

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

1.1. Product identifier

Product form : Mixture
 Product name : Prandin® 0.5 mg, Prandin® 1 mg, Prandin® 2 mg

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

GHS-US classification

Resp. Sens. 1 H334

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US)



GHS08

Signal word (GHS-US) : Danger
 Hazard statements (GHS-US) : H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
 Precautionary statements (GHS-US) : P261 - Avoid breathing dust
 P284 - [In case of inadequate ventilation] wear respiratory protection
 P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
 P342+P311 - If experiencing respiratory symptoms: Call a Poison Center
 P501 - Dispose of contents/container to comply with local/national/international regulations

2.3. Other hazards

Other hazards not contributing to the classification : This product contains the following inactive ingredients calcium hydrogen phosphate (anhydrous), microcrystalline cellulose, maize starch, polacrillin potassium, povidone, glycerol (85%), magnesium stearate, meglumine, and poloxamer. The 1 mg and 2 mg tablets contain iron oxides (yellow and red, respectively) as coloring agents.

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

Name	Product identifier	%	GHS-US classification
Glycerol	(CAS No) 56-81-5	≤85	Not classified
Repaglinide	(CAS No) 135062-02-1	≤15	Resp. Sens. 1, H334

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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 : Exposure not anticipated. Promptly wash with plenty of soap and water.
- First-aid measures after eye contact : Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get Immediate Medical Attention. 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 15 minutes. Open eyes wide. Remove any contact lenses.
- First-aid measures after ingestion : Rinse mouth thoroughly and then drink plenty of water. Seek medical advice in case of persistent discomfort.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : None under normal use. Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.
- Symptoms/injuries after skin contact : Not likely unless the tablets are crushed. May then cause slight irritation.
- Symptoms/injuries after eye contact : Not likely unless the tablets are crushed. May then cause temporary irritation.
- Symptoms/injuries after ingestion : May cause hyperglycemia or hypoglycemia.

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 : The product is not readily 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 : Do not inhale dust/vapors - 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 with non-combustible material and transfer to containers.

6.4. Reference to other sections

No additional information available

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.

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7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Protect from moisture. Keep bottles tightly closed. Dispense in tight containers with safety closures.
- Storage temperature : Do not store above 25° C (77° F).

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Contains no substances subject to reporting requirements.

8.2. Exposure controls

- Appropriate engineering controls : Work must be done with effective mechanical ventilation (e.g. local extractor fan). There must be access to running water and eye wash.
- Hand protection : Polyvinylchloride (PVC) /Nitrile rubber gloves.
- Eye protection : Chemical goggles or safety glasses.
- Skin and body protection : 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 : Solid
- Appearance : Tablet.
- Molecular mass : 165.63 g/mol
- Colour : 0.5 mg tablet (white);1 mg tablet (yellow);2 mg tablet (peach).
- Odour : None established.
- Odour threshold : No data available
- pH : No data available
- Relative evaporation rate (butylacetate=1) : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Auto-ignition temperature : No data available
- Decomposition temperature : No data available
- Flammability (solid, gas) : No data available
- Vapour pressure : No data available
- Relative vapour density at 20 °C : No data available
- Relative density : No data available
- Solubility : No data available
- Log Pow : No data available
- Log Kow : No data available
- Viscosity, kinematic : No data available
- Viscosity, dynamic : No data available
- Explosive properties : No data available
- Oxidising properties : No data available
- Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal use and conditions.

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10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

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Additional information	May cause hypoglycemia. Less common adverse clinical or laboratory events observed in clinical trials included elevated liver enzymes, thrombocytopenia, leukopenia, and anaphylactoid reactions. Although no causal relationship with repaglinide has been established, postmarketing experience includes reports of the following rare adverse events: alopecia, hemolytic anemia, pancreatitis, Stevens-Johnson Syndrome, and severe hepatic dysfunction including jaundice and hepatitis.

Glycerol (56-81-5)	
LD50 oral rat	12600 mg/kg Federation Proceedings, Federation of American Societies for Experimental Biology. Vol. 4, Pg. 142, 1945.
LD50 dermal rabbit	10000 mg/kg BIOFAX Industrial Bio-Test Laboratories, Inc., Data Sheets. Vol. 9-4/1970.

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Pregnancy category C
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: None under normal use. Not likely unless the tablets are crushed. Inhalation of dust may cause irritation to the upper airways.
Symptoms/injuries after skin contact	: Not likely unless the tablets are crushed. May then cause slight irritation.
Symptoms/injuries after eye contact	: Not likely unless the tablets are crushed. May then cause temporary irritation.
Symptoms/injuries after ingestion	: May cause hyperglycemia or hypoglycemia.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

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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

Glycerol (56-81-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Repaglinide (135062-02-1)

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

Glycerol (56-81-5)

U.S. - New Jersey - Right to Know Hazardous Substance List

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SECTION 16: Other information

Data sources

- U.S. National Library of Medicine: DAILY MED
[<http://dailymed.nlm.nih.gov/dailymed/index.cfm>].

Prandin prescribing 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:

Resp. Sens. 1	Sensitization — Respiratory, category 1
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

NFPA health hazard

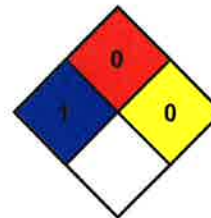
- 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

- 0 - Materials that will not burn.

NFPA reactivity

- 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



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