SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 23.03.2020  SDS Number: 4710365-00003  Date of last issue: 23.08.2019  Date of first issue: 30.07.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ivermectin (with Propylene Glycol) Formulation

Manufacturer or supplier's details
Company: MSD
Address: 91-105 Harpin Street
          Bendigo 3550, Victoria Australia
Telephone: 908-740-4000
Emergency telephone number: 1 800 033 461
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 1 800 817 414

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 2
Serious eye damage/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)

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements:
H225 Highly flammable liquid and vapour.
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.
Precautionary statements:

**Prevention:**
- P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
- P233 Keep container tightly closed.
- P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P309 + P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician.
- P314 Get medical advice/ attention if you feel unwell.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.

**Storage:**
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>&gt;= 30 -&lt; 60</td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical ad-
Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 23.03.2020  SDS Number: 4710365-00003  Date of last issue: 23.08.2019  Date of first issue: 30.07.2019

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 centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed:
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. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:
High volume water jet

Specific hazards during firefighting:
Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours 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 firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code:
•2YE

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/vapours/mists with a water spray jet.
- 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.

## SECTIONS 7. HANDLING AND STORAGE

### TECHNICAL MEASURES

- See Engineering measures under EXPOSURE CONTROLS/PERSOAL 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 vapour 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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

Materials to avoid:
Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components 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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particulate)</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>STEL</td>
<td>300 ppm 890 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>150 ppm 445 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</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>
</tbody>
</table>

Further information: Skin

| Wipe limit       | 0.5 mg/100 cm² | Internal |

5 / 21
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 shift (As soon as possible after exposure ceases)</td>
<td>2 mg/l</td>
<td>ACGIH</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: Combined particulates and organic vapour type

Hand protection: Chemical-resistant gloves

Material: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Remarks: Wear safety glasses with side shields or goggles.

Eye protection: 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

Colour: Colorless to pale yellow
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1
Revision Date: 23.03.2020
SDS Number: 4710365-00003
Date of last issue: 23.08.2019
Date of first issue: 30.07.2019

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>&lt; -66 °C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>81.5 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>16 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.04 - 1.08</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>slightly soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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 vapour. Vapours 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes:
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity:
Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity:
Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
Propylene glycol:
Acute oral toxicity:
LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity:
LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity:
LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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:
Ivermectin (with Propylene Glycol) Formulation

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: vapour
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:

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

1,3-Dioxan-5-ol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Butanone:
Assessment: Repeated exposure may cause skin dryness or cracking.
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Ivermectin:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

1,3-Dioxan-5-ol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Butanone:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Ivermectin:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

1,3-Dioxan-5-ol:
Test Type: Maximisation Test
Exposure routes: Skin contact
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 23.03.2020  SDS Number: 4710365-00003  Date of last issue: 23.08.2019  Date of first issue: 30.07.2019

Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Butanone:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Ivermectin:
Exposure routes: Dermal
Species: Humans
Result: Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  Species: Mouse  Application Route: Intraperitoneal injection  Result: negative

1,3-Dioxan-5-ol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  Result: negative
Test Type: In vitro mammalian cell gene mutation test  Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  Species: Mouse  Result: negative  Remarks: Based on data from similar materials

Butanone:
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

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:**

**Propylene glycol:**

Species: Rat  
Application Route: Ingestion  
Exposure time: 2 Years  
Result: negative

**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
Ivermectin (with Propylene Glycol) Formulation

Reproductive toxicity
Not classified based on available information.

**Components:**

**Propylene glycol:**
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

**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 foetal development: Test Type: Embryo-foetal 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 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

NOAEL: 2.0 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials
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:
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:

Propylene glycol:
Species : Rat, male
NOAEL : 1,700 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Butanone:
Species : Rat
NOAEL : 14.84 mg/l
Application Route : Inhalation (vapour)
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: 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

Aspiration toxicity
Not classified based on available information.

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:

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h
### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Ceriodaphnia dubia (water flea))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>18,340 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Skeletonema costatum (marine diatom))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>19,300 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Ceriodaphnia dubia (water flea))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>13,020 mg/l</td>
<td>7 d</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pseudomonas putida)</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>&gt; 20,000 mg/l</td>
<td>18 h</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>LL50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EL50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>308 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC10</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
</tr>
</tbody>
</table>

### Butanone

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>2,993 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>308 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Substance</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>2,029 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Substance</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin (with Propylene Glycol)</td>
<td>1,240</td>
<td></td>
</tr>
</tbody>
</table>

**Remarks:** Based on data from similar materials.
Ivermectin (with Propylene Glycol) Formulation

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

**Persistence and degradability**

**Components:**

**Propylene glycol:**

Biodegradability: Result: Readily biodegradable.
  Biodegradation: 98.3 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301F

**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

**Ivermectin:**

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

Components:

Propylene glycol:
Partition coefficient: n-octanol/water : log Pow: -1.07

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

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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

IATA-DGR
UN/ID No. : UN 1193
Proper shipping name : Ethyl methyl ketone solution
Class : 3
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1 Revision Date: 23.03.2020 SDS Number: 4710365-00003 Date of last issue: 23.08.2019 Date of first issue: 30.07.2019

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.

National Regulations

ADG
UN number: UN 1193
Proper shipping name: METHYL ETHYL KETONE SOLUTION
Class: 3
Packing group: II
Labels: 3
Hazchem Code: •2YE

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1 Revision Date: 23.03.2020 SDS Number: 4710365-00003 Date of last issue: 23.08.2019

Date of first issue: 30.07.2019

SECTION 16. OTHER INFORMATION

Further information
Revision Date: 23.03.2020

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
AU OEL / TWA: Exposure standard - time weighted average
AU OEL / STEL: Exposure standard - short term exposure limit

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 Chemicals 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 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.

AU / EN