

# 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**

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**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

**Additional labelling**

Not applicable

**Additional warnings**

Not applicable

**VOC**

Not applicable

**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)

**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.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

No specific requirements.

**6.2. Environmental precautions**

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.g. 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

Form	Liquid
Colour	No data available.
Odour	No data available.
Odour threshold (ppm)	No data available.
pH	7,4
Viscosity (40°C)	No data available.
Density (g/cm <sup>3</sup> )	No data available.

#### Phase changes

Melting point (°C)	No data available.
Boiling point (°C)	No data available.
Vapour pressure	No data available.
Decomposition temperature (°C)	No data available.
Evaporation rate (n-butylacetate = 100)	No data available.

#### Data on fire and explosion hazards

Flash point (°C)	No data available.
Ignition (°C)	No data available.
Auto flammability (°C)	No data available.
Explosion limits (% v/v)	No data available.
Explosive properties	No data available.

#### Solubility

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

### 9.2. Other information

Solubility in fat (g/L)	No data available.
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## 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

**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**

Substance	Biodegradability	Test	Result
No data available.			

**12.3. Bioaccumulative potential**

Substance	Potential bioaccumulation	LogPow	BCF
No data available.			

**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	-

**IATA/ICAO**

**UN-no.** -  
**Proper Shipping Name** -  
**Class** -  
**PG\*** -

**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**

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**Sources**

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP).  
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