

Section 1 - Identification of the Substance/Mixture and Supplier

Cronus Pharma LLC

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(USA)
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Doramectin
Dist. By:
Durvet, Inc.
100 SE
Magellan Dr.
Blue
Springs, MO
64014
800-821-5570

Email: contact@cronuspharma.com

| | |
|-----------------------------|--|
| Product Identifier: | Doramectin Injection 10 mg/mL |
| ANADA Number: | 200750 |
| Other names: | None |
| Chemical family: | Doramectin in an oily base |
| Recommended Use: | Veterinary product used as antiparasitic; endectocide. |
| Restrictions on use: | For veterinary use only |

Section 2 - Hazards Identification

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Specific target organ toxicity: Category 2 (Central nervous system)

Specific target organ Toxicity. Category 2 (Central nervous system, Liver, Kidney)

Short-term (Acute) Aquatic hazard: category

Long-term (chronic) aquatic hazard: category



Hazard pictograms:

Label Elements

Signal Word:

Warning

Hazard Statements:

H361 - Suspected of damaging fertility or the unborn child.

H362 - May cause harm to breast-fed children

H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements: P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P263 - Avoid contact during pregnancy/while nursing

P264 - Wash hands thoroughly after handling.

P270 - Do not eat, drink, or smoke when using this product

P273 - Avoid release to the environment.

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P391 - Collect spillage

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term: May be harmful if swallowed. (based on components). May cause nervous system effects. May cause eye and skin irritation.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. May cause effects on nervous system.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3 - Composition/Information on Ingredients

Hazardous

| Ingredients | CAS No | Conc, % | GHS Classification |
|-------------|-------------|---------|--|
| Doramectin | 117704-25-3 | 1.0% | Acute Tox. 4 (H302) Repr. 2 (H361) Lact (H362) Aq. Acute 1 (H400) Aq. Chronic 1 (H410) |

| Ingredients | CAS No | Conc, % | GHS Classification |
|--------------|-----------|---------|--------------------|
| Sesame oil | 8008-74-0 | Q.s | Not Listed |
| Ethyl oleate | 111-62-6 | 21.5% | Not Listed |

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 4 - First Aid Measures

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions None known

Aggravated by Exposure: Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Section 5 - Fire Fighting Measures

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Contain the source of the spill if it is safe to do so. absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.

Additional Consideration for Non-essential personnel should be evacuated from affected area.

Large Spill: Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7 - Handling and Storage

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Use only in a well-ventilated area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Avoid accidental injections. Wash thoroughly after handling. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

| | |
|-----------------------------|--|
| Storage Conditions: | Store as directed by product packaging. |
| Storage Temperature: | < 30 °C |
| Specific end use(s): | Veterinary Antiparasitic (veterinary); endectocide |

Section 8 - Exposure Controls and Personal Protection**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

Doramectin

OEL TWA 8-hr 200µg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposure. General room ventilation is adequate unless the process generates dust, mist, or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9 - Physical and Chemical Properties:

| | | | |
|---------------------------|-------------------|--------------------------|---------------------------|
| Physical State: | Liquid (Viscous) | Color: | A Clear pale-yellow color |
| Odor: | No data available | Odor Threshold: | No data available |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

Solvent Solubility: Highly soluble: Polar organic solvents

Water Solubility: No data available

Solubility: Insoluble: Water

pH: Between 5.0 and 8.0

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available

Partition Coefficient: (Method, pH, Endpoint, Value) Doramectin Measured

Log P 4.4

Decomposition Temperature (°C): No data available

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

SAFETY DATA SHEET

Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

Section 10 - Stability and Reactivity

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mist) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Thermal decomposition products may include carbon
monoxide, Products: carbon dioxide and other toxic vapors.

