MATERIAL SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product Name: ProZinc® (Protamine Zinc Recombinant Human Insulin)
Product No.: Not available
GHS Product Identifier: Not applicable

Synonyms: Protamine Zinc Recombinant Human Insulin (rDNA Origin) Suspension
Molecular Formula: Mixture, not applicable
Molecular Weight: Not applicable
CAS Number: Mixture, not applicable
Chemical Family: Not applicable

Manufacturer: AAI Pharma Services Corp.
4221 Faber Place Drive
Charleston, SC 29405

Emergency Telephone:
Transportation Emergency: (800) 424-9300
Medical Emergency (24HR): (866) 638-2226

Non-emergency Telephone: (800) 821-7467

Intended Use: Recommended for the treatment of diabetes in cats.

2 HAZARDS IDENTIFICATION

Emergency Overview

Physical State: Liquid Suspension
Color: Light milky white
Odor: Faint odor of phenol

WARNING!
Feline use only.
Not for human use.

Precautionary Statements:
Accidental human injection can cause serious local reactions or anaphylactic reaction and systemic effects.
Keep only in original container.
Keep at a temperature between 2 - 8° C. 
Do not freeze.
Fire-fighting: Use foam, carbon dioxide, dry powder and water fog or material appropriate for surrounding fire.
Avoid contact with eyes, skin and clothing.
Wash thoroughly with soap and water after handling.
Wear suitable gloves and eye/face protection.
Spills: Cover with absorbent or contain. Collect and incinerate.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If swallowed, seek medical advice immediately and show this container or label.
This material and its container must be disposed of in a safe way.
Keep out of reach of children.
Keep away from food, drink, and animal feedstuffs.

Acute effect: (Protamine Zinc Recombinant Human Insulin) is indicated for the treatment of diabetes in cats.

Precautions/Contraindications:
Hypersensitivity to insulin or protamine.

Overdosage: Overdosage of insulin leads to hypoglycemia. Symptoms can include tremors, palpitations, sweating, blurred vision, confusion and anxiety.

ADVERSE REACTIONS TO PRODUCT: May cause skin or membrane irritation in sensitive individuals or animals. May lead to mild hypoglycemia.

Potential Health Effects

Inhalation: Not expected to be an inhalation hazard with prescribed use.

Eye Contact: Not expected to be a hazard to the eye with prescribed use. May cause slight eye irritation if exposed. Exposure may cause eye tearing, redness, and discomfort.

Skin Contact: Not expected to be a hazard to the skin with prescribed use. May cause slight skin irritation. Prolonged or repeated contact may cause itching, redness, and rash in some individuals or animals.

Ingestion: Not expected to be an ingestion hazard. Exposure may cause vomiting, nausea, diarrhea or hypoglycemia.

Chronic Health Effects: Prolonged hypoglycemia may cause irreversible damage to the brain. Prolonged or repeated exposure may cause damage to kidney and liver. Ingredients have been shown to be mutagenic or fetotoxic in animals. Little, if any effects from this product exposure are expected. Although insulin does not cross the placenta, abnormal glucose concentrations in pregnant women have caused adverse effects in the fetus.

Target Organ(s): Endocrine system, brain, liver, kidney
Potential Physical Effects: None known.

OSHA Regulatory Status: Hazardous

Environment: No data available

3 COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>EC No.</th>
<th>CAS- No.</th>
<th>Concentration</th>
<th>Classification</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide</td>
<td>2152225</td>
<td>1314-13-2</td>
<td>proprietary</td>
<td>N; R50/53</td>
<td>-----</td>
</tr>
<tr>
<td>Glycerin</td>
<td>2002895</td>
<td>56-81-5</td>
<td>proprietary</td>
<td></td>
<td>-----</td>
</tr>
<tr>
<td>Phenol</td>
<td>2036327</td>
<td>108-95-2</td>
<td>proprietary</td>
<td>T, C; R23/24/25 R34 R48/20/21/22 R68</td>
<td>-----</td>
</tr>
<tr>
<td>Insulin (human)</td>
<td>2342797</td>
<td>11061-68-0</td>
<td>proprietary</td>
<td></td>
<td>-----</td>
</tr>
<tr>
<td>Protamine sulfate</td>
<td></td>
<td>9009-65-8</td>
<td>proprietary</td>
<td></td>
<td>-----</td>
</tr>
</tbody>
</table>

The full texts for all R-Phrases are displayed in Section 16.

4 FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact: Wash with soap and water. Get medical attention if symptoms occur.

Ingestion: Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

Note to Physician: For feline use only. Not for human use.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish with water spray, dry chemical, carbon dioxide, foam

Unsuitable Extinguishing Media: None known

Special Fire Fighting Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire & Explosion Hazards: None known.
**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, zinc oxides, sulfur oxides, nitrogen oxides

**Flammability Class:** IIIB [OSHA 1910.106(a) (18) (ii) (b)]

### 6 ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Wear appropriate personal protective equipment. (See Section 8).

