

# **Doramectin Formulation**

Version SDS Number: Date of last issue: 24.02.2025 **Revision Date:** 5191219-00016 8.0 14.04.2025 Date of first issue: 22.10.2019

**Section 1: Identification** 

Product name **Doramectin Formulation** 

Manufacturer or supplier's details

Company : MSD

Address 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

0800 800 543 Telephone

0800 764 766 (0800 POISON) Emergency telephone number: 0800 243 622 (0800

CHEMCALL)

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

Section 2: Hazard identification

**GHS Classification** 

Reproductive toxicity : Category 1

single exposure (Oral)

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

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Central nervous system, Liver, Kidney)

Hazardous to the aquatic

environment - acute hazard

Category 1

Hazardous to the aquatic

environment - chronic hazard

Category 1

**GHS** label elements

Hazard pictograms

Signal word

Hazard statements H360D May damage the unborn child.



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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 swal-

lowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

### Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe mist or vapours. 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 protec-

tion/ 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 ad-

vice 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.

Get medical attention.



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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

and effects, both acut delayed

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.

#### Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.
Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Hazchem Code : 3Z

#### Section 6: Accidental release measures

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.



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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.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbant

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 deter-

mine 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 vapours.

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 as-

sessment

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.

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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

Keep tightly closed.





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Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Doramectin	117704-25-3	TWA	35 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	350 µg/100 cm2	Internal	

**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 con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### Section 9: Physical and chemical properties



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Appearance : oily

Colour : light yellow

Odour : characteristic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : -7 °C

Initial boiling point and boiling

range

270 °C

Flash point : 215.7 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : 0.89 - 91

Density : No data available

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : 31.7 - 32.1 m2/s (25 °C)

Explosive properties : Not explosive



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Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size Not applicable

Section 10: Stability and reactivity

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

None known. Conditions to avoid Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### **Section 11: Toxicological information**

Exposure routes Inhalation

> Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute toxicity estimate: > 2,000 mg/kg Acute oral toxicity

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



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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Chronic toxicity** 

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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

May damage the unborn child.



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#### **Components:**

#### **Doramectin:**

Effects on foetal develop- : Test

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 0.3 mg/kg body weight

Symptoms: Reduced body weight

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Oral

Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight

Symptoms: Embryolethal effects

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: NOAEL: 0.75 mg/kg body weight

Symptoms: Maternal effects, Embryotoxic effects.

Reproductive toxicity - As-

sessment

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:**

Exposure routes : Oral

Target Organs : Central nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations 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:**

Exposure routes : Oral

Target Organs : Central nervous system, Liver, Kidney

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

### Repeated dose toxicity

### **Components:**

#### **Doramectin:**



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Species Rat 30 mg/kg LOAEL Application Route Exposure time 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 36 d Exposure time Target Organs : Eye

Symptoms Dilatation of the pupil

Species Dog NOAEL : 0.1 mg/kg Application Route Oral Exposure time 92 d

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:** 

: Target Organs: Gastro-intestinal system Skin contact

Symptoms: Nausea, Diarrhoea

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

Target Organs: Gastro-intestinal system Ingestion

Symptoms: Nausea, Abdominal pain, Diarrhoea

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

#### 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 environ- : log Koc: 4.94

mental compartments



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#### Other adverse effects

# **Components:**

**Doramectin:** 

Results of PBT and vPvB

assessment

Substance is not very persistent and very bioaccumulative

(vPvB).

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **Section 14: Transport information**

### **International Regulations**

**UNRTDG** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Doramectin)

Class 9 Ш Packing group Labels 9 Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Doramectin)

964

yes

Class Packing group Ш

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

964

Environmentally hazardous

**IMDG-Code** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Doramectin)

Class 9 Packing group Ш Labels 9



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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.

### **National Regulations**

**NZS 5433** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Doramectin)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : no

#### 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.

#### **Section 15: Regulatory information**

# Safety, health and environmental regulations/legislation specific for the substance or mixture

#### **HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

#### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

# The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

### **Section 16: Other information**



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**Further information** 

Sources of key data used to compile the Safety Data

Sheet

: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - 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



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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.

NZ / EN