SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin (with Propylene Glycol) 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
Telefax : 908-735-1496

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
Flammable liquids : Category 2
Acute toxicity (Oral) : Category 5
Eye irritation : Category 2A
Specific target organ toxicity - single exposure (Oral) : Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Central nervous system)
Aspiration hazard : Category 2
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:

- Flame
- Person Silhouette
- Exclamation Mark
- Tinted Diamond

Signal Word: Danger

Hazard Statements:
- H225 Highly flammable liquid and vapor.
- H303 May be harmful if swallowed.
- H305 May be harmful if swallowed and enters airways.
- H319 Causes serious eye irritation.
- 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:
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
- P233 Keep container tightly closed.
- P273 Avoid release to the environment.

Response:
- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P331 Do NOT induce vomiting.
- P391 Collect spillage.

Other hazards which do not result in classification:
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : 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>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>Flammable liquids, Category 4, Eye irritation, Category 2A</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>Flammable liquids, Category 2, Acute toxicity (Oral), Category 5, Eye irritation, Category 2A, Specific target organ toxicity - single expo-</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute toxicity (Oral), Category 2</th>
<th>Acute toxicity (Dermal), Category 3</th>
<th>Specific target organ toxicity - single exposure (Oral) (Central nervous system), Category 1</th>
<th>Specific target organ toxicity - repeated exposure (Oral) (Central nervous system), Category 1</th>
<th>Short-term (acute) aquatic hazard, Category 1</th>
<th>Long-term (chronic) aquatic hazard, Category 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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:
In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.

In case of eye contact:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed:
If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control center immediately. 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 be harmful if swallowed and enters airways. Causes serious eye irritation. 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: High volume water jet

Specific hazards during fire fighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapors may form explosive mixtures with air.
- 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:
- Remove all sources of ignition.
- Ventilate the area.
- 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:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- 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: If sufficient ventilation is unavailable, use with local exhaust ventilation. If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling: Avoid inhalation of vapor or mist. Do not swallow. Do not get in 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. Non-sparking tools should be used. Keep container tightly closed. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. 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.


Materials to avoid: Do not store with the following product types: Strong oxidizing agents Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
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>Butanone</td>
<td>78-93-3</td>
<td>LT</td>
<td>155 ppm 460 mg/m³</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>300 ppm</td>
<td>ACGIH</td>
</tr>
<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></td>
<td></td>
<td>Wipe limit 0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>methyl-ethyl-ketone</td>
<td>Urine</td>
<td>End of last day of the working day (recommended to avoid the first day of the week)</td>
<td>2 mg/l</td>
<td>BR BEI</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>methyl ethyl ketone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>2 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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**  
  **Hand protection**  
  **Material**  
  **Remarks**  
  - Combined particulates and organic vapor type  
  - Chemical-resistant gloves  
  - Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

- **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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: liquid  
  
- **Color**: Colorless to pale yellow  
  
- **Odor**: characteristic  
  
- **Odor Threshold**: No data available  
  
- **pH**: No data available  
  
- **Melting point/freezing point**: < -66 °C  
  
- **Initial boiling point and boiling range**: 81,5 °C  
  
- **Flash point**: 16 °C  
  
- **Evaporation rate**: No data available
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

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 : 1.04 - 1.08
Density : No data available
Solubility(ies)
  Water solubility : slightly soluble
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.
Molecular weight : No data available
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
  Highly flammable liquid and vapor.
  Vapors may form explosive mixture with air.
  Can react with strong oxidizing agents.
Conditions to avoid
  Heat, flames and sparks.
Incompatible materials
  Oxidizing agents
Hazardous decomposition products
  No hazardous decomposition products are known.
# SAFETY DATA SHEET

## Ivermectin (with Propylene Glycol) Formulation

<table>
<thead>
<tr>
<th>Version</th>
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<td>23.03.2020</td>
<td>4710380-00003</td>
<td>23.08.2019</td>
<td>30.07.2019</td>
</tr>
</tbody>
</table>

### 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: 4.167 mg/kg Method: Calculation method |
| Acute dermal toxicity | Acute toxicity estimate: > 5.000 mg/kg Method: Calculation method |

### Components:

#### 1,3-Dioxan-5-ol:

- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg
- **Acute dermal toxicity**: LD50 (Rat): > 2.000 mg/kg Remarks: Based on data from similar materials

#### Butanone:

- **Acute oral toxicity**: LD50 (Rat): 2.000 - 5.000 mg/kg Remarks: Based on data from similar materials
- **Acute inhalation toxicity**: LC50 (Rat): > 25.5 mg/l Exposure time: 4 h Test atmosphere: vapor Method: OECD Test Guideline 436 Remarks: Based on data from similar materials
- **Acute dermal toxicity**: LD50 (Rabbit): > 5.000 mg/kg

#### 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
Skin corrosion/irritation
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
<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>

Butanone:
Assessment: Repeated exposure may cause skin dryness or cracking.

