SECTION 1. IDENTIFICATION

Product name: Ivermectin (with Propylene Glycol) Formulation

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road, Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Flammable liquids: Category 2
Eye irritation: Category 2A
Specific target organ toxicity - single exposure (Oral): Category 1 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral): Category 1 (Central nervous system)

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements: H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H370 Causes damage to organs (Central nervous system) if swallowed.
H372 Causes 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 vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ eye protection/ face protection.  

Response:  
P303 + P361 + P353 IF ON SKIN (or hair): 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.  
P307 + P311 IF exposed: Call a POISON CENTER or doctor/ physician.  
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  
Vapors may form explosive mixture with air.  

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS  

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>1,3-Dioxan-5-ol</td>
</tr>
<tr>
<td></td>
<td>Butanone</td>
</tr>
<tr>
<td></td>
<td>Ivermectin</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret  

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:
Causes serious eye irritation.
Causes damage to organs if swallowed.
Causes 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 firefighting:
- 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:
- Do not breathe vapors or spray 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.

Conditions for safe storage:
- Keep in properly labeled 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:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</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></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST</td>
<td>300 ppm</td>
<td>NIOSH REL</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

**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 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: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material: Chemical-resistant gloves

Remarks: 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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: Colorless to pale yellow

Odor: characteristic

Odor Threshold: No data available

pH: No data available
### Melting point/freezing point
- \(< -87 °F / < -66 °C\)

### Initial boiling point and boiling range
- \(178.7 °F / 81.5 °C\)

### Flash point
- \(61 °F / 16 °C\)

### Evaporation rate
- No data available

### Flammability (solid, gas)
- Not applicable

### Flammability (liquids)
- Not applicable

### Upper explosion limit / Upper flammability limit
- No data available

### Lower explosion limit / Lower flammability limit
- No data available

### Vapor pressure
- No data available

### Relative vapor density
- \(1.04 - 1.08\)

### 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.
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 03/23/2020  SDS Number: 4710374-00003  Date of last issue: 08/23/2019
Date of first issue: 07/30/2019

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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

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:

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

1,3-Dioxan-5-ol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

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

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

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

**Components:**

**Propylene glycol:**
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

**1,3-Dioxan-5-ol:**
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formula-
tion

Version 2.1  Revision Date: 03/23/2020  SDS Number: 4710374-00003  Date of last issue: 08/23/2019  Date of first issue: 07/30/2019

Remarks: Based on data from similar materials

Butanone:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

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
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:

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
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:

Propylene glycol:
Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Embryo-fetal 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 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**
Causes 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**
Causes 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 y
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: 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, 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: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
- Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

**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
- 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
  Exposure time: 48 h
  Method: OECD Test Guideline 202

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)): 0.00025 mg/l
    Exposure time: 48 h

- Toxicity to algae/aquatic plants:
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l
    Exposure time: 72 h
    Method: OECD Test Guideline 201
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l
    Exposure time: 72 h
    Method: OECD Test Guideline 201

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
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 03/23/2020  SDS Number: 4710374-00003  Date of last issue: 08/23/2019
Date of first issue: 07/30/2019

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
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

49 CFR
UN/ID/NA number : UN 1193
Proper shipping name : Ethyl methyl ketone SOLUTION
Class : 3
Packing group : II
Labels : FLAMMABLE LIQUID
ERG Code : 127
Marine pollutant : yes(Ivermectin)

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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
</table>

19 / 22
Butanone | 78-93-3 | 5000 | 50000 |

**SARA 304 Extremely Hazardous Substances Reportable Quantity**
This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**
This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**
- Flammable (gases, aerosols, liquids, or solids)
- Specific target organ toxicity (single or repeated exposure)
- Serious eye damage or eye irritation

**SARA 313**
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**
- Propylene glycol: 57-55-6
- 1,3-Dioxan-5-ol: 4740-78-7
- Butanone: 78-93-3

**California List of Hazardous Substances**
- Butanone: 78-93-3

**California Permissible Exposure Limits for Chemical Contaminants**
- Butanone: 78-93-3

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

**SECTION 16. OTHER INFORMATION**

Further information
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Version 2.1  Revision Date: 03/23/2020  SDS Number: 4710374-00003  Date of last issue: 08/23/2019  Date of first issue: 07/30/2019

NFPA 704:

Flammability

Health

Instability

Special hazard

HMIS® IV:

HEALTH

* 4

FLAMMABILITY

3

PHYSICAL HAZARD

0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA Z-1 / TWA : 8-hour time weighted average
US WEEL / TWA : 8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Pre-
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Revision Date: 03/23/2020  
SDS Number: 4710374-00003  
Date of last issue: 08/23/2019  
Date of first issue: 07/30/2019

Revision Date: 03/23/2020

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.

US / Z8