**Spill Cleanup Methods:** STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

**Environmental Precautions:** Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

### 7 HANDLING AND STORAGE

**Handling:** HANDLING SIGNIFICANT QUANTITIES OF LIQUID: Avoid contact with eyes, skin or clothing. Absorb spilled liquid and collect for disposal. Wash hand thoroughly after handling.

**Storage:** Keep only in the original container. Reseal containers immediately after use. Store container upright at refrigerated temperatures between 2° and 8°C. Keep from freezing. Protect from light. Store away from foodstuffs.

### 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Limits:**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Source</th>
<th>Type</th>
<th>Exposure Limits</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerin ,mist</td>
<td>ACGIH</td>
<td>8-HR TWA</td>
<td>10 mg/m³</td>
<td>----</td>
</tr>
<tr>
<td>Glycerin mist, respirable fraction</td>
<td>OSHA Z-1</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>----</td>
</tr>
<tr>
<td>Glycerin mist, total dust</td>
<td>OSHA Z-1</td>
<td>PEL</td>
<td>15 mg/m³</td>
<td>----</td>
</tr>
<tr>
<td>Zinc oxide, respirable fraction</td>
<td>ACGIH</td>
<td>TWA</td>
<td>2 mg/m³</td>
<td>Metal fume fever</td>
</tr>
<tr>
<td>Zinc oxide, respirable fraction</td>
<td>OSHA Z-1</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>----</td>
</tr>
<tr>
<td>Zinc oxide, total dust</td>
<td>OSHA Z-1</td>
<td>PEL</td>
<td>15 mg/m³</td>
<td>----</td>
</tr>
</tbody>
</table>

Where lower governmentally imposed exposure limits exist, such limits should take precedence.

**Engineering Controls:** Not generally required when handling containers or liquid. (See exposure limits). Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions.
Respiratory Protection: Not generally required when handling liquid or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear lab coat, apron or appropriate clothing to prevent skin contact.

Hygiene Measures: Eye bath, washing facilities

9 PHYSICAL AND CHEMICAL PROPERTIES

Color: Light milky white
Odor: Faint odor of phenol
Odor Threshold: No data available
Physical State: Liquid Suspension
pH: 7.1 – 7.4
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: > 148.89°C (300°F)
Flammability Limit – Upper (%): No data available
Flammability Limit – Lower (%): No data available
Evaporation rate: No data available
Vapor Pressure: No data available
Vapor Density (Air=1): No data available
Volatility: No data available
Specific Gravity: 1.001
Solubility: No data available
Partition Coefficient (n-Octanol/water): No data available
Autoignition Temperature: No data available
Decomposition Temperature: No data available

10 STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: High temperatures, freezing, direct sunlight

Incompatible Materials: Strong oxidizing agents
**Hazardous Decomposition Products:** Carbon dioxide, carbon monoxide, zinc oxides, sulfur oxides, nitrogen oxides

**Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

## 11 TOXICOLOGICAL INFORMATION

### Specified Substances

#### Acute Toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc Oxide</td>
<td>Administration into the eye (rabbit): 500 mg/24 h, Mild Irritant Administration onto the skin (rabbit): 500 mg/24 h, Mild Irritant Lethal dose (rat): &gt;8437 mg/kg</td>
</tr>
<tr>
<td>Glycerin</td>
<td>Administration into the eye (rabbit): 500 mg/24 h, Mild Irritant Administration onto the skin (rabbit): 500 mg/24 h, Mild Irritant Oral LD$<em>{50}$ (rat): 12600 mg/kg Dermal LD$</em>{50}$ (rabbit): &gt;10000 mg/kg</td>
</tr>
<tr>
<td>Phenol</td>
<td>Administration into the eye (rabbit): 5 mg, Severe Irritant Administration onto the skin (rabbit): 500 mg/24 h, Severe Irritant Oral LD$<em>{50}$ (rat): 317 mg/kg Dermal LD$</em>{50}$ (rabbit): 630 mg/kg Inhalation LC$_{50}$ (rat): 316 mg/m$^3$/4h</td>
</tr>
</tbody>
</table>

#### Product

**Acute Toxicity**

<table>
<thead>
<tr>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD$<em>{50}$ (mice): &gt;10000 mg/kg Dermal LD$</em>{50}$ (rat): &gt;10000 mg/kg Inhalation LC$_{50}$ (rat): &gt;10000 ppm (in air, 4 hours) Skin or Eye Contact: Irritant</td>
</tr>
</tbody>
</table>

**Chronic Toxicity** – Prolonged or repeated exposure may cause damage to kidney and liver. Ingredients have been shown to be mutagenic or fetotoxic in animals. Little, if any effects from this product exposure are expected. Although insulin does not cross the placenta, abnormal glucose concentrations in pregnant women have caused adverse effects in the fetus.

