SAFETY DATA SHEET

DectoGard[™]



1. SUBSTANCE IDENTITY/COMPANY CONTACT INFORMATION

PRODUCT NAME: DectoGard[™] MOLECULAR FORMULA: Topical Solution CHEMICAL FAMILY: Anti-parasitic USE: Veterinary use. SUPPLIER:

Aurora Pharmaceutical 1196 South Highway 3 Northfield, MN 55057

TELEPHONE NUMBERS:

Emergency (Chemtrec 24 hours): (800) 424-9300 Information: (888) 215-1256

2. HAZARDS IDENTIFICATION

Signal word: Warning

Pictograms:



HAZARD STATEMENTS

- H255 Highly flammable liquid and vapor
- H303 May be harmful if swallowed
- H336 May cause drowsiness and dizziness
- H319 Causes serious eye irritation
- H361 Suspected of damaging fertility or unborn child
- H362 May cause harm to breast-fed children
- H410 Very toxic to aquatic life with long lasting effects

PRECAUTIONARY STATEMENTS

- P210 Keep away from heat/sparks/open flames/hot surfaces
- P240 Ground container and receiving equipment
- P233 Keep container tightly closed
- P241 Use explosion-proof
- electrical/ventilation/lighting/equipment
- P242 Use only non-sparking tools
- P243 Take precautionary measures against static discharge
- P260 Do not breathe
- dust/fume/gas/mist/vapors/spray
- P264 Wash thoroughly after handling
- P263 Avoid contact during pregnancy/while nursing P270 – Do not eat, drink or smoke when using this
- product
- P271 Use only outdoors or in a well-ventilated area
- P273 Avoid release to the environment
- P280 Wear protective gloves/protective clothing/eye protection/face protection

- P308 + P313 If exposed or concerned: Get medical attention/advice
- P312 Call poison control/doctor/physician if you feel unwell
- P303 + P361 + P353 If on skin or hair: Take off immediately all contaminated clothing, rinse skin with water/shower
- P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, continue rinsing
- P337 + P313 If eye irritation persists: Get medical advice
- P304 + P340 If inhaled: Remove victim to fresh air
- P370 + P378 In case of fire: Use water spray, carbon dioxide, dry chemical, foam for extinction
- P391 Collect spills
- P405 Store locked up
- P401 + P235 Store in a well-ventilated place. Keep cool
- P501 Dispose of contents/container in accordance with all local and national regulations
- **CARCINOGENIC STATUS:** No component of this product is listed as a known carcinogen.
- **EFFECTS OF EXPOSURE:** Breathing high vapor may result in dizziness, light-headedness, headache, nausea, and loss of coordination. Continues inhalation may result in unconsciousness and death.

3. COMPOSITION/INFORMATION OF INGREDIENTS

Mixture of the substances listed in this section.

INGREDIENT 1

COMMON NAME: Isopropyl alcohol % W/V: 60% - 85% CAS Number: 67-63-0

INGREDIENT 2

COMMON NAME: Triethanolamine % W/V: <1% CAS Number: 102-71-6

INGREDIENT 3

COMMON NAME: Doramectin % W/V: 0.5% CAS NUMBER: 138261-41-3

INGREDIENT 4

COMMON NAME: Cetearyl Octanoate CAS NUMBER: 59130-69-7

INGREDIENT 5

COMMON NAME: FD & C Blue No. 1 CAS NUMBER: 3844-45-9

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ADDITIONAL INGREDIENTS

Additional ingredients are considered non-hazardous.

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. Seek medical attention.
- **SKIN:** Remove affected clothing. After contact with skin, wash immediately with soap and water. If skin reaction occurs, obtain medical attention.
- **INHALATION:** Move to fresh air, seek medical attention.
- **INGESTION:** If swallowed, seek medical advice immediately. Wash mouth out with water, do not induce vomiting.

5. FIRE FIGHTING MEASURES

- **EXTINGUISHING MEDIA:** Carbon dioxide, dry chemical, or foam.
- **FIRE FIGHTING PROCEDURES:** Wear selfcontained breathing apparatus and full-body protective equipment. Use spark-proof tools and explosion-proof equipment. Evacuate area and fight fire from safe distance. Collect water used to fight fire.
- **UNUSUAL FIRE OR EXPLOSION HAZARDS:** Flammable liquid and vapor. Vapors will form flammable/explosive mixtures with air at room temperature.

HAZARDOUS COMBUSTION PRODUCTS: Carbon monoxide, carbon dioxide, Nitrogen oxide.

6. ACCIDENTAL RELEASE MEASURES

- **PERSONAL PRECAUTIONS:** Ensure adequate ventilation. Avoid contact with skin, eyes, and clothing. Use personal protective equipment. Eliminate all sources of ignition and use explosionproof equipment.
- **ENVIRONMENTAL PRECAUTIONS:** Do not flush into surface water. Do not flush to groundwater and soil. Place waste in appropriately labeled, sealed container for disposal.
- **METHODS FOR CLEANING UP:** Eliminate possible ignition sources. Absorb spills with non-combustible absorbent material and transfer into a labeled container.

