SAFETY DATA SHEET



Equisul-SDT® Oral

Item # 10-020

1. SUBSTANCE IDENTITY/COMPANY CONTACT INFORMATION

PRODUCT NAME: EQUISUL-SDT® Oral;

Trimethoprim and Sulfadiazine Oral suspension for

Horses

MOLECULAR FORMULA: Mixture CHEMICAL FAMILY: Antibiotic

USE: For us in Horses only

SUPPLIER:

Aurora Pharmaceutical, LLC 1196 South Highway 3 Northfield, MN 55057

TELEPHONE NUMBERS:

Emergency (Chemtrec 24 hours): (800) 424-9300

Information: (888) 215-1256

2. HAZARDS IDENTIFICATION

CARCINOGENIC STATUS: Ingredients are not considered carcinogenic by NTP, IARC, or OSHA.

PRIMARY ROUTE(S) OF EXPOSURE: Skin contact, eye contact, inhalation, and ingestion.

EFFECTS OF EXPOSURE: May cause skin, eye, and mucous membrane irritation and burns (symptoms such as discomfort, redness, tearing, sneezing, and runny nose). May cause allergic skin reactions. Exposure may cause nausea, vomiting, diarrhea, cramps, and colitis.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Hypersensitivity to trimethoprim or sulfadiazine.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of the substances listed below with nonhazardous additions.

INGREDIENT 1

COMMON NAME: Sodium Hydroxide

% BY WEIGHT: 4.58 % **CAS NUMBER:** 01310-73-2

EXPOSURE LIMIT(S): OSHA PEL-TWA: 2 mg/m³; ACGIH TLV-Ceiling: 2 mg/m³

INGREDIENT 2

COMMON NAME: Trimethoprim

% BY WEIGHT: 5.67 % **CAS NUMBER:** 00738-70-5

EXPOSURE LIMIT(S): Not established.

INGREDIENT 3

COMMON NAME: Sulfadiazine % BY WEIGHT: 28.3 %

EXPOSURE LIMIT(S): Not established.

EXPOSURE LIMIT(S) FOR THE MATERIAL:

Not established.

4. FIRST AID MEASURES

EYES: Remove contact lenses, if present. Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. If irritation persists, obtain medical attention.

SKIN: Wash off with soap and water. Take off all contaminated clothing immediately. May cause skin reactions.

INHALATION: Move to fresh air.

INGESTION: Contact a physician or poison control

center.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not applicable (60% water). LOWER EXPLOSION LIMIT (LEL): Not applicable.

UPPER EXPLOSION LIMIT (UEL): Not applicable.

EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.

FIRE FIGHTING PROCEDURES: Wear selfcontained breathing apparatus and full-body protective equipment.

UNUSUAL FIRE OR EXPLOSION HAZARDS: None known.

HAZARDOUS COMBUSTION PRODUCTS:

Carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

ENVIRONMENTAL PRECAUTIONS: Do not let product enter drains. Do not flush into surface water. Do not flush to groundwater and soil.

METHODS FOR CLEANING UP: Absorb the liquid with suitable material, then transfer into a suitable container for disposal.

7. HANDLING AND STORAGE

HANDLING: Use with adequate ventilation. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Launder contaminated clothing before reuse.

STORAGE: Store at room temperature. Store in a dry area away from direct sunlight, heat, and incompatible materials. Protect from freezing and physical damage. Reseal containers immediately

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after use. Store away from food and beverages. Keep out of reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESIPRATORY PROTECTION: Not required. **VENTILATION:** Good general ventilation should

suffice.

HAND PROTECTION: Not normally required.

EYE PROTECTION: Not normally required.

However, care should be taken to avoid accidental

OTHER PROTECTIVE EQUIPMENT: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White to off-white aqueous suspension.

Odor: Apple pH: 10.1

Flash Point: NA, 60% water Auto ignition Temperature: NA Boiling Point/Range: NA Melting Point/Range: NA Flammability (solid, gas): NA Upper/Lower Flammability: NA

Vapor Pressure: NA Vapor Density: NA Specific Gravity: 1.17

Water Solubility: Slightly soluble

Reactivity in Water: NA

Decomposition Temperature: NA

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.

PHYSICAL CONDITIONS TO AVOID: Heat - high temperature.

INCOMPATIBILITY WITH OTHER

MATERIALS: Will react with sodium and lithium metals and acids

HAZARDOUS DECOMPOSITION PRODUCTS:
No data

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Trimethoprim

LD₅₀ Oral rat >5300mg/kg LD₅₀ Oral mouse: 2764mg/kg

Sulfadiazine

LD₅₀ Oral Mouse: 1500mg/kg

CHRONIC TOXICITY:

In animal studies the main toxic effects of trimethoprim were on the hematopoietic system. Administration of sulfadiazine caused nephrotoxic and endocrine effects in animal studies.

GENOTOXICITY:

Trimethoprim: Possible mutagen.

Sulfadiazine: No relevant reports identified.

REPRODUCTIVE/DEVELOPMENTAL TOXICITY:

Trimethoprim: Crosses the placenta and is excreted into breast milk. Reported to cause birth defects when administered to rats during pregnancy. Reported to decrease the number of successful pregnancies in rabbits.

Sulfadiazine: Reported to cause birth defects when administered to rats and mice during pregnancy. Reported to decrease the number of successful pregnancies in rats.

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by incineration in accordance with applicable local and national regulations.

14. TRANSPORT REGULATIONS

Not regulated by the United States Department of Transportation (DOT), International Maritime Organization (IMO), or International Air Transport Association (IATA).

15. REGULATORY INFORMATION

Equisul-SDT® Oral is a new animal drug approved by FDA, NADA 141-360 (21CFR 520.2612); therefore it is exempt from the labeling requirements of the OSHA Hazard Communication Standard.

16. OTHER INFORMATION

Revision Date: 07/16/15

The information and recommendations presented in this SDS are based on sources believed to be accurate. Aurora Pharmaceutical, LLC assumes no liability for the accuracy or completeness of this information. It is the user's responsibility to determine the suitability of the information for their particular purposes.