

SAFETY DATA SHEETS

This SDS packet was issued with item:

078921511

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

078921510



Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: Caninsulin

SYNONYM(S): Caninsulin
Vetsulin

MSDS NUMBER: SP002435

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only
Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Crystalline powder
White to off-white
Odorless
May cause sensitization by inhalation.
May cause effects to:
endocrine system
central nervous system

POTENTIAL HEALTH EFFECTS:

The toxicological properties of this material have not been fully characterized in humans and animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

The health hazard information presented below is for the active ingredient in this product.

Insulin may cause sensitization by inhalation. Symptoms of exposure may include low blood sugar, headache, pallor, sweating, visual disturbances, hunger, anxiety, temulousness, heart palpitations, and slurred speech.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Insuline (porcine)	12584-58-6	0.137
Zinc Chloride	7646-85-7	<0.1

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

NOTE TO PHYSICIAN: This product contains insulin which can affect blood glucose levels. Treat supportively and symptomatically.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

EXPLOSION HAZARDS:

Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed. The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

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SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE**HANDLING:**

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:

Store at -20 deg C. Store in a container sealed against moisture (keep dry). Protect from light.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**OCCUPATIONAL EXPOSURE BAND (OEB):**

OEB 3: $\geq 10 < 100$ mcg/m³. Materials in an OEB 3 category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Body Protection:	<p>In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p> <p>In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.</p>

EXPOSURE LIMIT VALUES

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INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Zinc Chloride	7646-85-7	1 mg/m ³	1 mg/m ³

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Zinc Chloride	7646-85-7	2 mg/m ³			

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Crystalline powder
COLOR: White to off-white
ODOR: Odorless
SOLUBILITY:
 Water: Practically insoluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
 Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
 Exposure to light. Moisture.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
 No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s). The information presented below is for human insulin which is structurally similar to porcine insulin.

ACUTE TOXICITY DATA

INHALATION:
 No data available.

SKIN:
 No data available.

EYE:
 No data available.

ORAL:
 Zinc chloride: Oral LD50: 350 mg/kg (rat)

DERMAL AND RESPIRATORY SENSITIZATION:
 Human Insulin: Delayed hypersensitivity may occur shortly after introduction of insulin therapy via injection. Erythema occurs at the injection site 2-24 hours after the injection and occurs slowly over 2 to 3 days. These reactions are rare.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
 No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

Human Insulin: Insulin may be applied according to normal dosing instructions during pregnancy without a threat to the fetus.

During breast-feeding, insulin can be applied without any influence on lactation and without a threat to the child.

It is unclear whether insulin causes congenital abnormalities, although diabetes can cause congenital abnormalities. Hypoglycemia as well as hyperglycemia have a negative influence on fetal growth and differentiation.

Insulin administered during pregnancy (11.4-27.6 units for human insulin) did not induce adverse effects on the mother or fetus, and there was no statistically significant difference between birth weight of newborns when 2 different types of insulin (known as insulin and human insulin separately) were tested. It was concluded that insulin is safe during pregnancy.

MUTAGENICITY / GENOTOXICITY:

Biosynthetic human insulin: negative with respect to changes in bacteria, DNA repair and SCE.

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

SECTION 12. ECOLOGICAL INFORMATION**ECOTOXICITY DATA**

There are no ecotoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS**MATERIAL WASTE:**

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION**TSCA LISTING**

INGREDIENT	TSCA
Zinc Chloride	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Zinc Chloride		X	2030		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Zinc Chloride	X	X	X	X

Check state requirements for ingredient listing.

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SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:

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(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SUPERSEDES DATE:

18-Nov-2011

SIGNIFICANT CHANGES (US SUBFORMAT):

New regional format, Synonyms, OEB