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 2
- 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.
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
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Version 4.0  Revision Date: 2020/03/23  SDS Number: 1496912-00008  Date of last issue: 2019/09/13

Date of first issue: 2017/03/29

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>
</tr>
<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 firefighting: Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance. Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- 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:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- 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>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>10 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
## Ivermectin (with Isopropyl Alcohol) Formulation

<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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
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<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.

### 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: 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>solvent-like</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>28 °C</td>
</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
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:
2-(2-Butoxyethoxy)ethanol:
Acute oral toxicity : LD50 (Mouse): 2,410 mg/kg
Acute dermal toxicity : LD50 (Rabbit): 2,764 mg/kg
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

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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

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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

### 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
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

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

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

Genotoxicity in vivo: Test Type: Unscheduled DNA synthesis (UDS) test with
mammalian liver cells in vivo
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  
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
Effects on foetal development:

- Test Type: Embryofetal 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.
SAFETY DATA SHEET

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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

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

Ivermectin:
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Ivermectin (with Isopropyl Alcohol) Formulation

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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
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formula-
tion

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): \( \geq 100 \) 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

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24

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plants

mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (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
Method: OECD Test Guideline 210

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)): 0.000025 mg/l
Exposure time: 48 h

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Persistence and degradability

Components:

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: 2.23BOD/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. (Propan-2-ol)
- Class: 3
- Packing group: III
- Labels: Flammable Liquids

**IATA-DGR**
- UN/ID No.: UN 1993
- Proper shipping name: Flammable liquid, n.o.s. (Propan-2-ol)
- Class: 3
- Packing group: III
- Labels: Flammable Liquids
- Packing instruction (cargo aircraft): 366
- Packing instruction (passenger aircraft): 355

**IMDG-Code**
- UN number: UN 1993
- Proper shipping name: FLAMMABLE LIQUID, N.O.S.
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(Propan-2-ol, Ivermectin, 2,6-Di tert-butyl-p-cresol)

Class: 3  
Packing group: III  
Labels: 3  
EmS Code: F-E, S-E  
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 2 petroleum, 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</td>
<td>&gt;=50 - &lt;60</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substances Subject to be Indicated Names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 57 (Enforcement Order Article 18)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diethylene glycol monobutyl ether</td>
<td>224</td>
</tr>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
</tr>
</tbody>
</table>

| Propyl alcohol                  | 494 |
| 2,6-Di-tert-butyl-4-cresol     | 262 |

Substances Subject to be Indicated Names

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
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)
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

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect
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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