SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ivermectin (with Isopropyl Alcohol) 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

Flammable liquids : Category 3
Serious eye damage/eye irritation : Category 2A
Skin sensitisation : Category 1
Specific target organ toxicity - single exposure : Category 3
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :

Signal word : Warning
Hazard statements : H226 Flammable liquid and vapour.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
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.
- P261 Avoid breathing mist or vapours.
- P264 Wash skin thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- 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.
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- 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**

| Substance / Mixture | Mixture |
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tion

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Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>&gt;= 50 - &lt; 60</td>
<td>2-422, 7-97</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 40</td>
<td>2-207</td>
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<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>2386-87-0</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td>3-2452</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td>3-540, 9-1805</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td></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.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Causes serious eye irritation.
May cause drowsiness or dizziness.

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 fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
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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.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**: Remove all sources of ignition. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**: Avoid release to the environment. 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. Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling: Do not get on skin or clothing. Avoid breathing mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. 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, hot surfaces, sparks, open flames and other ignition sources. No smoking. 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. Contaminated work clothing should not be allowed out of the workplace. 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


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 / Reference concentration / Basis</th>
</tr>
</thead>
</table>

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Permissible concentration

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>TWA (Inhalable fraction and vapor)</th>
<th>TWA</th>
<th>STEL</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td></td>
<td>10  ppm</td>
<td></td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>ACL</td>
<td>200 ppm</td>
<td>400 ppm</td>
<td>980 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-C</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
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<td>JP OEL JSOH</td>
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<tr>
<td></td>
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<td>TWA</td>
<td>200 ppm</td>
<td></td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td></td>
<td></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></td>
<td></td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th></th>
<th>Wipe limit</th>
<th>0.5 mg/100 cm²</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-buty1-p-cresol</td>
<td>128-37-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>(Inhalable fraction and vapor)</td>
<td>2 mg/m3</td>
</tr>
</tbody>
</table>

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>Propan-2-ol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 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.
- Use explosion-proof electrical, ventilating and lighting equipment.

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: Organic vapour type

Hand protection:

Material: Chemical-resistant gloves

Remarks:

- Consider double gloving. Take note that the product is flam-
Eye protection: mable, which may impact the selection of hand 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: yellow

Odour: solvent-like

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: 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

Flash point: 28 °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
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10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
- 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

Solubility(ies):
- Water solubility: No data available
- Partition coefficient: n-octanol/water: No data available
- Vapour pressure: No data available
- Density and/or relative density:
  - Relative density: No data available
  - Density: 0.855 - 0.905 g/cm³
- Relative vapour density: No data available
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Particle characteristics:
  - Particle size: Not applicable
Components:

2-(2-Butoxyethoxy)ethanol:
Acute oral toxicity : LD50 (Mouse): 2,410 mg/kg
Acute dermal toxicity : LD50 (Rabbit): 2,764 mg/kg

Propan-2-ol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 25 mg/l
   Exposure time: 6 h
   Test atmosphere: vapour
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Acute oral toxicity : LD50 (Rat, male): 2,959 - 5,000 mg/kg
   Method: OECD Test Guideline 401
Acute inhalation toxicity : LC50 (Rat): >= 5.19 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: OECD Test Guideline 436
   Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity

2,6-Di-tert-butyl-p-cresol:
Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg
   Method: OECD Test Guideline 401
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity

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:**

**2-(2-Butoxyethoxy)ethanol:**

- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** Mild skin irritation

**Propan-2-ol:**

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

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation

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

- **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:**

**2-(2-Butoxyethoxy)ethanol:**

- **Species:** Rabbit
- **Result:** Irritation to eyes, reversing within 21 days
Propan-2-ol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Ivermectin:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation
Skin sensitisation
May cause an allergic skin reaction.
Respiratory sensitisation
Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Propan-2-ol:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: positive
Assessment: Probability or evidence of skin sensitisation in humans
### Components:

#### 2,6-Di-tert-butyl-p-cresol:
- **Test Type**: Human repeat insult patch test (HRIPT)
- **Exposure routes**: Skin contact
- **Species**: Humans
- **Result**: negative

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

#### Germ cell mutagenicity
Not classified based on available information.

#### Components:

#### 2-(2-Butoxyethoxy)ethanol:
- **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

#### Propan-2-ol:
- **Genotoxicity in vitro**
  - **Test Type**: Bacterial reverse mutation assay (AMES)
  - **Result**: negative
  - **Test Type**: In vitro mammalian cell gene mutation test
    - **Result**: negative

#### 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
- **Genotoxicity in vitro**
  - **Test Type**: In vitro mammalian cell gene mutation test
    - **Result**: positive
  - **Test Type**: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
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Species: Rat Application Route: Ingestion Method: OECD Test Guideline 486 Result: negative

Test Type: Micronucleus test Species: Mouse Application Route: Intraperitoneal injection Result: negative

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

2,6-Di-tert-butyl-p-cresol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Test Type: In vitro mammalian cell gene mutation test Result: negative

Test Type: Chromosome aberration test in vitro Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Ingestion Result: negative

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:

Propan-2-ol:
Species: Rat Application Route: Inhalation (vapour) Exposure time: 104 weeks Method: OECD Test Guideline 451 Result: negative
2,6-Di-tert-butyl-p-cresol:
Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
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:

2-(2-Butoxyethoxy)ethanol:
Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 415
Result: negative

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

Propan-2-ol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Effects on foetal development : Test Type: Embryo-foetal development
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</tr>
</tbody>
</table>

| **Species**: Rat  
| **Application Route**: Ingestion  
| **Method**: OECD Test Guideline 414  
| **Result**: negative

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

- **Effects on fertility**
  - Test Type: Two-generation reproduction toxicity study  
  - Species: Rat  
  - Application Route: Ingestion  
  - Result: negative

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

**Ivermectin:**

- **Effects on fertility**
  - Test Type: Fertility  
  - Species: Rat  
  - Application Route: Oral  
  - Fertility: NOAEL: 0.6 mg/kg body weight  
  - Result: Animal testing did not show any effects on fertility.

