C₁₁₂H₂₉₀N₄₃O₃₁

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Drug Product

1.3. Details of the supplier of the safety data sheet

Novo Nordisk
800 Scudders Mill Road
Plainsboro, NJ 08536
T 800-727-6500
www.novonordisk-us.com

1.4. Emergency telephone number

Emergency number : 800-727-6500

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (GHS-US)
Acute Tox. 4 (Oral) H302
Resp. Sens. 1 H334
Skin Sens. 1 H317
Carc. 2 H351

2.2. Label elements

GHS-US labeling
Hazard pictograms (GHS-US)

Signal word (GHS-US) : Danger
Hazard statements (GHS-US)
H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H351 - Suspected of causing cancer (Injection)

Precautionary statements (GHS-US)
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing mist, fume, spray, vapors
P264 - Wash exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear appropriate PPE
P284 - [In case of inadequate ventilation] wear respiratory protection
P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352 - IF ON SKIN: Wash with plenty of soap and water
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P306+P313 - IF exposed or concerned: Get medical advice/attention
P321 - Specific treatment (see Section 4 on this label)
P330 - If swallowed, rinse mouth
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P342+P311 - If experiencing respiratory symptoms: Call a Poison Center
P362+P364 - Take off contaminated clothing and wash it before reuse
P405 - Store locked up
P501 - Dispose of contents/container to comply with local/ regional/ national/ international regulations
2.3. Other hazards
Other hazards not contributing to the classification: Inactive ingredients include: disodium phosphate dihydrate, propylene glycol, phenol and water for injection.

2.4. Unknown acute toxicity (GHS-US)
No data available

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable
Full text of H-phrases: see section 16

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution for injection containing liraglutide [DNA origin]</td>
<td>(CAS No) 204656-20-2</td>
<td>100</td>
<td>Acute Tox. 4 (Oral), H302, Resp. Sens. 1, H334, Skin Sens. 1, H317, Carc. 2, H351</td>
</tr>
<tr>
<td>Phenol</td>
<td>(CAS No) 108-95-2</td>
<td>≤0.5</td>
<td>Acute Tox. 3 (Oral), H301, Acute Tox. 3 (Dermal), H311, Acute Tox. 3 (Inhalation), H331, Skin Corr. 1B, H314, Muta. 2, H341, STOT RE 2, H373, Aquatic Acute 3, H402</td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures
First-aid measures general: Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
First-aid measures after inhalation: Not an anticipated route of entry. If inhaled, remove person to fresh air.
First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse.
First-aid measures after eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
First-aid measures after ingestion: When swallowed, seek medical attention if symptoms persist and show the physician the package insert. Do NOT induce vomiting. Not expected to be active orally (hypoglycaemia).

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/injuries after inhalation: Not investigated. Inhalation of mist containing protein may cause sensitization.
Symptoms/injuries after skin contact: May cause irritation by the active substance or any of the excipients.
Symptoms/injuries after eye contact: May cause irritation. Avoid contact with the eyes.
Symptoms/injuries after ingestion: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.
Symptoms/injuries upon inadvertent injection: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients. May cause hypoglycemia. May cause headache, nausea and diarrhea.

4.3. Indication of any immediate medical attention and special treatment needed
No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media
Suitable extinguishing media: Any, Use media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture
Fire hazard: Not flammable.
Reactivity: Not reactive under normal use and conditions.

5.3. Advice for firefighters
Protection during firefighting: Positive pressure self-contained breathing apparatus (SCBA) and structural firefighters' protective clothing will provide adequate protection.
SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Seek fresh air.

6.1.1. For non-emergency personnel
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders
Protective equipment : Equip cleanup crew with proper protection.

6.2. Environmental precautions
Under normal use, this product is not expected to impact the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up
For containment : Do not touch or walk through spilled material.
Methods for cleaning up : Absorb spillage to prevent material damage.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Precautions for safe handling : Do not get in eyes, on skin, or on clothing. Use personal protective equipment as required.
Hygiene measures : Do not eat, drink or smoke when using this product. Practice good housekeeping. Wash thoroughly after handling. Change contaminated clothing. Do not reuse until laundered.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions : Must be kept in tightly original packings and store according to product instruction and to prevent degradation.
Storage temperature : Keep refrigerated 2 to 8 °C (36 to 46 °F) but not in the freezer. Do not freeze. After initial use of the Victoza pen, the pen can be stored for 30 days at controlled room temperature (59°F to 86°F; 15°C to 30°C) or in a refrigerator (36°F to 46°F; 2°C to 8°C).

