

SAFETY DATA SHEETS

This SDS packet was issued with item:

078770108

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078770090



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

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

Non-emergency Telephone: (800) 821-7467

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

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

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:

Chemical Name	Source	Type	Exposure Limits	Notes
Glycerin ,mist	ACGIH	8-HR TWA	10 mg/m ³	----
Glycerin mist, respirable fraction	OSHA Z-1	PEL	5 mg/m ³	----
Glycerin mist, total dust	OSHA Z-1	PEL	15 mg/m ³	----
Zinc oxide, respirable fraction	ACGIH	TWA	2 mg/m ³	Metal fume fever
Zinc oxide, respirable fraction	OSHA Z-1	PEL	5 mg/m ³	----
Zinc oxide, total dust	OSHA Z-1	PEL	15 mg/m ³	----

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

Chemical Name	Test Results
Zinc Oxide	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): >8437 mg/kg
Glycerin	Administration into the eye (rabbit): 500 mg/24 h, Mild Irritant Administration onto the skin (rabbit): 500 mg/24 h, Mild Irritant Oral LD ₅₀ (rat): 12600 mg/kg Dermal LD ₅₀ (rabbit): >10000 mg/kg
Phenol	Administration into the eye (rabbit): 5 mg, Severe Irritant Administration onto the skin (rabbit): 500 mg/24 h, Severe Irritant Oral LD ₅₀ (rat): 317 mg/kg Dermal LD ₅₀ (rabbit): 630 mg/kg Inhalation LC ₅₀ (rat): 316 mg/m ³ /4h

Product

Acute Toxicity

Test Results
Oral LD ₅₀ (mice): >10000 mg/kg Dermal LD ₅₀ (rat): >10000 mg/kg Inhalation LC ₅₀ (rat): >10000 ppm (in air, 4 hours) Skin or Eye Contact: Irritant

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

Germany WGK: Zinc Oxide: ID No: 2187; Class 2: water-endangering. Phenol: ID No: 170; Class 2: water-endangering. Glycerin: ID No: 116; Class 1: slightly water-endangering.

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):

Component	Reportable	Reportable
-----------	------------	------------

	Quantity Code	Quantity
Phenol	C	1000lbs

CERCLA Hazardous Substance List (40 CFR 302.4):

Component	Reportable Quantity
Phenol	1000lbs
Zinc oxide (as zinc compounds)	----

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

Component	Reportable Quantity
Phenol	1000lbs

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

Component	CAS No	Weight %
Zinc oxide (as zinc compounds)	1314-13-2	proprietary
Phenol	108-95-2	proprietary

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

	Health Hazard	Fire Hazard	Reactivity Hazard
HMIS	1	1	0

	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	1	1	0	N/A

* – 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.
2. Ariel WebInsight Regulatory Database. Regulatory Summary for North America, Western Europe, and Global Inventories Database.
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

Disclaimer: The information provided herein is offered by Boehringer Ingelheim Vetmedica, Inc. (“BIV”) in good faith as accurate as of the date hereof, but without guarantee. This information includes information which has been generated by other parties and provided to BIV, and which BIV has not independently verified. The information provided herein relates only to the specific product designated, and may not be valid where such product is used in combination with any other materials or in any process. The information provided herein is offered solely for your consideration, investigation and verification, and Boehringer Ingelheim Vetmedica, Inc. (“BIV”) expressly disclaims all liability for reliance thereon. BIV EXPRESSLY DISCLAIMS ALL WARRANTIES OF EVERY KIND AND NATURE (INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE) WITH RESPECT TO THE USE OR SUITABILITY OF THE PRODUCT. In addition, since the conditions of use and suitability of the product for particular uses are beyond BIV’s control, ALL RISKS OF USE OF THE PRODUCT ARE THEREFORE ASSUMED BY THE USER, AND BIV EXPRESSLY DISCLAIMS ANY AND ALL LIABILITY AS TO ANY RESULTS OBTAINED OR ARISING FROM ANY USE OF THE PRODUCT. Use or transmission of the information

contained herein in any other format than the format as presented is strictly prohibited. Nothing herein shall be construed as permission or recommendation for the use of the product in a manner that might infringe an existing patent. BIV neither represents nor warrants that the format, content or product formulas contained in this document comply with the laws of any other country except the United States of America.

© Copyright 2001 Boehringer Ingelheim Vetmedica, Inc. All rights reserved.