SAFETY DATA SHEET

1. Identification

Product identifier **ProZinc® (Protamine Zinc Recombinant Human Insulin)**

Other means of identification

Synonyms Protamine Zinc Recombinant Human Insulin (rDNA Origin) Suspension

Recommended use Recommended for the treatment of diabetes in cats.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer Boehringer Ingelheim Vetmedica, Inc.

Address 2621 North Belt Hwy
St. Joseph, MO 64506-2002

Transportation emergency For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

Medical Emergency (24HR): (866)638-2226

Non-Emergency calls: (800) 821-7467

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials.

Disposal Dispose of waste and residues in accordance with local authority requirements.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Zinc oxide	1314-13-2	proprietary
Glycerin	56-81-5	proprietary
Phenol	108-95-2	proprietary
Insulin (human)	11061-68-0	proprietary
Protamine sulfate	9009-65-8	proprietary

4. First-aid measures

Inhalation — If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact — Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact — Rinse with water. Get medical attention if irritation develops and persists.

Ingestion — Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed — Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects.

Indication of immediate medical attention and special treatment needed — Not for human use. For use in animals only. Treat symptomatically. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

General information — Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media — Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media — None known.

Specific hazards arising from the chemical — During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters — Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions — Move containers from fire area if you can do so without risk.

Specific methods — Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards — No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures — Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up — Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions — Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling — Avoid prolonged exposure. Use care in handling/storage. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities — Store in original tightly closed container. Store in upright position. Protect from light. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Keep refrigerated. Store material between 2°C (35°F) and 8°C (46°F).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Glycerin (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
Phenol (CAS 108-95-2)	PEL	19 mg/m3	
		5 ppm	

US. ACGIH Threshold Limit Values

Components	Type	Value
Phenol (CAS 108-95-2)	TWA	5 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
Phenol (CAS 108-95-2)	Ceiling	60 mg/m3
		15.6 ppm
	TWA	19 mg/m3
		5 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling Time
Phenol (CAS 108-95-2)	250 mg/g	Phenol with hydrolysis	Creatinine in urine	*

* - For sampling details, please see the source document.

Exposure guidelines

US - California OELs: Skin designation

Phenol (CAS 108-95-2) Can be absorbed through the skin.

US - Minnesota Haz Subs: Skin designation applies

Phenol (CAS 108-95-2) Skin designation applies.

US - Tennessee OELs: Skin designation

Phenol (CAS 108-95-2) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Phenol (CAS 108-95-2) Can be absorbed through the skin.

US. NIOSH: Pocket Guide to Chemical Hazards

Phenol (CAS 108-95-2) Can be absorbed through the skin.

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Phenol (CAS 108-95-2) Can be absorbed through the skin.

Appropriate engineering controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Skin protection

Other Wear suitable protective clothing.

Respiratory protection 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.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid suspension

Color Milky white.

Odor Slight phenolic.

Odor threshold Not available.

pH	7.1 - 7.4
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	> 300.0 °F (> 148.9 °C)
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	1.001
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. High temperatures. Freezing. Sunlight.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Thermal decomposition or combustion may produce: carbon dioxide, carbon monoxide, zinc oxides, sulfur oxides, nitrogen oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Components	Species	Test Results
Glycerin (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	12600 mg/kg

Components	Species	Test Results
Phenol (CAS 108-95-2)		
Acute		
Dermal		
LD50	Rat	525 mg/kg
Oral		
LD50	Rat	317 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Phenol (CAS 108-95-2) 3 Not classifiable as to carcinogenicity to humans.

NTP Report on Carcinogens

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Possible hyper sensitization (development of abnormal sensitivity).

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components		Species	Test Results
Glycerin (CAS 56-81-5)			
Aquatic			
Crustacea	EC50	Crustacea	> 10000 mg/l, 24 Hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Glycerin (CAS 56-81-5)	-1.76
Phenol (CAS 108-95-2)	1.46

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not established.

15. Regulatory information

US federal regulations

One or more components are not listed on TSCA.
Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use.
FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Phenol (CAS 108-95-2)	Listed.

SARA 304 Emergency release notification

Phenol (CAS 108-95-2)	1000 LBS

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Chemical name	CAS number	Reportable quantity (pounds)	Threshold planning quantity (pounds)	Threshold planning quantity, lower value (pounds)	Threshold planning quantity, upper value (pounds)
Phenol	108-95-2	1000		500	10000

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Phenol (CAS 108-95-2)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Glycerin (CAS 56-81-5)	Other Flavoring Substances with OSHA PEL's
Phenol (CAS 108-95-2)	Low priority

US state regulations

US. Massachusetts RTK - Substance List

Glycerin (CAS 56-81-5)
Phenol (CAS 108-95-2)

US. New Jersey Worker and Community Right-to-Know Act

Glycerin (CAS 56-81-5)

Phenol (CAS 108-95-2)

US. Pennsylvania Worker and Community Right-to-Know Law

Glycerin (CAS 56-81-5)
Phenol (CAS 108-95-2)

US. Rhode Island RTK

Glycerin (CAS 56-81-5)
Phenol (CAS 108-95-2)

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Phenol (CAS 108-95-2)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 06-May-2015

Revision date 11-May-2018

Version # 02

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
HMIS® is a registered trade and service mark of the American Coatings Association (ACA).

HMIS® ratings
Health: 1
Flammability: 1
Physical hazard: 0

NFPA ratings

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