Product Name: Glucagon for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Hospira Australia Pty Ltd
1 Lexia Place
Mulgrave, VIC 3170
Australia

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Glucagon for Injection

Synonyms
Synthetic Glucagon; His-Ser-Gln-Gly-Thr-Thr-Ser-Asp-Tyr-Ser-Lys-Tyr-Leu-
Asp-Ser-Arg-Arg-Ala-Gln-Asp-Phe-Val-Gln-Trp-Leu-Met-Asn-Thr

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Glucagon as hydrochloride

Chemical Formula
C_{155}H_{225}N_{43}O_{49}S

Preparation
Non-hazardous ingredients include lactose monohydrate. Hydrochloric acid may be
added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon as hydrochloride</td>
<td>&lt;1</td>
<td>16941-32-5</td>
<td>NA</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon as hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Glucagon for Injection is a powder containing synthetic glucagon; it is identical to endogenous
glucagon, a polypeptide hormone produced by cells in the pancreas. Normally, glucagon
increases blood sugar levels by mobilizing glucose through the activation of liver
glycogenolysis. In clinical use, glucagon is used to treat severe hypoglycemic reactions when a
patient cannot take glucose by mouth and intravenous glucose is not feasible. In the workplace,
this material should be considered a potent drug and potentially irritating to the eyes and
respiratory tract. Based on clinical use, potential target organs include the liver, gastrointestinal
system and the cardiovascular system.

Occupational Exposure
Information on the absorption of this product via inhalation or skin contact is not available.
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Potential
However, studies suggest that glucagon is bioavailable following intranasal administration. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposures. In clinical use, nausea and vomiting may occur after use of glucagon. Hypersensitivity reactions, abdominal pain, hypotension, tachycardia, and hypokalemia have also been reported. Glucagon may also produce a positive cardiac chronotropic and inotropic effects but is not generally considered suitable for heart failure.

Medical Conditions
Pre-existing hypersensitivity to glucagon of other components of this formulation; chronic hypoglycemia; starvation.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this product. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard
None anticipated for this product. As with all powders, avoid the creation of dusty environments.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect spilled material using techniques that minimize powder migration and the creation of airborne dust. If the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
7. HANDLING AND STORAGE

Handling
No special handling required for hazard control under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon as hydrochloride</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Sterile, lyophilized white powder in a vial</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>2.5 - 3.5 (when reconstituted with water)</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Glucagon for Injection

Vapor Pressure: NA
Vapor Density: NA
Specific Gravity: NA
Solubility: NA
Partition coefficient: n-octanol/water: Na
Auto-ignition temperature: NA
Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.
Chemical Stability Stable under standard use and storage conditions.
Hazardous Reactions Not determined.
Conditions to avoid Not determined.
Incompatibilities Not determined.

Hazardous decomposition products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon</td>
<td>100</td>
<td>LD50</td>
<td>Intramuscular</td>
<td>&gt;200</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Glucagon</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>&gt;200</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Glucagon</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>100</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Glucagon</td>
<td>100</td>
<td>LD50</td>
<td>Subcutaneous</td>
<td>200</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce mild irritation and redness.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product.

Reproductive Effects Studies conducted in rats at dosages up to 2 mg/kg pancreatic glucagon administered two times a day (up to 40 times the human dose based on body surface area, mg/m2) have revealed no evidence of impaired fertility.
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Reproduction studies were performed in rats and rabbits at dosages of 0.4, 2.0, and 10 mg/kg. These dosages represent exposures of up to 100 and 200 times the human dose based on mg/m² for rats and rabbits, respectively, and revealed no evidence of harm to the fetus.

Mutagenicity

Studies have been conducted to evaluate the mutagenic potential of glucagon. When evaluated in the Ames and human lymphocyte assays, results were 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. The weight of evidence suggests that glucagon does not pose a genotoxic risk.

Carcinogenicity

Long term studies in animals to evaluate carcinogenic potential have not been performed.

Target Organ Effects

Based on clinical use, potential target organs include the liver, gastrointestinal system, and the cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Not determined for product.

Persistence/Biodegradability

Not determined for product.

Bioaccumulation

Not determined for product.

Mobility in Soil

Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal

All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal

Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None
15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon as hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Not Listed
U.S. OSHA Classification: Target Organ Toxin

GHS Classification: *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Glucagon as hydrochloride.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and eye/face protection.
**Product Name:** Glucagon for Injection

### 16. OTHER INFORMATION:

<table>
<thead>
<tr>
<th>Notes:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** 08/11/2011  
**Obsolete Date:** 01/12/2009

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