



300 Northfield Road
 Bedford, OH 44146
 Telephone: (800) 562-4797
 -or- (440) 232-3320

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: GlucaGen® 1mg/lyophilized
Chemical Names: Peptide C₁₅₃H₂₂₅N₄₃O₄₉S
Synonyms: Glucagen (rDNA origin) for Injection
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800) 424-9300
Telephone Number for Info.: (440) 232-3320 or (800) 562-4797
Medical Emergency: Professional Services: 1(800) 521-5169
Date Prepared: September 30, 1999
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Glucagen (rDNA origin)	0.93%	NONE	NONE	NONE	NONE
Lactose Monohydrate	99.07%	5989-81-1	NONE	NONE	NONE

Glucagen is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Glucagen may be absorbed through inhalation of aerosols and skin contact.
 Exposure is not expected under normal use.
Health Hazard (Acute & Chronic): Glucagen is a drug used to treat severe hypoglycemia (low blood sugar) in diabetic patients treated with insulin. Product affects the gastrointestinal system and liver.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: Product is an antihypoglycemic agent and acts to slow gastrointestinal activity. Signs/symptoms of exposure are minimal. A person may exhibit a rapid heart rate and nausea and vomiting. May increase blood pressure.

Medical Conditions Generally Aggravated by Exposure: Persons who have pheochromocytomas; may cause allergic reaction in sensitive persons.

BVL Hazard Category: 1

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with water.

Skin Exposure: Wash skin with soap and water.

Ingestion: Do not induce vomiting. Seek medical attention from physician immediately.

Inhalation: If difficulty breathing, administer oxygen. Seek medical attention immediately. If necessary, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not determined

Flammable Limits: Glucagen is not flammable **LEL:** NA **UEL:** NA

Extinguishing Media: Use water or an ABC dry chemical fire extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wet Glucagen with water and absorb with absorbent materials; dispose of according to local, state, and federal regulations.

Release to Air: If dust is generated, avoid and reduce exposures by ventilating area; clean up spill immediately.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive dusts are generated.

Waste Disposal Method: Incinerate in an approved/permitted incinerator is recommended. Refer to federal, state, and local rules.

Precautions to be taken in handling and storing: Store in refrigeration between 2-8°C (36-46°F) Avoid freezing and protect from light.

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respiratory protection is not required. If dusts are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit

tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: None

Work/Hygienic Practices: Wash hands prior to and following use. No eating, drinking, or smoking while handling product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid

Appearance and Odor: White powder with no odor

Boiling Point: Not Applicable

Vapor Pressure: Not Applicable

Vapor Density: Not Applicable

Specific Gravity: Not Applicable

Melting Point: Not Available

Evaporation Rate: Not Applicable

Solubility in Water: >0.1%

pH: Not Applicable

(When reconstituted, forms a solution with a pH of 2.5-3.5)

Section X - STABILITY AND REACTIVITY DATA

Stability: None

Incompatibility (Materials to Avoid): None

Hazardous Decomposition or Byproducts: May emit toxic fumes when heated to combustion. As with any fire carbon monoxide and carbon dioxide or other toxic gases may be produced.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: None

Section XI - TOXICOLOGICAL INFORMATION

LD₅₀ subcutaneous and intravenous, rats and mice > 100 mg/kg

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Glucagen. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.

Review local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

Glucagen is not a D.O.T. Hazardous Material.

Glucagen is not a Marine Pollutant

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician. This MSDS does not address the therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.