SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ivermectin (3.5%) 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
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Specific target organ toxicity - single exposure (Oral): Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Central nervous system)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: ![Hazard Pictograms]

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 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.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
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.

Additional Labeling:
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 2.5 - &lt; 5</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>

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 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 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.

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 products:
Carbon oxides
Metal 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.
Evacuate area.

Special protective equipment for fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
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 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 : Use only with adequate ventilation.
Advice on safe handling : Avoid inhalation of vapor or mist.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure
assessment
Take care to prevent spills, waste and minimize release to the
environment.

Conditions for safe storage : Keep in properly labeled 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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information: Skin
Wipe limit: 0.5 mg/100 cm² Internal

Further information: A4 - Not classifiable as a human carcinogen:
Agents which cause concern that they could be carcinogenic for
humans but which cannot be assessed conclusively because of a
lack of data. In vitro or animal studies do not provide indications of
carcinogenicity which are sufficient to classify the agent into one
of the other categories., Irritation

<table>
<thead>
<tr>
<th>TWA (Respirable fraction)</th>
<th>1 mg/m³ (Aluminum)</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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Ivermectin (3.5%) Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>Solubility</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>CMP</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

Further information: Vapour and aerosol, A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. In vitro or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories.

Irritation

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 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: Combined particulates and organic vapor type

Hand protection

Material: Chemical-resistant gloves

Remarks

Consider double gloving.

Eye protection

Wear safety glasses with side shields or 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: gel
Color: off-white
Odor: characteristic
Odor 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): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: No data available
Relative vapor density: No data available
Relative density: 0,93 - 0,95
Density: No data available
Solubility(ies)
  Water solubility: practically insoluble
Partition coefficient: n-
SAFETY DATA SHEET

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 octanol/water
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : 382 - 384 mPa.s (25 °C)
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
                                      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
**Safe Data Sheet**

Ivermectin (3.5%) Formulation

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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

**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:**
Method: OECD Test Guideline 439  
Result: No skin irritation  
Remarks: Based on data from similar materials

**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:**
- **Species:** Rabbit
- **Result:** Mild eye irritation

**Aluminum tristearate:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405
- **Remarks:** Based on data from similar materials

**2,6-Di-tert-butyl-p-cresol:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405
- **Remarks:** Based on data from similar materials

### Respiratory or skin sensitization

#### Skin sensitization
Not classified based on available information.

#### Respiratory sensitization
Not classified based on available information.

#### Components:

**Ivermectin:**
- **Routes of exposure:** Dermal
- **Species:** Humans
- **Result:** Does not cause skin sensitization.

**Aluminum tristearate:**
- **Test Type:** Local lymph node assay (LLNA)
- **Routes of exposure:** 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)
- **Routes of exposure:** 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)
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Test system: human diploid fibroblasts
  Result: negative
- Test Type: Mouse Lymphoma
  Result: negative

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

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)
  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
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 fetal development: 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 offspring were detected.
Remarks: The mechanism or mode of action may not be relevant 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 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 fetal development: 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 fetal development: Test Type: Embryo-fetal 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 concentrations of 100 mg/kg bw or less.
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:** $\geq 5.000$ 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, Vomiting, anorexia, Lack of coordination
SECTION 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 toxicity):
- 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

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
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
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**Ivermectin (3.5%) Formulation**

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Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1  
Toxicity to fish (Chronic toxicity): NOEC (Oryzias latipes (Japanese medaka)): 0,053 mg/l  
Exposure time: 30 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0,316 mg/l  
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity): 1  
Toxicity to microorganisms: EC50: > 10.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

### 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)  
Bioconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-octanol/water: log Pow: 5,1

**Mobility in soil**

No data available
SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
Class : 9
Packing group : III
Labels : 9

IATA-DGR

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

International Regulations

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)

AR OEL: Argentina. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average

AR OEL / CMP: TLV (Threshold Limit Value)

AICS - Australian Inventory of Chemical Substances; 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;
SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Version 2.1
Revision Date: 08/19/2019
SDS Number: 4698076-00002
Date of last issue: 29.07.2019
Date of first issue: 29.07.2019

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; 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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