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Doramectin

Rat (M) Oral LD50 1000-2000
 mg/kg Rat (F) Oral LD50
 500-1000mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Doramectin

Eye Irritation Rabbit Non-irritating
 Skin Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Doramectin

3 Month(s) Rat Oral 2 mg/kg/day NOEL Liver
 3 Month(s) Dog Oral 0.1 mg/kg/day NOEL Central Nervous
 System,

Chronic Effects/Carcinogenicity No carcinogenic data available. However, the carcinogenic potential of a structurally related avermectin, abamectin, has been investigated in rodents. No evidence of carcinogenicity was seen in these studies.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Doramectin

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

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Doramectin

Bacterial Mutagenicity (Ames) *Salmonella* Negative
 Mammalian Cell Mutagenicity Mouse Lymphoma

DNA Synthesis

Negative Unscheduled
Rat Hepatocyte Negative**Carcinogen Status:**

by IARC, NTP or OSHA.

None of the components of this formulation are listed as a carcinogen

Product Level Toxicity Data**Acute Toxicity Estimate (ATE), oral:** >5000 mg/kg**Section 12 - Ecological Information**

Environmental Overview: Releases to the environment should be avoided. As with other members of the avermectin family, doramectin is highly toxic to fish and certain aquatic organisms. However, once in contact with soil, it is tightly bound and does not readily absorb. It is unlikely to reach groundwater and is also biodegradable by soil microflora.

Toxicity:**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)****Doramectin**

| | | | | |
|---|-----|------|----------|--------------|
| <i>Daphnia magna</i> (Water Flea) | TAD | EC50 | 48 Hours | 0.00010 mg/L |
| <i>Lepomis macrochirus</i> (Bluegill Sunfish) | TAD | LC50 | 96 Hours | 0.011 mg/L |
| <i>Oncorhynchus mykiss</i> (Rainbow Trout) | TAD | LC50 | 96 Hours | 0.0051 mg/L |

Bacterial Inhibition: (Inoculum, Method, End Point, Result)**Doramectin**

| | | | |
|--|-----|-----|----------|
| <i>Aspergillus niger</i> (Fungus) | TAD | MIC | 600 mg/L |
| <i>Clostridium perfringens</i> (Bacterium) | TAD | MIC | 40 mg/L |

Persistence and Degradability: No data available**Bio-accumulative Potential:****Doramectin**

Measured Log P 4.4

Mobility in Soil: No data available**Section 13 - Disposal Considerations**

Disposal: Special help is available for the disposal of Agricultural Chemicals. The product label will give general advice regarding disposal of small quantities, and how to cleanse containers. However, for help with the collection of unwanted rural chemicals, contact Chem Clear 1800 008 182 <http://www.chemclear.com.au/> and for help with the disposal of empty drums, contact Drum Muster <http://www.drummuster.com.au/> where you will find contact details for your area.

Section 14 - Transport Information**ADG:** Not regulated for transportation due to Special Provision AU01

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packaging's containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to IATA or IMDG transport regulations provided the general

packaging requirements of those regulations are met.

UN number: UN 3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Doramectin)

Transport hazard class(es): 9

Packing group: III

Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

Section 15 - Regulatory Information

Canadian regulations: This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act: Not regulated.

Export Control List (CEPA 1999, Schedule 3): Not listed.

Greenhouse Gases: Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Phenol (CAS 108-95-2)

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories:

| Country(s) or region | Inventory name |
|-----------------------------|---|
| Canada | Domestic Substances List (DSL) |
| Canada | Non-Domestic Substances List (NDSL) |
| China | Inventory of Existing Chemical Substances in China (IECSC) |
| Europe | European Inventory of Existing Commercial Chemical No Substances (EINECS) |
| Europe | European List of Notified Chemical Substances (ELINCS) |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) |
| Korea | Existing Chemicals List (ECL) |
| New Zealand | New Zealand Inventory |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances No (PICCS) |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory |

Section 16 - Other Information

This SDS contains only safety-related information. For other data see product literature.

Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from published literature.

Acronyms:

| | |
|---------------------|---|
| CAS number | Chemical Abstracts Service Registry Number |
| Hazchem Code | Emergency action code of numbers and letters that provide information to emergency services, especially firefighters. |
| IARC | International Agency for Research on Cancer |
| NOS | Not otherwise specified. |
| NTP | National Toxicology Program (USA) |
| SUSMP | Standard for the Uniform Scheduling of Medicines & Poisons |
| UN Number | United Nations Number |

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Supersedes: NA

Revision History:

| Date of Revision | Reason |
|------------------|--------|
| NA | NA |