

Pfizer

DECTOMAX 1% INJECTABLE SOLUTION (10MG/ML) FOR CATTLE

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

MANUFACTURER: PFIZER INC.

ANIMAL HEALTH GROUP
812 SPRINGDALE DRIVE
EXTON, PA 19341

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HOURS OF OPERATION: 24 Hours

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PRODUCT NAME: DECTOMAX 1% injectable solution (10mg/ml) for cattle

SYNONYMS: B1-Cyclohexyl Avermectin; Doramectin; Avermectin Ala, 25-cyclohexyl-5-O-dimethyl-25-di(1-methylpropyl)-
CHEMICAL FAMILY: Antiparasitic agent belonging to the avermectin class of macrocyclic lactones.

THERAPEUTIC USE: Antiparasitic (veterinary); endectocide
DESCRIPTION: Clear, colorless to pale yellow solution.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient	CAS Number	Amount (%)
Doramectin	117704-25-3	1%
Ethyl Oleate	111-62-6	<25%
Sesame Oil	8008-74-0	>70%

SECTION 3 - HAZARDS IDENTIFICATION

NFPA RATINGS (Scale 0-4)

HEALTH: 2

FIRE: 0

REACTIVITY: 0

SIGNAL WORD: WARNING!

STATEMENTS OF HAZARD:

MAY CAUSE EYE, SKIN AND RESPIRATORY TRACT IRRITATION.
MAY BE HARMFUL IF SWALLOWED
MAY BE A LIVER OR REPRODUCTIVE TOXIN (BASED ON ANIMAL DATA).

EYE:

SHORT TERM EFFECTS: May cause eye irritation

LONG TERM EFFECTS: None known or expected

SKIN:

SHORT TERM EFFECTS: May cause skin irritation.

LONG TERM EFFECTS: None known or expected

INHALATION:

SHORT TERM EFFECTS: May cause irritation of respiratory tract and other mucous membranes.

LONG TERM EFFECTS: Not known.

INGESTION:

SHORT TERM EFFECTS: Although not an expected route of overexposure, accidental ingestion of large amounts may cause nausea, abdominal discomfort, headache or dizziness.

LONG TERM EFFECTS: Chronic exposure to large amounts may cause fetotoxicity based on animal data.

SECTION 4 - FIRST AID MEASURES

EYES: Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention at once.

SKIN: Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.

INHALATION: Remove to fresh air. Get medical attention. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen by qualified personnel.

INGESTION: If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel.

Never give anything by mouth to an unconscious persons.

ANTIDOTE: No data available

NOTE TO PHYSICIANS: Not applicable (NA).

SECTION 5 - FIRE FIGHTING MEASURES

GENERAL HAZARD: Toxic emissions may be given off in a fire. See decomposition products in Section 10-STABILITY AND REACTIVITY.

FIRE FIGHTING INSTRUCTIONS: Wear NIOSH/MSHA approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.

EXTINGUISHER TO USE: Water, carbon dioxide, dry chemical or foam.

HAZARDOUS COMBUSTION: Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen.

FLASH POINT: Not known

AUTOIGNITION: Not known

MINIMUM EXPLOSIVE CONCENTRATION FOR DUST/VAPOR: Not known

FLAMMABILITY LIMITS: Not applicable

SECTION 6 - ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL SPILL: Review Sections 3 and 8 before proceeding with the clean up. Shut off the source of the spill or leak and all electrical equipment if it is safe to do so. Eliminate possible ignition sources. Absorb spills with noncombustible absorbent material. Clean spill area thoroughly.

CLEAN UP - LARGE SPILL: Dike large spills and pump into metal drums or absorb with noncombustible material. Put saturated absorbent material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Clean spill area thoroughly.

REPORTABLE QUANTITY: Not applicable (N/A).

SOIL RELEASE: Studies indicate that when doramectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time.

AIR RELEASE: No data available.

WATER RELEASE: Free doramectin may adversely affect fish and certain waterborne organisms on which they feed.

ADDITIONAL INFORMATION: Do not permit water runoff from feedlots to enter lakes, streams or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

SECTION 7 - HANDLING AND STORAGE

GENERAL HANDLING: Keep away from heat, sparks and flame. Use with adequate ventilation. Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. Avoid breathing vapor or mist. When handling, use proper personal protective equipment specified in Section 8. Wash thoroughly after handling.

STORAGE: Store out of direct sunlight in a cool, well ventilated dry area. Store in light resistant containers. Keep containers tightly closed when not in use.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS:

HAZARDOUS INGREDIENT: Doramectin

OEL: PFIZER

TYPE: TWA

VALUE: 0.2 mg/m3

EXPOSURE INFORMATION: No Short Term Exposure Limit (STEL) has been established.

MEASUREMENT METHOD: DORAMECTIN: CAM-JWT-93-08 (contact Pfizer for additional details).

VENTILATION: Keep airborne contamination levels below the Exposure Limits listed above in this section. General room ventilation is adequate unless the process generates mist or vapor. Do not use in a confined space.

VENTILATION (large scale): See "Ventilation" above.

EYE PROTECTION: Chemical goggles are recommended if eye contact is possible.

