1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ivermectin (with Propylene Glycol) Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

<table>
<thead>
<tr>
<th>Flammable liquids</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure (Oral)</td>
<td>Category 2 (Central nervous system)</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure (Oral)</td>
<td>Category 2 (Central nervous system)</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard</td>
<td>Category 1</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

GHS label elements

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammable</td>
</tr>
</tbody>
</table>

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.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
P337 + P313 IF eye irritation persists: Get medical advice/ attention.
P391 Collect spillage.

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:
Important symptoms and outlines of the emergency assumed:

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS:

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 40 - &lt; 50</td>
<td>2-234</td>
</tr>
</tbody>
</table>
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 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.

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 cir-
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.

7. HANDLING AND STORAGE

Handling

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 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.

Avoidance of contact: Oxidizing agents

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.

Storage
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:
Oxidizing solids
Oxidizing liquids

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-M</td>
<td>200 ppm 590 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ACL</td>
<td>200 ppm</td>
<td>JP OEL ISHL</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></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
SAFETY DATA SHEET

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Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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>Methylethylketone</td>
<td>Urine</td>
<td>End of shift or a few hours after high exposure</td>
<td>5 mg/l</td>
<td>JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>methyl ethyl ketone</td>
<td></td>
<td></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
Filter type: Combined particulates and organic vapour type
Hand protection: 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.
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : Colorless to pale yellow

Odour : characteristic

Odour Threshold : No data available

Melting point/freezing point : < -66 °C

Boiling point, initial boiling point and boiling range : 81.5 °C

Flammability (solid, gas) : Not applicable

Flammability (liquids) : Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : 16 °C

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : slightly soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density

Relative density : 1.04 - 1.08

Density : No data available
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.

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: > 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:
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:**
Species : Rabbit

**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

Species : Rabbit
Result : No skin irritation

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

**Butanone:**
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

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

Species : Rabbit
Result : Mild eye 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

**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:

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

Butanone:

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

Ivermectin:

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

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:

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

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

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
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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:
  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
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<table>
<thead>
<tr>
<th>Component</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butanone</td>
<td>1,700 mg/kg</td>
<td>Ingestion</td>
<td>2 yr</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
<td>NOAEL: 14.84 mg/l</td>
<td>Application Route: inhalation (vapour)</td>
<td>Exposure time: 90 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 413</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin:</td>
<td>0.5 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>Central nervous system: Dilatation of the pupil, Tremors, Lack of coordination, anorexia</td>
</tr>
<tr>
<td>Species</td>
<td>Dog</td>
<td>LOAEL: 1 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
<td>Exposure time</td>
<td>14 Weeks</td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Central nervous system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Species | 1.2 mg/kg | Oral | 2 Weeks | No significant adverse effects were reported |
| NOAEL | |
| Application Route | Oral | Exposure time | 2 Weeks | |

| Species | 0.4 mg/kg | Oral | 3 Months | spleen, Bone marrow, Kidney |
| NOAEL | 0.8 mg/kg | |
| Application Route | Oral | Exposure time | 3 Months | |
| Target Organs | |

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:

<table>
<thead>
<tr>
<th>Exposed Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Remarks: Can be absorbed through skin.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Remarks: May irritate eyes.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-</td>
</tr>
</tbody>
</table>
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
  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
### Ivermectin (with Propylene Glycol) Formulation

#### Version 3.0
Revision Date: 2020/03/23
SDS Number: 4710369-00003
Date of last issue: 2019/08/23
Date of first issue: 2019/07/30

---

<table>
<thead>
<tr>
<th>Exposures and Methods</th>
<th>EC50</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>308 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>2,029 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>1,240 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposures and Methods</th>
<th>LC50</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncorhynchus mykiss (rainbow trout)</td>
<td>0.003 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>Lepomis macrochirus (Bluegill sunfish)</td>
<td>0.0048 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposures and Methods</th>
<th>EC50</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>0.000025 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Pseudokirchneriella subcapitata (green algae)</td>
<td>&gt; 9.1 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity):** 10,000

**M-Factor (Chronic aquatic toxicity):** 10,000

---

### 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:**

---

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## Biodegradability

<table>
<thead>
<tr>
<th>Substance</th>
<th>Biodegradability</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ivermectin</td>
<td>Result: Not readily biodegradable.</td>
<td>Biodegradation: 50 %, Exposure time: 240 d</td>
</tr>
</tbody>
</table>

## Bioaccumulative potential

### Components:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td></td>
<td>-1.07</td>
<td></td>
</tr>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td></td>
<td>-0.65</td>
<td></td>
</tr>
<tr>
<td>Butanone</td>
<td></td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td></td>
<td>3.22</td>
<td></td>
</tr>
</tbody>
</table>

### Mobility in soil

No data available

### Hazardous to the ozone layer

Not applicable

### Other adverse effects

No data available

## 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 ex- |
pose 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.

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
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
Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Type 1 petroleums, Water insoluble liquid, (200 litre), Hazardous rank II
SAFETY DATA SHEET

Ivermectin (with Propylene Glycol) Formulation

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>Methyl ethyl ketone</td>
<td>115</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl ethyl ketone</td>
<td>570</td>
<td>&gt;=10 - &lt;20</td>
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</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl ethyl ketone</td>
<td>570</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Inflammable Substance

Poisonous and Deleterious Substances Control Law
Not applicable
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Specially Controlled Industrial Waste

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

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.

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
### SAFETY DATA SHEET

**Ivermectin (with Propylene Glycol) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<tbody>
<tr>
<td>3.0</td>
<td>2020/03/23</td>
<td>4710369-00003</td>
<td>2019/08/23</td>
<td>2019/07/30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH BEI</td>
<td>ACGIH - Biological Exposure Indices (BEI)</td>
</tr>
<tr>
<td>JP OEL ISHL</td>
<td>Japan. Administrative Control Levels</td>
</tr>
<tr>
<td>JSOH</td>
<td>Occupational exposure limits based on biological monitoring (JSOH).</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>JP OEL ISHL / ACL</td>
<td>Administrative Control level</td>
</tr>
<tr>
<td>JP OEL JSOH / OEL-M</td>
<td>Occupational Exposure Limit-Mean</td>
</tr>
</tbody>
</table>

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; IECCS: 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; SDAT: 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.

JP / EN