SAFETY DATA SHEETS

This SDS packet was issued with item:

078822164

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078822172

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: **Diclazuril For Horses**

SYNONYM(S): Diclazuril For Horses
Diclazuril Top Dress
Symmetry

MSDS NUMBER: SP000085

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

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

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

Pellets
Amber, Brown
Grain odor
Irritating to eyes.
May cause effects to:
liver
respiratory system
immune system

POTENTIAL HEALTH EFFECTS:

SECTION 2. HAZARDS IDENTIFICATION

The active ingredient, diclazuril, is an anti-coccidial drug. Diclazuril is practically not toxic acutely. Based upon animal studies, diclazuril may cause effects to the liver, lungs, and immune system following repeated exposure. Skin sensitization may occur in sensitive individuals.

Calcium carbonate is irritating to the skin and a severe eye irritant. Inhalation exposure to high levels of calcium cabonate dust might produce eye and respiratory tract irritation. Acute oral exposure to calcium salts may produce stomach and intestinal bleeding. Chronic oral exposure may cause irritability, sluggishness, stupor, elevated levels of calcium in the blood (hypercalcemia), alkalosis, kidney impairment, and coma.

LISTED CARCINOGENS

Not listed as a carcinogen by OSHA, IARC, NTP or ACGIH.

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
Diclazuril	101831-37-2	1.56
Calcium Carbonate	471-34-1	5-10

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 has not been characterized in humans. This product contains a protein, which may cause hypersensitivity in sensitive individuals.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

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

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:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

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 in a cool, dry, well ventilated area.

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 3: 10-100 mcg/m^3. 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:	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. 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.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Calcium Carbonate	471-34-1		15 mg/m^3

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Pellets
COLOR: Amber, Brown
ODOR: Grain odor
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

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 of this material and not to the formulated product.

ACUTE TOXICITY DATA

INHALATION:
Diclazuril: No mortality or clinical effects occurred in rats exposed to 2.24 mg/L.

SKIN:
Calcium carbonate caused moderate irritation to rabbit skin.

EYE:
Calcium carbonate caused severe irritation to the eyes of rabbits.

ORAL:
Diclazuril: Oral LD50: >5000 mg/kg (rat, mouse, dog)
Clinical effects of diclazuril in rats and mice were non-specific and were mainly on the central nervous system. In dogs following orally administered diclazuril, vomiting and defecation were observed.

Calcium carbonate: Oral LD50 (rat): 6450 mg/kg

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Subchronic to chronic (3 months to 12 months) oral (dietary or gavage) toxicity studies with diclazuril were conducted in mice, rats, and dogs. Dosages varied with species ranging from 1 mg/kg/day to 920 mg/kg/day. Effects observed in mice included decreased body weight gain, increased liver weight, pale and swollen livers, and decreased serum bilirubin. No mortality or significant clinical signs were noted in mice [NOEL: 30 mg/kg/day]. Effects observed in rats included increased liver weight, microscopic changes in the liver, lymph nodes, and lungs. No mortality, clinical chemistry, hematology, or urinalysis changes were noted in rats [NOEL: 4 mg/kg/day]. Effects observed in the dogs included increased blood urea nitrogen and microscopic changes in the liver. These changes were reversible [NOEL: 20 mg/kg/day].

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Oral teratology studies with diclazuril were conducted in rats and rabbits. Dose levels ranged from 1 to 160 mg/kg/day administered to rats on gestation days 6-16. Findings in rats included slight maternal toxicity and decreased litter weights (20 to 160 mg/kg/day). Teratogenicity was not evident at any dose level [NOEL: 5 mg/kg/day]. Rabbits were administered diclazuril on gestation days 6-18 at dose levels ranging from 5 to 160 mg/kg/day. No adverse effects on the dams or their litters were observed. Teratogenicity was not evident at any dose level [NOEL:160 mg/kg/day].

A two generation, two litter reproduction study with diclazuril in rats was conducted at dose levels of 5, 20, or 80 mg/kg/day. Copulation and fertility indices and duration of gestation were not affected by treatment. Teratogenicity was not observed in any litter. Litter weight, pup weight gain, and food consumption during pregnancy and lactation were affected by diclazuril [NOEL: 5 mg/kg/day].

MUTAGENICITY / GENOTOXICITY:
Diclazuril was negative in a battery of in vitro and in vivo mutagenicity tests including Ames, DNA repair, SOS chromotest, mouse lymphoma TK +/- assay, Drosophila sex-linked recessive lethality test, human lymphocyte chromosome aberrations; and micronucleus tests.

CARCINOGENICITY:
Diclazuril was not carcinogenic in mice and rats when given in their diet. In mice at dose levels ranging from 3 to 220 mg/kg/day for up to 25 months, reduced body-weight gain and decreased food consumption, poor general condition, and evidence of liver damage was observed. In rats administered diclazuril at dose levels ranging from 1 to 80 mg/kg/day for up to 28 months, adverse findings occured in macrophages [NOEL: 4 mg/kg/day].

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Diclazuril: LC50 (Bluegill sunfish): 0.58 mg/L
Diclazuril: LC50 (Daphnid): 0.63-1.34 mg/L
Diclazuril: EC50 (Algae): > 4.8 mg/L

ENVIRONMENTAL DATA

There are no environmental data available for this product.

ENVIRONMENTAL FATE AND EFFECTS:
The bioconcentration of diclazuril was evaluated in bluegill sunfish, midge, and earthworms. The bioconcentration factor (BCF) was 160, 0.97-6.0, and 0.55 in the three studies, respectively.

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.

This material does not meet the definition of hazard classes 1-8. However, it contains one ingredient which meets the definition of an environmentally hazardous substance (aquatic environment) in accordance with IMDG Code Chapter 2.9.3 and ADR 2.2.9. Based on the summation method, this ingredient does not meet the concentration to classify the mixture as an environmentally hazardous substance.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Calcium Carbonate	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
Calcium Carbonate			4001		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Calcium Carbonate	X	X		X

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

X: Listed on applicable state hazardous substance or right-to-know lists.

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).

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Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE: 28-Jul-2009

SUPERSEDES DATE: 28-Jul-2009

SECTIONS CHANGED (US SUBFORMAT): New SDS
SIGNIFICANT CHANGES (US SUBFORMAT): New regional format, OEB