SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Ivermectin (3.5%) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             20 Spartan Road
             1619 Spartan, South Africa
   Telephone : +27119239300
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
   Acute toxicity, Category 4 : H302: Harmful if swallowed.
   Specific target organ toxicity - single exposure, Category 2 : H371: May cause damage to organs.
   Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Warning
   Hazard statements : H302 Harmful if swallowed.
                     H371 May cause damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.
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:**
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.

Hazardous components which must be listed on the label:
Ivermectin

**Additional Labelling**
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 1,42 %

**2.3 Other hazards**
None known.

---

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>EC-No. Index-No.</td>
<td>Registration number</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td>&gt;= 2,5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Classification</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute Tox.2; H300 Acute Tox.3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE1; H370 STOT RE1; H372 Aquatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute1; H400 Aquatic Chronic1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.000 M-Factor (Chronic aquatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>toxicity): 10.000</td>
<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>204-881-4</td>
<td>&gt;= 0,25 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute1; H400 Aquatic Chronic1;</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>H410</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Harmful if swallowed. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical
SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Version: 2.1
Revision Date: 23.03.2020
SDS Number: 4698085-00003
Date of last issue: 19.08.2019
Date of first issue: 29.07.2019

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Metal oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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 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.
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 vapour 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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></td>
<td>TWA</td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-</td>
<td>128-37-0</td>
<td>TWA OEL-RL</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>
Further information: Recommended Limit

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerides, mixed decanoyl and octanoyl</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>177,79 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>25,21 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>43,84 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>12,61 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>12,61 mg/kg bw/day</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3,5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0,5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0,86 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0,25 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0,25 mg/kg bw/day</td>
</tr>
</tbody>
</table>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerides, mixed decanoyl and octanoyl</td>
<td>Oral (Secondary Poisoning)</td>
<td>0,03 mg/kg food</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water</td>
<td>0,199 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0,02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>0,17 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0,0996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,00996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,04769 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>8,33 mg/kg food</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**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**

- **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.

- **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 vapour type (A-P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic 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
- **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

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

9.2 Other information
Flammability (liquids) : Not applicable
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects
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: > 2.000 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:
**SAFETY DATA SHEET**

**Ivermectin (3.5%) Formulation**

**Version** 2.1  
**Revision Date**: 23.03.2020  
**SDS Number**: 4698085-00003  
**Date of last issue**: 19.08.2019  
**Date of first issue**: 29.07.2019

**Species**: Rabbit  
**Result**: No skin irritation

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**

Not classified based on available information.

---

**Components**:

**Ivermectin**:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

---

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

---

**Components**:

**Ivermectin**:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>Does not cause skin sensitisation.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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

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 foetal 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 foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

STOT - single exposure
May cause damage to organs.

Components:

Ivermectin:

Target Organs: Central nervous system
Assessment: Causes damage to organs.
STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

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

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:
**SAFETY DATA SHEET**

**Ivermectin (3.5%) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>23.03.2020</td>
<td>4698085-00003</td>
<td>19.08.2019</td>
<td>29.07.2019</td>
</tr>
</tbody>
</table>

**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

#### 12.1 Toxicity

**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

**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
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms: EC50: > 10,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity): 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 (Chronic toxicity): NOEC: 0,316 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity): 1

12.2 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

12.3 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

12.4 Mobility in soil
No data available
SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Version 2.1
Revision Date: 23.03.2020
SDS Number: 4698085-00003
Date of last issue: 19.08.2019
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12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
ADN: UN 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
IATA: UN 3082

14.2 UN proper shipping name
ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)
IATA: Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)

14.3 Transport hazard class(es)
ADN: 9
ADR: 9
RID: 9
14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes
Ivermectin (3.5%) Formulation

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H370 : Causes damage to organs if swallowed.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous...
SAFETY DATA SHEET

Ivermectin (3.5%) Formulation

Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
- Acute Tox. 4 H302 Calculation method
- STOT SE 2 H371 Calculation method
- STOT RE 2 H373 Calculation method
- Aquatic Acute 1 H400 Calculation method
- Aquatic Chronic 1 H410 Calculation method

Further information:

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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