7. HANDLING AND STORAGE

- **HANDLING:** Eliminate possible sources of ignition and follow appropriate grounding and bonding procedures. Use in well-ventilated area. Avoid Breathing vapor or mist. Avoid contact with eyes, skin and clothing. Use appropriate personal protective equipment.
- **STORAGE:** Keep away from heat, sparks, flame, and other sources of ignition. Keep containers closed in a cool, well-ventilated place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Not required under normal conditions of use. VENTILATION: Well ventilated location. HAND PROTECTION: Impervious gloves. EYE PROTECTION: Safety glasses or goggles if eye contact is possible. SKIN: Impervious protective clothing if contact with

SKIN: Impervious protective clothing if contact with drug product is possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear blue liquid Odor: Characteristic pH: Not Determined Flash Point: 14.4°C Auto ignition Temperature: Not Determined Boiling Point/Range: 84°C Melting Point/Range: Not Determined Flammability (solid, gas): Not Determined Vapor Pressure: Not Determined Vapor Density: Not Determined Density: 0.794-0.800 g/mL at 25°C Water Solubility: Not Determined Reactivity in Water: Not Determined Decomposition Temperature: Not Determined

10. STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions.
PHYSICAL CONDITIONS TO AVOID: Eliminate possible ignition sources.
INCOMPATIBILITY WITH OTHER MATERIALS: Strong oxidizers
HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: No data available.

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11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY:

Isopropyl Alcohol: Rat Oral LD50 - > 2000 mg/kg Mouse Oral LD50 - 3600 mg.kg Rat Inhalation LC50/8hr - 16000 ppm Rabbit Dermal LD50 – 12800 mg/kg Rat Inhalation LC50 – 30mg/L

Doramectin:

Rat Male Oral LD50 – 1000-2000 mg/kg Rate Female Oral LD50 – 500-1000 mg/kg

Triethanolamine:

Rat Oral LD50 – 8g/kg Rabbit Dermal LD50 – 20g/kg

CHRONIC TOXICITY:

Isopropyl Alcohol:

20 Weeks Rat Inhalation – 4000 ppm – Liver central nervous system 104 Weeks Rate Inhalation – 5000 ppm - Kidney

Doramectin:

3 Months Rat Oral – 2 mg/kg/day - Liver 3 Months Dog Oral – 0.1 mg/kg/day – Central Nervous System

REPRODUCTIVE/DEVELOPMENTAL TOXICITY:

Isopropyl Alcohol:

Prenatal/Postnatal Development Rat Inhalation – 7000 ppm – Maternal toxicity, Fetotoxicity, Embryotoxicity 2 Generation Reproductive Toxicity Rat Oral – 1000 mg/kg/day – Maternal Toxicity, Fetal mortality Prenatal/Postnatal Development Rat Oral – 1200 mg/kg/day – No effects at maximum dose

Doramectin:

Embryo/Fetal Development Rat Oral - >6 mg/kg/day – Not teratogenic Embryo/Fetal Development Mouse Oral – 3 mg/kg/day – Fetotoxicity, Not Teratogenic Embryo/Fetal Development Rabbit Oral – 0.75 mg/kg/day – Maternal Toxicity, Teratogenic

12. ECOLOGICAL INFORMATION

AQUATIC TOXICITY

Doramectin

Daphnia magna TAD EC50/48hr – 0.00010 mg/L

Lepornis macrochirus TAD LC50/96hr – 0.011 mg/L Oncorhynchus mykiss TAD LC50/96hr – 0.0051 mg/L

Triethanolamine

Brachydanio rerio LC50/96hr – 11800 mg/L Ceriodaphnia dubia EC50/48hr – 610 mg/L Daphnia magna EC50/24hr – 1386 mg/L Daphnia magna NOEC/21 days – 16 mg/L

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Dispose of by applicable local and nation regulations. Do not release into the environment.

14. TRANSPORT REGULATIONS

This material is regulated for transportation as a hazardous material/dangerous good.

UN Number: UN 1219 Proper Shipping Name: Isopropanol solution, Marine Pollutant (Doramectin) Hazard Class: 3 Packing Group: II Environmentally Hazardous: Yes, Marine Pollutant (Doramectin) Flash Point: 14.4°C

DOT

DOT Proper shipping name: Consumer Commodity DOT Hazard Class: ORM-D

International Air transport Association (IATA) IATA UN Number: ID 8000 Proper Shipping Name: Consumer Commodity Hazard Class: 9 Packing Group: NA Limits: Inner packaging <= 500 mL, outer packaging <= 30 kg gross weight

15. REGULATORY INFORMATION

The following components are listed in the United States TSCA (Toxic Substance Control Act)

Isopropyl Alcohol Triethanolamine Cetearyl octanoate FD & C Blue No.1

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16. OTHER INFORMATION

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The information and recommendations presented in this SDS are based on sources believed to be accurate. Aurora Pharmaceutical 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.