- **Effects on foetal development**
  - Test Type: Development  
  - Species: Mouse  
  - Application Route: Oral  
  - Developmental Toxicity: NOAEL: 0.2 mg/kg body weight  
  - Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

  - Test Type: Development  
  - Species: Rat  
  - Application Route: Oral  
  - Developmental Toxicity: LOAEL: 0.4 mg/kg body weight  
  - Result: Embryotoxic effects and adverse effects on the offspring were detected.  
  - Remarks: The mechanism or mode of action may not be relevant in humans.

  - Test Type: Development  
  - Species: Rabbit  
  - Application Route: Oral  
  - Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

**STOT - single exposure**

May cause drowsiness or dizziness.
Components:

Propan-2-ol:
Assessment: May cause drowsiness or dizziness.

Ivermectin:
Target Organs: Central nervous system
Assessment: Causes damage to organs.

STOT - repeated exposure
Not classified based on available information.

Components:

2,6-Di-tert-butyl-p-cresol:
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Ivermectin:
Target Organs: Central nervous system
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

2-(2-Butoxyethoxy)ethanol:
Species: Rat
NOAEL: 250 mg/kg
LOAEL: 1,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Method: OECD Test Guideline 408

Species: Rat
NOAEL: >= 0.094 mg/l
Application Route: inhalation (vapour)
Exposure time: 90 Days
Method: OECD Test Guideline 413

Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 90 Days

Propan-2-ol:
Species: Rat
NOAEL: 12.5 mg/l
Application Route: inhalation (vapour)
Exposure time: 104 Weeks
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Version: 5.1
Revision Date: 2021/08/27
SDS Number: 1496912-00011
Date of last issue: 2021/04/09
Date of first issue: 2017/03/29

2,6-Di-tert-butyl-p-cresol:
Species: Rat
NOAEL: 25 mg/kg
Application Route: Ingestion
Exposure time: 22 Months

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.

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-(2-Butoxyethoxy)ethanol:
Toxicity to fish:
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,300 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 201
- NOEC (Desmodesmus subspicatus (green algae)): >= 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms:
- EC10: > 1,995 mg/l
  Exposure time: 30 min

Propan-2-ol:
Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  Exposure time: 24 h

Toxicity to microorganisms:
- EC50 (Pseudomonas putida): > 1,050 mg/l
  Exposure time: 16 h

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Toxicity to fish:
- LC50 (Oncorhynchus mykiss (rainbow trout)): 24 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 40 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- ErC50 (Selenastrum capricornutum (green algae)): > 110 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Selenastrum capricornutum (green algae)): 30 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to microorganisms:
- EC10 (Natural microorganism): 409 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

2,6-Di-tert-butyl-p-cresol:
Toxicity to fish

- LC50 (Danio rerio (zebra fish)): > 0.57 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

- EC50 (Daphnia magna (Water flea)): 0.48 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

- NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to algae/aquatic plants

- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity)

- 1

Toxicity to fish (Chronic toxicity)

- NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l
  Exposure time: 30 d
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- NOEC (Daphnia magna (Water flea)): 0.316 mg/l
  Exposure time: 21 d

M-Factor (Chronic aquatic toxicity)

- 1

Toxicity to microorganisms

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

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

Persistence and degradability

Components:

2-(2-Butoxyethoxy)ethanol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 85 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Propan-2-ol:
Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1.19 (BOD5)/COD: 2.23 BOD/COD: 53 %

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Biodegradability : Biodegradation: 71 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Stability in water : Degradation half life (DT50): 2 d

2,6-Di-tert-butyl-p-cresol:
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4.5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

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

Bioaccumulative potential

Components:

2-(2-Butoxyethoxy)ethanol:
Partition coefficient: n-octanol/water : log Pow: 1

Propan-2-ol:
Partition coefficient: n-octanol/water : log Pow: 0.05

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Partition coefficient: n-octanol/water : log Pow: 1.34

2,6-Di-tert-butyl-p-cresol:
Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-octanol/water : log Pow: 5.1

Ivermectin:
Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-octanol/water : log Pow: 3.22

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 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
(Printane-2-ol)
Class : 3
Packing group : III
Labels : 3

IATA-DGR
UN/ID No. : UN 1993
Proper shipping name : Flammable liquid, n.o.s.
(Printane-2-ol)
Class : 3
Packing group : III
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Type 2 petroleums, Water insoluble liquid, (1000 litre), Hazardous rank III

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>102</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-4-methylphenol</td>
<td>64</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>Diethylene glycol monobutyl ether</td>
<td>224 $\equiv$ 3</td>
<td>&gt;=50 - &lt;60</td>
</tr>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
<td>&gt;=30 - &lt;40</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-4-cresol</td>
<td>262</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</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>
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<td>224 $\equiv$ 3</td>
</tr>
<tr>
<td>Propyl alcohol</td>
<td>494</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

Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
JP OEL ISHL : Japan. Administrative Control Levels

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
JP OEL ISHL / ACL : Administrative Control level
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

AIIC - Australian Inventory of Industrial Chemicals; 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 Chemi-
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

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<td>1496912-00011</td>
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</tbody>
</table>

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