1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Ivermectin (with Isopropyl Alcohol) Formulation

Manufacturer or supplier’s details

Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification

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/ sparks/ open flames/ hot surfaces.
No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
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/ shower.
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
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 60</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; 10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>&gt;= 0.25 - &lt; 2.5</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

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.

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

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>NAB</td>
<td>400 ppm (983 mg/m³)</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PSD</td>
<td>500 ppm (1,230 mg/m³)</td>
<td>ID OEL</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>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 0.5 mg/100 cm² Internal

<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>2,6-Di-tert-butyl-p-cresol</td>
<td>128-37-0</td>
<td>NAB</td>
<td>10 mg/m³</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Version 2.6  Revision Date: 2020/03/23  SDS Number: 1496915-00008  Date of last issue: 2019/09/13  Date of first issue: 2017/03/29

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.

**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.

**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.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</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>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>28 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.855 - 0.905 g/cm3</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

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
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Version 2.6 Revision Date: 2020/03/23 SDS Number: 1496915-00008 Date of last issue: 2019/09/13 Date of first issue: 2017/03/29

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

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

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
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

**Ivermectin:**
Species: Rabbit  
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

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
Ivermectin:
Species : Rabbit
Result : Mild eye irritation

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

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

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

2,6-Di-tert-butyl-p-cresol:
Test Type : Human repeat insult patch test (HRIPT)
Exposure routes : Skin contact
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.

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

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

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

Ivermectin:
Species: Rat
Application Route: Oral
NOAEL: 1.5 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials
Species: Mouse
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Application Route: Oral
NOAEL: 2.0 mg/kg body weight
Result: negative
Remarks: Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:
Species: Rat
Application Route: Ingestion
Exposure time: 22 Months
Result: negative

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

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

**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

**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:

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

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

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

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

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

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

**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
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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

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 plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24 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

M-Factor (Chronic aquatic toxicity): 1

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

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

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

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

Ivermectin:
Bioaccumulation: Bioconcentration factor (BCF): 74
Partition coefficient: n-octanol/water: log Pow: 3.22

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
octanol/water

Mobility in soil
No data available

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.
(Class : 3
Packing group : III
Labels : 3

IATA-DGR
UN/ID No. : UN 1993
Proper shipping name : Flammable liquid, n.o.s.
(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.
(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.

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

Safety, health and environmental regulations/legislation specific for the substance or mixture

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Propan-2-ol
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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
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IVERMECTIN (with Isopropyl Alcohol) Formula-

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Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
ID OEL: Indonesia. Occupational Exposure Limits

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
ID OEL / NAB: Long term exposure limit
ID OEL / PSD: Short term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
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Ivermectin (with Isopropyl Alcohol) Formulation

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