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SKIN PROTECTION: Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas.
HAND PROTECTION: Latex gloves are recommended if there is a potential for skin contact.
RESPIRATORY PROTECTION: If the applicable OEL is exceeded, wear an approved respirator sufficient to reduce exposures to below TWA-OEL.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL FORM: Liquid
COLOR: Colorless to pale yellow solution
CLARITY: Clear
ODOR: No data available.
TASTE: No data available.
MOLECULAR WEIGHT: 899.14
MOLECULAR FORMULA: C50H74O14
pH: Not applicable
BOILING POINT: No data
POUR POINT: Not applicable
VAPOR PRESSURE: Not known
WATER SOLUBILITY: Doramectin is insoluble in water.
SOLVENT SOLUBILITY: Doramectin is freely soluble in methylene chloride or methanol and soluble in isopropanol.

SECTION 10 - STABILITY AND REACTIVITY

REACTIVITY: Stable.
CONDITIONS TO AVOID: Direct sunlight, heat, sparks or open flames.
INCOMPATIBILITIES: Incompatible with oxidizing agents, strong acids and strong bases.
HAZARDOUS DECOMPOSITION PRODUCTS: Carbon monoxide, carbon dioxide and oxides of nitrogen.
HAZARDOUS POLYMERIZATION: Will not occur.
OXIDIZING PROPERTIES: No data available.
EXPLOSIVE PROPERTIES: None expected

SECTION 11 - TOXICOLOGY INFORMATION

ACUTE TOXICITY:

Type	Route	Species	Dosage
LD50	Oral	Rat	500 - 2000 mg/kg
LD50	Oral	Rat	50 - 200 mg/kg

EYE: Not determined for this mixture.
SKIN: The acute dermal LD50 (rabbit) for doramectin in sesame oil is reported to be >2 gm/kg.
INHALATION: Not determined for this mixture.
INGESTION: Not determined for this mixture.
MUTAGENICITY: No evidence of mutagenicity was observed for doramectin when tested in vitro and in vivo in the following assays: the Ames test, the mouse lymphoma L5178Y assay and the unscheduled DNA synthesis (UDS) assay in cultures of rat hepatocytes.
ADDITIONAL ACUTE TOXICITY INFORMATION: The acute oral, single-dose toxicity of doramectin in rats, when suspended in 0.1% aqueous methylcellulose solution or sesame oil, is summarized above, respectively.
SUBCHRONIC EFFECTS: Repeat-dose and subchronic oral toxicity studies of doramectin were conducted in rats at doses up to 8 mg/kg for 3 months and in dogs at doses up to 4 mg/kg for 1 month or 2 mg/kg for 3 months. In rats, no evidence of drug-related toxicity other than increased absolute liver weight in high-dose females was seen. In dogs, dose-dependent mydriasis (pronounced or abnormal pupillary dilation) was the primary clinical observation in all treated animals. Decreased food consumption and body weight in all treated animals, but most pronounced at high dose (4 mg/kg/day) were also seen. High-dose males also exhibited tremors, salivation and ataxia; emesis was observed in high-dose females.

CHRONIC TOXICITY: No data available.
CHRONIC EFFECTS/CARCINOGENICITY: No carcinogenic data available. However, the carcinogenic potential of a structurally related avermectin has been investigated in rodents. No evidence of carcinogenicity were seen in these studies.
OSHA CARCINOGEN: No
NTP CARCINOGEN: Not classified
IARC CARCINOGEN: Not classified
REPRODUCTIVE EFFECTS: No reproductive effects were observed in a two-generation oral toxicity study in rats.
TERATOGENICITY: No evidence of drug-related maternal toxicity, embryotoxicity or teratogenicity were seen in mice or rats at doses up to 6 mg/kg. However, increased embryomortality was seen in mice at 6 mg/kg/day. Delayed developmental abnormalities were seen in the rabbit at 1.5 and 3 mg/kg/day. Also, fetotoxicity was seen in the rabbit at a maternally toxic dose 3 mg/kg/day.
TARGET ORGANS: Liver
AT INCREASED RISK FROM EXPOSURE: Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. This material has also been shown to be excreted in breast milk; nursing mothers should exercise caution regarding exposure.
TARGET EFFECTS: No data available.

SECTION 12 - ECOLOGICAL INFORMATION

ENVIRONMENTAL OVERVIEW: Free doramectin may adversely affect fish and certain waterborne organisms on which they feed.
PARTITION COEFFICIENT (N-octanol/water): Not available

SECTION 13 - DISPOSAL INFORMATION

DISPOSAL PROCEDURE: Do not dispose of even small amounts in the sewage system. This material may be disposed in a municipal landfill. Dispose of in accordance with all Federal, State and local regulations.

SECTION 14 - TRANSPORTATION INFORMATION

PROPER SHIPPING NAME: Non-regulated

SECTION 15 - REGULATORY INFORMATION

SUMMARY: Not applicable

SECTION 16 - OTHER

SOURCES OF DATA: 1) Doramectin Experimental Substance MSDS# 0132 by Pfizer Central Research (5/94). 2) Final Occupational Exposure Limit Monograph for Doramectin by Pfizer (11/17/95).
SUMMARY: Not applicable.
DISCLAIMER: Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate. While Pfizer provides this information in good faith, it does not expressly or impliedly warrant its accuracy.

MSDS NO.: 00175-01; DECTOMAX Injectable
CREATION DATE: 7/18/96
VERSION: 1.0

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