according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

**Revision Date:** Date of last issue: 04.04.2023 Version SDS Number: 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Ivermectin (3.5%) Formulation Product name

Manufacturer or supplier's details

Company : MSD

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Veterinary product Recommended use Restrictions on use Not applicable

## 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Acute toxicity (Oral) : Category 4

Specific target organ toxicity - :

single exposure (Oral)

Category 2 (Central nervous system)

repeated exposure (Oral)

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

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms







according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4698078-00017 Date of first issue: 29.07.2019

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

H371 May cause damage to organs (Central nervous system) if

swallowed.

H373 May cause damage to organs (Central nervous system)

through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P260 Do not breathe vapours.

P264 Wash skin thoroughly after handling.

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

P273 Avoid release to the environment.

Response:

P301 + P317 + P330 IF SWALLOWED: Get medical help.

Rinse mouth.

P308 + P316 IF exposed or concerned: Get emergency medi-

cal help immediately. P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### **Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 1.42 %

### Other hazards which do not result in classification

None known.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (%
		w/w)
Ivermectin	70288-86-7	>= 2.5 - < 5
Aluminum tristearate	637-12-7	>= 1 - < 5
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.25 - < 1

## 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.

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

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 unless directed to do

so by medical personnel. 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 acu delayed

Harmful if swallowed.

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.

#### 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

Exposure to combustion products may be a hazard to health.

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.

### **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.

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.

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

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 absor-

bent.

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.

#### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling

Do not breathe vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

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

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 labelled containers.

Store locked up.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	300 μg/100 cm2	Internal	
Aluminum tristearate	637-12-7	TWA (Inhal-	10 mg/m3	ACGIH	
		able particu-			
		late matter)			
		TWA (Res-	3 mg/m3	ACGIH	
		pirable par-			
		ticulate mat-			

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

		ter)		
		TWA (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ACGIH
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m3	ACGIH

**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 contain-

ment 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. Combined particulates and organic vapour type

Filter 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.

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : gel

Colour : off-white

Odour : characteristic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

170 °C

Flash point : 237.2 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

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 : 0.93 - 0.95

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, dynamic : 382 - 384 mPa.s (25 °C)

Viscosity, kinematic : No data available

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,511 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

**Components:** 

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

LD50 (Rat): > 660 mg/kg

Aluminum tristearate:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit

Result : No skin irritation

Aluminum tristearate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Ivermectin:

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

Species : Rabbit

Result : Mild eye irritation

**Aluminum tristearate:** 

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

### **Components:**

### Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

## **Components:**

Ivermectin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Aluminum tristearate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Ivermectin:

Species : Rat

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4698078-00017 Date of first issue: 29.07.2019

Application Route : Oral

NOAEL : 1.5 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

Species : Mouse Application Route : Oral

NOAEL : 2.0 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 0.2 mg/kg body weight Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 0.4 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Development

Species: Rabbit Application Route: Oral

Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

toxic doses

Aluminum tristearate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

## STOT - single exposure

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

#### **Components:**

Ivermectin:

Target Organs : Central nervous system Assessment : Causes damage to organs.

### STOT - repeated exposure

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

## **Components:**

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4698078-00017 Date of first issue: 29.07.2019

## Repeated dose toxicity

## **Components:**

#### Ivermectin:

Species : Dog
NOAEL : 0.5 mg/kg
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Target Organs : Central nervous system

Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey
NOAEL : 1.2 mg/kg
Application Route : Oral
Exposure time : 2 Weeks

Remarks : No significant adverse effects were reported

Species : Rat

NOAEL : 0.4 mg/kg

LOAEL : 0.8 mg/kg

Application Route : Oral

Exposure time : 3 Months

Target Organs : spleen, Bone marrow, Kidney

### Aluminum tristearate:

Species : Rat

NOAEL : >= 5,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

#### 2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

## **Aspiration toxicity**

Not classified based on available information.

# Experience with human exposure

## **Components:**

#### Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, anorexia, Lack of coordination

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 4.2
 30.09.2023
 4698078-00017
 Date of first issue: 29.07.2019

#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

## Components:

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10,000

M-Factor (Chronic aquatic

toxicity)

10,000

## Aluminum tristearate:

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.48 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 ( Pseudokirchneriella subcapitata (green algae)): >

0.24 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

1

Toxicity to microorganisms : EC50: > 10,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.053 mg/l

Exposure time: 30 d

Species: Oryzias latipes (Japanese medaka)

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.316 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic

toxicity)

1

### Persistence and degradability

### **Components:**

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4.5 % Exposure time: 28 d

Method: OECD Test Guideline 301C

### **Bioaccumulative potential**

## **Components:**

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

log Pow: 3.22

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

**Revision Date:** Version SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-

octanol/water

log Pow: 5.1

Mobility in soil

No data available

Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

### **International Regulations**

**UNRTDG** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

Class 9 Packing group Ш Labels Environmentally hazardous yes

**IATA-DGR** 

UN/ID No. UN 3082

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

(Ivermectin)

Class 9 Packing group Ш

Labels Miscellaneous

Packing instruction (cargo 964

aircraft)

Packing instruction (passen-964

ger aircraft)

Environmentally hazardous

yes

**IMDG-Code** 

**UN** number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Ivermectin)

Class 9 Packing group Ш Labels

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

**EmS Code** F-A, S-F yes Marine pollutant

## Transport in bulk according to IMO instruments

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.

#### 15. REGULATORY INFORMATION

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

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

**AICS** not determined

DSL not determined

**IECSC** not determined

#### 16. OTHER INFORMATION

**Revision Date** 30.09.2023

**Further information** 

Sources of key data used to

compile the Safety Data

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

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

Date format dd.mm.yyyy

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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 Or-

according to the Globally Harmonized System



# Ivermectin (3.5%) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 4.2 30.09.2023 4698078-00017 Date of first issue: 29.07.2019

ganisation 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.

IN / EN