**Listed Carcinogens:** None listed.

## 12 ECOLOGICAL INFORMATION

**Ecotoxicity:** No data available

**Persistence and degradability:** No data available

**Mobility in soil:** No data available

**Other adverse effects:** No data available

13 DISPOSAL CONSIDERATIONS

General Information: Dispose of in accordance with local, state and federal regulations.

Disposal Methods: No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14 TRANSPORT INFORMATION

DOT: Not regulated

TDG: Not regulated

ADR/RID: Not regulated

IATA: Not regulated

IMDG: Not regulated

15 REGULATORY INFORMATION

Canadian Controlled Products Regulations: This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

WHMIS Classification: Noncontrolled, exempt

Inventory Status

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.

This material is not listed on the DSL Inventory. Therefore, it can only be used for DSL exempt purposes such as R&D or veterinary use.

US Regulations

FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):

<table>
<thead>
<tr>
<th>Component</th>
<th>Reportable</th>
<th>Reportable</th>
</tr>
</thead>
</table>

7/10
<table>
<thead>
<tr>
<th>Phenol</th>
<th>Quantity Code</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C</td>
<td>1000lbs</td>
</tr>
</tbody>
</table>

**CERCLA Hazardous Substance List (40 CFR 302.4):**

<table>
<thead>
<tr>
<th>Component</th>
<th>Reportable Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenol</td>
<td>1000lbs</td>
</tr>
<tr>
<td>Zinc oxide (as zinc compounds)</td>
<td>----</td>
</tr>
</tbody>
</table>

**SARA Title III- Section 302 Extremely Hazardous Substances (40 CFR 355, Appendix A):**

<table>
<thead>
<tr>
<th>Component</th>
<th>Reportable Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenol</td>
<td>1000lbs</td>
</tr>
</tbody>
</table>

**SARA Title III- Section 313 Toxic Chemicals (Reporting Form R Instructions for RY2007):**

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS No</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide (as zinc compounds)</td>
<td>1314-13-2</td>
<td>proprietary</td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>proprietary</td>
</tr>
</tbody>
</table>

**State Regulations**

**California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):** None listed

**Massachusetts Right-To-Know List:** Phenol, zinc oxide fume, glycerine mist

**Minnesota Hazardous Substances List:** Phenol, zinc oxide (fume and dust), glycerin mist

**New Jersey Right-To-Know List:** Phenol, zinc oxide

**Pennsylvania Right-To-Know List:** Zinc oxide, glycerin

**Rhode Island Right-To-Know List:** Phenol, zinc oxide, glycerin mist

**European Regulations**

**Austria MAK List (Annex I):** Phenol, zinc oxide

**Denmark:** The MAL-factor Phenol - 160 m3 air/10g substance. (The MAL-factor applies to concentrations > 0% by weight). The MAL-factor Zinc oxide – 0 m3 air/10g substance. (The MAL-factor applies to concentrations > 0% by weight)

**Norway (List of Dangerous Substance):** Phenol, zinc oxide

**Switzerland Toxins List 1:** Phenol, zinc oxide, glycerin

### 16 OTHER INFORMATION

**Hazard Ratings**

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Fire Hazard</th>
<th>Reactivity Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NFPA</th>
<th>Health Hazard</th>
<th>Fire Hazard</th>
<th>Reactivity Hazard</th>
<th>Special Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

* – Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

**From Section 3**

C – Corrosive

T – Toxic

N – Dangerous for the environment
R23/24/25 – Toxic by inhalation, in contact with skin and if swallowed.
R34 – Causes burns.
R48/20/21/22 – Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
R68 – Possible risks of irreversible effects.
R50/53 – Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Mixture** –
N – Dangerous for the environment
R51/53 – Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Handle in accordance with good industrial hygiene and safety practice.

**ABBREVIATIONS:**
BIV – Boehringer Ingelheim Vetmedica, Inc.
AIHA – American Industrial Hygiene Association
mppcf – million particles/cubic foot
N/A – Not applicable.
N/E – Not established.

**References:**
1. PZIR (Protamine Zinc Recombinant Human Insulin) MSDS. IDEXX Laboratories.
3. RTECS No. ZH4810000 – Zinc oxide
4. RTECS No. MA8050000 – Glycerol
5. RTECS No. SJ3325000 – Phenol
6. GHS Manual

**Revision Information:** New MSDS
**Prepared by:** Boehringer Ingelheim Vetmedica, Inc.
**Issue Date:** 8/12/2010

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