7.3. Specific end use(s)
Drug Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

<table>
<thead>
<tr>
<th>Phenol (108-95-2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
<td>ACGIH TWA (ppm)</td>
</tr>
<tr>
<td>USA ACGIH</td>
<td>Remark (ACGIH)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>USA OSHA</td>
<td>OSHA PEL (TWA) (ppm)</td>
</tr>
</tbody>
</table>

8.2. Exposure controls
Appropriate engineering controls : Work must be done with effective mechanical ventilation. There must be access to running water and eye wash,
Personal protective equipment : Avoid all unnecessary exposure.
Hand protection : Polyvinylchloride (PVC) / nitrile rubber gloves.
Eye protection : Eye protection such as chemical splash goggles and/or face shield must be worn when possibility exists for eye contact due to splashing or spraying liquid. Contact lenses should not be worn.
Skin and body protection : PVC gloves, nitrile rubber or similar protection are recommended for waste clear-up and manufacturing operations.
Respiratory protection : Not normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state : Liquid
Appearance : Clear, colorless liquid.
Molecular mass : 3751.2 Daltons
Color : Colorless, clear.
Odor : No data available

01/13/2015 EN (English US)
**Victoza®, Liraglutide**

**Safety Data Sheet**

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor threshold</td>
<td>Phenol</td>
</tr>
<tr>
<td>pH</td>
<td>9.1</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**SECTION 10: Stability and reactivity**

10.1. Reactivity

Not reactive under normal use and conditions.

10.2. Chemical stability

Product is stable.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong Oxidizers. Victoza should be protected from excessive heat and sunlight.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

**SECTION 11: Toxicological information**

11.1. Information on toxicological effects

Acute toxicity: Harmful if swallowed.

**Victoza®, Liraglutide**

Additional information: Hypersensitivity to the active substance or to any of the excipients.

**Phenol (108-95-2)**

<table>
<thead>
<tr>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>270 mg/kg Gigiena i Sanitariya. For English translation, see HYSAAV, Vol. 38(8), Pg. 6, 1973.</td>
</tr>
<tr>
<td>LD50 dermal rabbit</td>
<td>630 mg/kg Union Carbide Data Sheet. Vol. 1/6/1966.</td>
</tr>
<tr>
<td>LC50 inhalation rat (ppm)</td>
<td>81 ppm Nagorny 1976</td>
</tr>
<tr>
<td>ATE CLP (oral)</td>
<td>100,000 mg/kg body weight</td>
</tr>
<tr>
<td>ATE CLP (dermal)</td>
<td>300,000 mg/kg body weight</td>
</tr>
<tr>
<td>ATE CLP (gases)</td>
<td>700,000 ppmV/4h</td>
</tr>
<tr>
<td>ATE CLP (vapors)</td>
<td>3,000 mg/l/4h</td>
</tr>
</tbody>
</table>
## Phenol (108-95-2)

### ATE CLP (dust, mist)
0.500 mg/l/4h

### Solution for injection containing liraglutide [rDNA origin] (204656-20-2)

<table>
<thead>
<tr>
<th>LD50 oral rat</th>
<th>980 mg/kg</th>
</tr>
</thead>
</table>

**Skin corrosion/irritation**: Not classified

**Serious eye damage/irritation**: Not classified

**Respiratory or skin sensitization**: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

**Germ cell mutagenicity**: Not classified

(Liraglutide was negative with and without metabolic activation in the Ames test for mutagenicity and in a human peripheral blood lymphocyte chromosome aberration test for clastogenicity. Liraglutide was negative in repeat-dose in vivo micronucleus tests in rats.)

**Carcinogenicity**: Liraglutide causes dose-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies.

### Phenol (108-95-2)

<table>
<thead>
<tr>
<th>IARC group</th>
<th>3 - Not classifiable</th>
</tr>
</thead>
</table>

**Reproductive toxicity**: Not classified

(No direct adverse effects on male fertility was observed at doses up to 1.0 mg/kg/day, a high dose yielding an estimated systemic exposure 11-times the human exposure at the MRHD based on plasma AUC. In female rats, an increase in early embryonic deaths occurred at 1.0 mg/kg/day.)