<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>

Ivermectin:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

1,3-Dioxan-5-ol:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Butanone:
<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
</tbody>
</table>

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>

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
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</tbody>
</table>

### Respiratory sensitization

Not classified based on available information.

### Components:

#### 1,3-Dioxan-5-ol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Butanone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Ivermectin:

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>Humans</td>
<td>Does not cause skin sensitization.</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 1,3-Dioxan-5-ol:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
<th>Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
<th>Species: Mouse</th>
<th>Result: negative</th>
<th>Remarks: Based on data from similar materials</th>
</tr>
</thead>
</table>

#### Butanone:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
<th>Result: negative</th>
<th>Test Type: In vitro mammalian cell gene mutation test</th>
<th>Result: negative</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
</table>
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Ivermectin (with Propylene Glycol) Formulation

Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro)
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

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

Reproductive toxicity
Not classified based on available information.

Components:
Butanone:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Inhalation
Method: OECD Test Guideline 414
Result: negative

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.

STOT-single exposure
May cause damage to organs (Central nervous system) if swallowed.

Components:

Butanone: Assessment: May cause drowsiness or dizziness.
Ivermectin (with Propylene Glycol) Formulation

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</tbody>
</table>

**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.

**Repeated dose toxicity**

**Components:**

**Butanone:**
- Species: Rat
- NOAEL: 14.84 mg/l
- Application Route: Inhalation (vapor)
- Exposure time: 90 Days
- Method: OECD Test Guideline 413

**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:**
- NOAEL: 1.2 mg/kg
- Application Route: Oral
- Exposure time: 2 Weeks
- Remarks: No significant adverse effects were reported

**Species:**
- NOAEL: 0.4 mg/kg
- Application Route: Oral
- Exposure time: 3 Months
- Target Organs: spleen, Bone marrow, Kidney

**Aspiration toxicity**
- May be harmful if swallowed and enters airways.
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formula-

Version 3.0  Revision Date: 23.03.2020  SDS Number: 4710380-00003  Date of last issue: 23.08.2019
Date of first issue: 30.07.2019

Components:
Butanone:
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

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:
1,3-Dioxan-5-ol:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Remarks: Based on data from similar materials

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l Exposure time: 72 h Remarks: Based on data from similar materials

Toxicity to microorganisms: EC10: > 1.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

Butanone:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 2.993 mg/l Exposure time: 96 h Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 308 mg/l
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#### aquatic invertebrates

<table>
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<tr>
<th>Exposure time: 48 h</th>
<th>Method: OECD Test Guideline 202</th>
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</thead>
</table>

#### Toxicity to algae/aquatic plants

- **ErC50** (Pseudokirchneriella subcapitata (green algae)): 2.029 mg/l  
  - Exposure time: 96 h  
  - Method: OECD Test Guideline 201

- **NOEC** (Pseudokirchneriella subcapitata (green algae)): 1.240 mg/l  
  - Exposure time: 96 h  
  - Method: OECD Test Guideline 201

#### 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

#### Persistence and degradability

**Components**:

- **1,3-Dioxan-5-ol**:
  - Biodegradability: Result: Inherently biodegradable.  
  - Remarks: Based on data from similar materials

- **Butanone**:
  - Biodegradability: Result: Readily biodegradable.  
  - Biodegradation: 98 %  
  - Exposure time: 28 d  
  - Method: OECD Test Guideline 301D
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**Ivermectin:**

**Biodegradability**  
Result: Not readily biodegradable.  
Biodegradation: 50%  
Exposure time: 240 d

**Bioaccumulative potential**

**Components:**

1,3-Dioxan-5-ol:

Partition coefficient: n-octanol/water  
log Pow: -0.65

Butanone:

Partition coefficient: n-octanol/water  
log Pow: 0.3

**Ivermectin:**

Bioaccumulation  
Bioconcentration factor (BCF): 74  
Partition coefficient: n-octanol/water  
log Pow: 3.22

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**UNRTDG**

- **UN number**: UN 1193
- **Proper shipping name**: METHYL ETHYL KETONE SOLUTION
- **Class**: 3
- **Packing group**: II
- **Labels**: 

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SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

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UN/ID No. : UN 1193
Proper shipping name : Ethyl methyl ketone solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code
UN number : UN 1193
Proper shipping name : ETHYL METHYL KETONE SOLUTION (Ivermectin)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
UN number : UN 1193
Proper shipping name : METHYL ETHYL KETONE, SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazard Identification Number : 33

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

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

International Regulations
The ingredients of this product are reported in the following inventories:
AICS : not determined
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DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further 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 other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
BR BEI : Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents
BR OEL : Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
BR OEL / LT : Up to 48 hours /week

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; 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 Tempera-
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*ture; 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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