# Safety data sheet

## PrandiMet® Tablets
## (Repaglinide 1 mg/Metformin 500 mg and 2 mg/Metformin 500 mg)

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

**Product use:** Tablets

Supplier:
**Novo Nordisk A/S, Miljøafdelingen**
**Sauntesvej 13**
**2820 Gentofte**
**Tel:44 44 88 88 Fax:**
**Contact person:Bente Jørgensen**

### 2. Hazards identification

Harmful if swallowed. Irritating to eyes and skin.

### 3. Composition/information on ingredients

| Einecs no. | CAS No. | Substances | Classification | w/w% |
|---|---|---|---|---|
| 214-230-6 | 1115-70-4 | Metformin hydrochloride | Xn;R22 Xi;R36/38 | 40 |
| - | 135062-02-1 | Repaglinide 1mg, 2mg | Xn;R63, R64 | 0.15 (0.32) |

*Please see section 16 for the full text of the R-phrases*

### 4. First aid measures

**Inhalation**
Seek fresh air. Seek medical advice in case of persistent discomfort.

**Ingestion**
Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.

**Skin**
Remove contaminated clothing. Wash skin with soap and water.

**Eyes**
Not likely unless the tablets are crushed. If you get dust in the eyes, rinse immediately with water (preferably using eye wash) for at least 5 minutes. Open eyes wide. Remove any contact lenses.

**Other information**
When obtaining medical advice, show the safety data sheet or label.

### 5. Fire-fighting measures

The product is not directly flammable. Avoid inhalation of vapour and flue gases – seek fresh air.

### 6. Accidental release measures

Use the same personal protection as for item 8. Sweep/pick up spill and place in suitable waste containers. For information on disposal please see item 13

### 7. Handling and storage

**Handling**
Please see item 8 for information on personal protection.

**Storage**
Store at +15°C to 25°C Max. 60% humidy RH.

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## 8. Exposure controls/ personal protection

**Precautions for use**
There must be access to running water and eye wash.

**Respiratory protection**
Not required.

**Gloves and protective clothing**
Disposable gloves of type PVC are recommended.

**Eye protection**
Not required.

**Occupational exposure limits**

| Ingredients | Exposure limit | Remarks |
|---|---|---|
| | | |

**Control methods**
Compliance with occupational exposure limits may be checked by occupational hygiene measurements

## 9. Physical and chemical properties

| | |
|---|---|
| Appearance: Tablets | Specific gravity or relative density: |
| Odor: | Solubility: |
| Odor threshold: | pH: |
| Physical state: | Melting/freezing point: |

## 10. Stability and reactivity

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

## 11. Toxicological information

***Acute***

**Inhalation**
Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.

**Ingestion**
Harmful if swallowed.

**Skin contact**
Not likely unless the tablets are crushed. May then cause slight irritation.

**Eye contact**
Not likely unless the tablets are crushed. May then cause temporary irritation.

***Long-term effects***
None known.

## 12. Ecological information

Avoid discharge to drain or surface water.

## 13. Disposal considerations

Collect spills and waste in closed and sealed containers and send to the local disposal facility for chemical waste.

## 14. Transport information

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

## 15. Regulatory information

Harmful

**Hazard designation:** Harmful

**Hazard symbols:** Xn

**Contains**
Repaglinide 1 mg, 2 mg, Metformin hydrochloride 500 mg

**R-phrases**
Harmful if swallowed (R22)
Irritating to eyes and skin (R36/38)

**S-phrases**
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice (S26)
Wear suitable protective clothing (S36)
(S36)

**Other labelling**

**Chemical safety assessment**

## 16. Other information

**Restrictions on use**
None.

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

**Sources used**
The Chemicals (Hazard Information and Packaging for Supply) Regulations
The list of dangerous substances

**Other information**

**Full text of the R-phrases that are stated in section 3.**
R22 Harmful if swallowed
R36/38 Irritating to eyes and skin
R63 Possible risk of harm to the unborn child
R64 May cause harm to breast-fed babies