SAFETY DATA SHEET

Ivermectin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Acute toxicity (Oral) : Category 5
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 in accordance with ABNT NBR 14725 Standard
Hazard pictograms : ⚠️ ⚠️
Signal Word : Warning
Hazard Statements :
H303 May be 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:**
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.

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

**Storage:**
P405 Store locked up.

Other hazards which do not result in classification
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Substances / Mixtures
Mixture

#### Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>Acute toxicity (Oral), Category 2 Acute toxicity (Dermal), Category 3 Specific target organ toxicity - single exposure (Oral) (Central nervous system), Category 1 Specific target organ toxicity - repeated exposure (Oral) (Central nervous system), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>
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: May be 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

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 (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.

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:
- Do not breathe mist or vapors.
- 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 assessment.
- 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 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/PERS...
### Appearance
- oily

### Color
- light yellow

### Odor
- characteristic

### Odor Threshold
- No data available

### pH
- No data available

### Melting point/freezing point
- No data available

### Initial boiling point and boiling range
- 167.5 °C

### Flash point
- 219.2 °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
- 0.88 - 0.92

### Density
- No data available

### Solubility(ies)
- Water solubility: practically insoluble

### Partition coefficient: n-octanol/water
- Not applicable

### Autoignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity
- Viscosity, kinematic: No data available

### Explosive properties
- Not explosive

### Oxidizing properties
- The substance or mixture is not classified as oxidizing.
### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>Not classified as a reactivity hazard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 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
- **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
- **Acute dermal toxicity:**
  - LD50 (Rabbit): 406 mg/kg
  - LD50 (Rat): > 660 mg/kg

#### 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

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

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.
SAFETY DATA SHEET

Ivermectin Formulation

Version: 2.1  
Revision Date: 27.08.2021  
SDS Number: 6097533-00003  
Date of last issue: 04.11.2020

Date of first issue: 30.06.2020

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

Genotoxicity in vivo:
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

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

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

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

Test Type: Chromosome aberration test in vitro
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

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
SAFETY DATA SHEET

Ivermectin Formulation

**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)): 0,00025 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

**2,6-Di-tert-butyl-p-cresol:**
- **Toxicity to fish:** LC50 (Danio rerio (zebra fish)): > 0,57 mg/l Exposure time: 96 h
SAFETY DATA SHEET

Ivermectin Formulation


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
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- log Pow: 3.22
octanol/water

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

Bioaccumulation: Species: Cyprinus carpio (Carp)
Biocenconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-octanol/water

Mobility in soil

No data available

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.
(Ivermectin, 2,6-Di-tert-butyl-p-cresol)

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

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

Class: 9
Packing group: III
 SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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)
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.