**Specific target organ toxicity (single exposure)**: Not classified

**Specific target organ toxicity (repeated exposure)**: Not classified

### Phenol (108-95-2)

<table>
<thead>
<tr>
<th>LOAEL (oral, rat, 90 days)</th>
<th>1.8 mg/kg bodyweight/day</th>
</tr>
</thead>
</table>

**Aspiration hazard**: Not classified

**Symptoms/injuries after inhalation**: Not investigated. Inhalation of mist containing protein may cause sensitization.

**Symptoms/injuries after skin contact**: May cause irritation by the active substance or any of the excipients.

**Symptoms/injuries after eye contact**: May cause irritation. Avoid contact with the eyes.

**Symptoms/injuries after ingestion**: Not expected to be active orally. Absorption is not expected. Ingestion is not known to cause health effects.

**Symptoms/injuries upon inadvertent intravenous administration**: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients. May cause hypoglycemia. May cause headache, nausea and diarrhea.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general: Avoid discharge to drain or surface water.

### Phenol (108-95-2)

<table>
<thead>
<tr>
<th>LC50 fish</th>
<th>20.5 mg/l</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>EC50 Daphnia</th>
<th>20 mg/l</th>
</tr>
</thead>
</table>
**Phenol (108-95-2)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 Daphnia</td>
<td>12.6 mg/l</td>
</tr>
<tr>
<td>ErC50 (algae)</td>
<td>229 mg/l (72 hours)</td>
</tr>
<tr>
<td>ErC50 (other aquatic plants)</td>
<td>84.5 mg/l (96 hours)</td>
</tr>
</tbody>
</table>

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

**Phenol (108-95-2)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>1.5</td>
</tr>
</tbody>
</table>

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste disposal recommendations: The product is not hazardous waste. Dispose in a safe manner in accordance with local/national regulations.

### SECTION 14: Transport information

In accordance with DOT

Not regulated for transport

### Additional information

Other information: No supplementary information available.

**ADR**

Transport document description

**Transport by sea**

No additional information available

**Air transport**

No additional information available
SECTION 15: Regulatory information

15.1. US Federal regulations

**Phenol (106-95-2)**

- Listed on the United States TSCA (Toxic Substances Control Act) inventory
- Listed on United States SARA Section 313
- RQ (Reportable quantity, section 304 of EPA’s List of Lists): 1000 lb

**Solution for injection containing liraglutide [rDNA origin] (204656-20-2)**

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

**CANADA**

No additional information available

**EU-Regulations**

No additional information available

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

**Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]**

Not classified

15.2.2. National regulations

No additional information available

15.3. US State regulations

**Phenol (106-95-2)**

- U.S. - Idaho - Non-Carcinogenic Toxic Air Pollutants - Acceptable Ambient Concentrations
- U.S. - Maine - Air Pollutants - Hazardous Air Pollutants
- U.S. - Massachusetts - Right To Know List
- U.S. - New Jersey - Right to Know Hazardous Substance List
- U.S. - New York - Reporting of Releases Part 597 - List of Hazardous Substances
- U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information


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

Full text of H-phrases: see section 16:

- Acute Tox. 4 (Oral)
- Carc. 2
- Resp. Sens. 1
- Skin Sens. 1
- H302
- H317
- H334
- H351

Acute toxicity (oral) Category 4
Carcinogenicity Category 2
Respiratory sensitisation Category 1
Skin sensitization Category 1
Harmful if swallowed
May cause an allergic skin reaction
May cause allergy or asthma symptoms or breathing difficulties if inhaled
Suspected of causing cancer
Victoza®, Liraglutide
Safety Data Sheet
according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>NFPA health hazard</th>
<th>1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NFPA fire hazard</td>
<td>0 - Materials that will not burn.</td>
</tr>
<tr>
<td>NFPA reactivity</td>
<td>0 - Normally stable, even under fire exposure conditions, and are not reactive with water.</td>
</tr>
</tbody>
</table>

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.