According to EC-Regulation 2015/830

SAFETY DATA SHEET

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

1.1. Product identifier

   Trade name
   Ozempic® (Semaglutide) for Injection
   All doses

   Product no.
   -

   REACH registration number

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

   Relevant identified uses of the substance or mixture
   Closed handling with occasional open handling, e.g. for sampling

   Uses advised against
   The full text of any mentioned and identified use categories are given in section 16

1.3. Details of the supplier of the safety data sheet

   Company and address
   Novo Nordisk A/S
   Novo Allé
   DK-2880 Bagsværd
   Denmark
   Tel.: +45 44 44 88 88

   Contact person
   -

   E-mail
   SDSsupport@novonordisk.com

   SDS date
   2018-01-22

   SDS Version
   1.0

1.4. Emergency telephone number

   Contact The National Poisons Information Service. See section 4 “First aid measures”.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

   Not classified according to Regulation (EC) No. 1272/2008 (CLP)

2.2. Label elements

   Hazard pictogram(s)
   -

   Signal word
   -

   Hazard statement(s)
   -

   Safety statement(s)
   General
   -
   Prevention
   -
   Response
   -
   Storage
   -
   Disposal
   -

   Identity of the substances primarily responsible for the major health hazards
   Not applicable

2.3. Other hazards

   Contains a pharmacologically active substance
   Consult the package insert
According to EC-Regulation 2015/830

**Additional labelling**
- Not applicable

**Additional warnings**
- Not applicable

**VOC**
- Not applicable

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### SECTION 3: Composition/information on ingredients

#### 3.1/3.2. Substances/Mixtures

- **NAME:** Solution for injection containing Semaglutide and small amount of phenol
- **IDENTIFICATION NOS.:**
- **CONTENT:** 95-100%
- **CLP CLASSIFICATION:** NA

(*) See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

**Other information**

Contains < 1 % Phenol (Preservative)

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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

**General information**
- In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person’s condition or if the symptoms persist. Never give an unconscious person water or other drink.

**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.

**Ingestion**
- Rinse mouth thoroughly and then drink plenty of water. Do not induce vomiting. Seek medical advice in case of persistent discomfort.

**Burns**
- Not applicable

#### 4.2. Most important symptoms and effects, both acute and delayed
- Nothing special

#### 4.3. Indication of any immediate medical attention and special treatment needed
- Nothing special

**Information to medics**
- Bring this safety data sheet.

---

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media
- Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Waterjets should not be used, since they can spread the fire.

#### 5.2. Special hazards arising from the substance or mixture
- Nothing special

#### 5.3. Advice for firefighters
- No specific requirements.

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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures
- No specific requirements.

#### 6.2. Environmental precautions
According to EC-Regulation 2015/830

No specific requirements.

6.3. 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.

6.4. Reference to other sections
See section on "Disposal considerations" in regard of handling of waste. See section on 'Exposure controls/personal protection' for protective measures.

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities
Always store in containers of the same material as the original container. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature
Refrigerator, 2 to 8°C

7.3. Specific end use(s)
This product should only be used for applications quoted in section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL
Comply with any national regulations regarding occupational exposure limit if is any.

DNEL / PNEC
No data available

8.2. Exposure controls
Control is unnecessary if the product is used as intended.

General recommendations
Observe general occupational hygiene standards.

Exposure scenarios
In the event exposure scenarios are appended to the safety data sheet, the operational conditions and risk management measures in these shall be complied with.

Exposure limits
Comply with any national regulations regarding occupational exposure limit if is any.

Appropriate technical measures
Apply standard precautions during use of the product. Avoid inhalation of gas or dust.

Hygiene measures
In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Always wash hands, forearms and face.

Measures to avoid environmental exposure
No specific requirements.

Individual protection measures, such as personal protective equipment

Generally
Use only CE marked protective equipment.

Respiratory Equipment
At normal use is respiratory protection equipment not necessary

Skin protection
No specific requirements.

