

**Doramectin Formulation**

Version 4.8      Revision Date: 30.09.2023      SDS Number: 5191213-00012      Date of last issue: 04.04.2023  
Date of first issue: 22.10.2019

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**SECTION 1. IDENTIFICATION**

Product name : Doramectin Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

Restrictions on use : Not applicable

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Acute toxicity (Oral) : Category 5

Reproductive toxicity : Category 1B

Specific target organ toxicity - : Category 2 (Central nervous system)  
single exposure (Oral)

Specific target organ toxicity - : Category 2 (Central nervous system, Liver, Kidney)  
repeated exposure (Oral)

Short-term (acute) aquatic : Category 1  
hazard

Long-term (chronic) aquatic : Category 1  
hazard

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.

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H360D May damage the unborn child.  
 H371 May cause damage to organs (Central nervous system) if swallowed.  
 H373 May cause damage to organs (Central nervous system, Liver, Kidney) through prolonged or repeated exposure if swallowed.  
 H410 Very toxic to aquatic life with long lasting effects.

## Precautionary Statements

:

**Prevention:**

P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe mist or vapors.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.  
 P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Doramectin	117704-25-3	>= 1 -< 2,5

**SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
 Remove contaminated clothing and shoes.

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		Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution.
		Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting.
		Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	:	May be harmful if swallowed. May damage the unborn child. May cause damage to organs if swallowed. May cause damage to organs through prolonged or repeated exposure if swallowed.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

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**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so.
Special protective equipment for fire-fighters	:	Evacuate area. In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
 Clean up remaining materials from spill with suitable absorbent.  
 Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
 Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
 Do not breathe mist or vapors.  
 Do not swallow.  
 Avoid contact with eyes.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Doramectin	117704-25-3	TWA	25 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	250 µg/100 cm <sup>2</sup>	Internal

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**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : oily

Color : light yellow

Odor : characteristic

Odor Threshold : No data available



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Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

May be harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 5.000 mg/kg  
Method: Calculation method

**Components:****Doramectin:**

Acute oral toxicity : LD50 (Rat): 500 mg/kg  
Target Organs: Central nervous system

LD50 (Mouse): > 2.000 mg/kg  
Target Organs: Central nervous system

LD50 (Rat): 50 mg/kg  
Target Organs: Central nervous system

LD50 (Mouse): 75 mg/kg  
Target Organs: Central nervous system

Acute toxicity (other routes of administration) : LD50 (Rat): > 300 mg/kg  
Application Route: Intraperitoneal  
Target Organs: Central nervous system

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

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**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Doramectin:**

Genotoxicity in vitro	:	Test Type: Ames test Result: negative  Test Type: Mouse Lymphoma Result: negative  Test Type: unscheduled DNA synthesis assay Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Result: negative
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**

Not classified based on available information.

**Components:****Doramectin:**

Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen
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**Reproductive toxicity**

May damage the unborn child.

**Components:****Doramectin:**

Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Oral Embryo-fetal toxicity.: NOAEL: 0,3 mg/kg body weight Symptoms: Reduced body weight  Test Type: Embryo-fetal development Species: Mouse Application Route: Oral Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight Symptoms: Embryo-lethal effects.  Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral General Toxicity Maternal: NOAEL: 0,75 mg/kg body weight Symptoms: Maternal effects., Embryotoxic effects.
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Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**

May cause damage to organs (Central nervous system) if swallowed.

**Components:****Doramectin:**

Routes of exposure : Oral  
 Target Organs : Central nervous system  
 Assessment : Shown to produce significant health effects in animals at concentrations of 300 mg/kg bw or less.

**STOT-repeated exposure**

May cause damage to organs (Central nervous system, Liver, Kidney) through prolonged or repeated exposure if swallowed.

**Components:****Doramectin:**

Routes of exposure : Oral  
 Target Organs : Central nervous system, Liver, Kidney  
 Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

**Repeated dose toxicity****Components:****Doramectin:**

Species : Rat  
 LOAEL : 30 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Target Organs : Central nervous system

Species : Rat  
 NOAEL : 2 mg/kg  
 Application Route : Oral  
 Exposure time : 3 Months  
 Target Organs : Central nervous system, Liver, Kidney

Species : Dog  
 NOAEL : 2 mg/kg  
 Application Route : Oral  
 Exposure time : 36 d  
 Target Organs : Eye  
 Symptoms : Dilatation of the pupil

Species : Dog  
 NOAEL : 0,1 mg/kg  
 Application Route : Oral  
 Exposure time : 92 d

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Target Organs : Central nervous system, Eye  
Symptoms : Dilatation of the pupil

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Doramectin:**

Skin contact	:	Target Organs: Gastro-intestinal system Symptoms: Nausea, Diarrhea Target Organs: Central nervous system Symptoms: Dizziness, Headache Target Organs: Eye Symptoms: Irritation Target Organs: Skin Symptoms: Irritation Target Organs: Respiratory system Symptoms: Breathing difficulties
Ingestion	:	Target Organs: Gastro-intestinal system Symptoms: Nausea, Abdominal pain, Diarrhea Target Organs: Central nervous system Symptoms: Dizziness

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Doramectin:**

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 11 µg/l Exposure time: 96 h Method: OECD Test Guideline 203  LC50 (Oncorhynchus mykiss (rainbow trout)): 5,1 µg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,1 µg/l Exposure time: 48 h Method: OECD Test Guideline 202
M-Factor (Chronic aquatic toxicity)	:	10.000

**Ecotoxicology Assessment**

Acute aquatic toxicity : Very toxic to aquatic life.

**Persistence and degradability**

No data available

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**Bioaccumulative potential****Components:****Doramectin:**

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)  
Bioconcentration factor (BCF): 71  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,5  
pH: 7

**Mobility in soil****Components:****Doramectin:**

Distribution among environmental compartments : log Koc: 4,94

**Other adverse effects****Components:****Doramectin:**

Results of PBT and vPvB assessment : This substance is not considered to be very persistent and very bioaccumulating (vPvB).

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Doramectin)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

**IATA-DGR**

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

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(Doramectin)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

**IMDG-Code**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Doramectin)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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**SECTION 15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION**

Revision Date : 30.09.2023  
Date format : dd.mm.yyyy

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### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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