

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

1.1. Product identifier

Product name : GlucaGen® Hypokit
 Formula : C₁₅₃H₂₂₅N₄₃O₄₉S

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

Use of the substance/mixture : Drug Product. GlucaGen is used to treat severe hypoglycemic (low blood sugar) reactions which may occur in patients with diabetes mellitus treated with insulin. GlucaGen is indicated for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract.

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

Skin Sens. 1 H317

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

Signal word (GHS-US) : Warning
 Hazard statements (GHS-US) : H317 - May cause an allergic skin reaction
 Precautionary statements (GHS-US) : P261 - Avoid breathing dust, mist
 P272 - Contaminated work clothing should not be allowed out of the workplace
 P280 - Wear appropriate PPE
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water
 P321 - Specific treatment (see see Section 4 on this label)
 P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
 P362+P364 - Take off contaminated clothing and wash it before reuse
 P501 - Dispose of contents/container to comply with local/national regulations

2.3. Other hazards

Other hazards not contributing to the classification : Inactive ingredients include: lactose monohydrate and sterile water for reconstitution.

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
GlucaGen HypoKit 1 mg powder and solvent for solution for injection Glucagon [rDNA origin] hydrochloride (active ingredient)	(CAS No) 16941-32-4	100	Skin Sens. 1, H317

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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 : Remove person to fresh air. If signs/symptoms continue, get medical attention.
- 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 : Rinse mouth. 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 : Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
- Symptoms/injuries after skin contact : May cause irritation by the active substance or any of the excipients. Hypersensitivity reactions, including anaphylaxis have been reported with Glucagen® Hypokit.
- 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 intravenous administration : Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension.

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 : 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.

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	: Before Reconstitution: The GlucaGen package may be stored up to 24 months at controlled room temperature 20° to 25° C (68° to 77° F) prior to reconstitution. Do not freeze. Keep in the original package to protect from light. GlucaGen should not be used after the expiry date on the vials. After Reconstitution: Reconstituted GlucaGen should be used immediately. Discard any unused portion. If the solution shows any sign of gel formation or particles, it should be discarded.
Incompatible products	: Heat sources.
Maximum storage period	: 24 months
Storage temperature	: 20 - 25 °C

7.3. Specific end use(s)

Drug Product. GlucaGen is used to treat severe hypoglycemic (low blood sugar) reactions which may occur in patients with diabetes mellitus treated with insulin. GlucaGen is indicated for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract.

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.
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	: Solid/solution
Appearance	: White powder/ aqueous solution.
Molecular mass	: 3483 g/mol
Color	: White. Clear when reconstituted.
Odor	: No special smell.
Odor threshold	: No data available
pH	: 2.5 - 3.5
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
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
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

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Oxidising properties	: No data available
Explosive limits	: No data available

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

No known incompatibilities.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified pH: 2.5 - 3.5
Serious eye damage/irritation	: Not classified pH: 2.5 - 3.5
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (The weight of evidence indicates that GlucaGen is not different from glucagon pancreatic origin and does not pose a genotoxic risk to humans.)
Carcinogenicity	: Not classified (Long term studies in animals to evaluate carcinogenic potential have not been performed. Several studies have been conducted to evaluate the mutagenic potential of glucagon. The mutagenic potential tested in the Ames and human lymphocyte assays, was borderline positive under certain conditions for both glucagon (pancreatic) and glucagon (rDNA) origin. In vivo, very high doses (100 and 200 mg/kg) of glucagon (both origins) gave a slightly higher incidence of micronucleus formation in male mice but there was no effect in females.)
Reproductive toxicity	: Not classified (GlucaGen (rDNA origin) was not tested in animal fertility studies. Studies in rats have shown that pancreatic glucagon does not cause impaired fertility.)
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Not investigated. Inhalation of mist/dust containing protein may cause sensitization.
Symptoms/injuries after skin contact	: May cause irritation by the active substance or any of the excipients. Hypersensitivity reactions, including anaphylaxis have been reported with Glucagen® Hypokit.
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 intravenous administration	: Allergic reactions may occur and include generalized rash, and in some cases anaphylactic shock with breathing difficulties, and hypotension.

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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

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

Glucagen HypoKit 1 mg powder and solvent for solution for injection Glucagon [rDNA origin] hydrochloride (active ingredient) (16941-32-4)

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

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15.3. US State regulations

No additional information available

SECTION 16: Other information

Data sources : Novo Nordisk Medical Information for Health Care Professionals.
[<http://www.novonordiskmedicalinformation.com/products.aspx>]. U.S. National Library of
Medicine: DAILY MED [<http://dailymed.nlm.nih.gov/dailymed/index.cfm>].

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

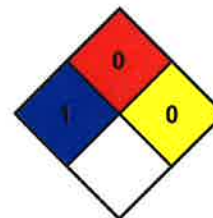
Full text of H-phrases: see section 16:

Skin Sens. 1	Sensitisation — Skin, category 1
H317	May cause an allergic skin reaction

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