Hand protection
Recommendation: Protective gloves may be used, e.q. if risk of direct contact

Eye protection
No specific requirements.
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
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</tr>
<tr>
<td>Colour</td>
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</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour threshold (ppm)</td>
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</tr>
<tr>
<td>pH</td>
<td>7.4</td>
</tr>
<tr>
<td>Viscosity (40°C)</td>
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</tr>
<tr>
<td>Density (g/cm³)</td>
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</tr>
<tr>
<td>Phase changes</td>
<td></td>
</tr>
<tr>
<td>Melting point (°C)</td>
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<tr>
<td>Boiling point (°C)</td>
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<tr>
<td>Vapour pressure</td>
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<tr>
<td>Decomposition temperature (°C)</td>
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</tr>
<tr>
<td>Evaporation rate (n-butylacetate = 100)</td>
<td>No data available</td>
</tr>
<tr>
<td>Data on fire and explosion hazards</td>
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<tr>
<td>Flash point (°C)</td>
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</tr>
<tr>
<td>Ignition (°C)</td>
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<tr>
<td>Auto flammability (°C)</td>
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<tr>
<td>Explosion limits (% v/v)</td>
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</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2. Other information

| Solubility in water                           | Soluble                                   |
| n-octanol/water coefficient                   | No data available                         |

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

10.2. Chemical stability

The product is stable under the conditions, noted in the section “Handling and storage”.

10.3. Possibility of hazardous reactions

Nothing special

10.4. Conditions to avoid

Do not expose to any forms of heat (e.g. solar radiation). May lead to excess pressure. Avoid freezing.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

- Substance: For relevant information, see package insert
- Species: -
- Test: -
- Route of exposure: -
- Result: N/A

Skin corrosion/irritation

Data on substance: For relevant information, see package insert

Serious eye damage/irritation

Data on substance: For relevant information, see package insert

Respiratory or skin sensitisation

Data on substance: For relevant information, see package insert

Germ cell mutagenicity

Data on substance: For relevant information, see package insert

Carcinogenicity

Data on substance: For relevant information, see package insert
According to EC-Regulation 2015/830

Data on substance: For relevant information, see package insert

Reproductive toxicity
Data on substance: For relevant information, see package insert

STOT-single exposure
Data on substance: For relevant information, see package insert

STOT-repeated exposure
Data on substance: For relevant information, see package insert

Aspiration hazard
Data on substance: For relevant information, see package insert

Long term effects
Nothing special

SECTION 12: Ecological information

12.1. Toxicity
No data available.

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Substance</th>
<th>Biodegradability</th>
<th>Test</th>
<th>Result</th>
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<tbody>
<tr>
<td></td>
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</table>

12.3. Bioaccumulative potential

<table>
<thead>
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<th>Substance</th>
<th>Potential bioaccumulation</th>
<th>LogPow</th>
<th>BCF</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>No data available.</td>
<td></td>
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</tr>
</tbody>
</table>

12.4. Mobility in soil
No data available

12.5. Results of PBT and vPvB assessment
This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

12.6. Other adverse effects
Nothing special

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Dispose in accordance with local and national regulations

Waste
- EWC code
- Specific labelling
- Contaminated packing
  No specific requirements.

SECTION 14: Transport information

14.1 – 14.4
Not dangerous goods according to ADR, IATA and IMDG.

ADR/RID

14.1. UN number
- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- Notes
- Tunnel restriction code

IMDG

UN-no.
- Proper Shipping Name
- Class
- PG*
- EmS
- MP**
- Hazardous constituent
-
According to EC-Regulation 2015/830

<table>
<thead>
<tr>
<th>IATA/ICAO</th>
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<td>UN-no.</td>
<td>-</td>
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<tr>
<td>Proper Shipping Name</td>
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<tr>
<td>Class</td>
<td>-</td>
</tr>
<tr>
<td>PG*</td>
<td>-</td>
</tr>
</tbody>
</table>

14.5. Environmental hazards

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No data available

(*) Packing group  
(**) Marine pollutant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Restrictions for application

Demands for specific education

Additional information

Not applicable

Seveso

Sources


EC regulation 1907/2006 (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

The full text of identified uses as mentioned in section 1

Additional label elements

Not applicable

Other

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The safety data sheet is validated by

JGOA

Date of last essential change

(First cipher in SDS version)

2018-01-22

Date of last minor change

(Last cipher in SDS version)

2018-01-22