SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formulation

Version 3.3 Revision Date: 23.03.2020 SDS Number: 1497024-00008 Date of last issue: 13.09.2019 Date of first issue: 29.03.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Ivermectin (with Isopropyl Alcohol) Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Eye irritation, Category 2: H319: Causes serious eye irritation.
Skin sensitisation, Category 1: H317: May cause an allergic skin reaction.
Specific target organ toxicity - single exposure, Category 3: H336: May cause drowsiness or dizziness.
Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Warning
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formula-
tion

Version: 3.3  Revision Date: 23.03.2020  SDS Number: 1497024-00008  Date of last issue: 13.09.2019  Date of first issue: 29.03.2017

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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
Propan-2-ol
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate

2.3 Other hazards
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>203-961-6</td>
<td>603-096-00-8</td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>603-117-00-0</td>
<td></td>
<td>Flam. Liq. 2; H225</td>
<td>&gt;= 30 - &lt; 50</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>219-207-4</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319; STOT SE 3; H336</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td></td>
<td></td>
<td>Acute Tox. 2; H300; Acute Tox. 3; H311; STOT SE 1; H370</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

For explanation of abbreviations see section 16.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause an allergic skin reaction. Causes serious eye irritation. May cause drowsiness or dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Remove all sources of ignition. Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

### 6.2 Environmental precautions

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.

### 6.3 Methods and material for containment and cleaning up

Methods for 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 dyeing or other appropriate containment to keep material from spreading. If dyed 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit flammable gases
Explosives
Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>112-34-5</td>
<td>TWA</td>
<td>10 ppm 67.5 mg/m3</td>
<td>2006/15/EC</td>
</tr>
</tbody>
</table>

Further information: Indicative

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>STEL</th>
<th>15 ppm 101.2 mg/m3</th>
<th>2006/15/EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>OELV - 8 hrs</td>
<td></td>
<td>10 ppm</td>
<td>1E OEL</td>
<td></td>
</tr>
</tbody>
</table>
Ivermectin (with Isopropyl Alcohol) Formulation

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.18 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0.18 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.05 mg/kg bw/day</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>500 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>888 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>319 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>26 mg/kg bw/day</td>
</tr>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>67.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>67.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>83 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>40.5 mg/m³</td>
</tr>
</tbody>
</table>
Ivermectin (with Isopropyl Alcohol) Formulation

<table>
<thead>
<tr>
<th></th>
<th>Consumers</th>
<th>Inhalation</th>
<th>Long-term local effects</th>
<th>40.5 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>50 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0.5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>0.86 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Dermal</td>
<td>Long-term systemic effects</td>
<td>0.25 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.25 mg/kg bw/day</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>Fresh water</td>
<td>0.024 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0024 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.24 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>19.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.211 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.0211 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0282 mg/kg</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2251 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td></td>
<td>160 mg/kg food</td>
</tr>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>Fresh water</td>
<td>1.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>11 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.11 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>200 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>4.4 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.44 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.32 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formulation

Version 3.3  Revision Date: 23.03.2020  SDS Number: 1497024-00008  Date of last issue: 13.09.2019  Date of first issue: 29.03.2017

<table>
<thead>
<tr>
<th>Secondary Poisoning</th>
<th>56 mg/kg food</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Fresh water 0.199 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release 0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water 0.02 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant 0.17 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment 0.0996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment 0.00996 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil 0.04769 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning) 8.33 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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

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.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

Skin and body protection

Material: Work uniform or laboratory coat.
Remarks: 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.

Respiratory protection

Material: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Remarks: Equipment should conform to I.S. EN 14387

Filter type: Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006  

**Ivermectin (with Isopropyl Alcohol) Formula-**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<tr>
<td>3.3</td>
<td>23.03.2020</td>
<td>1497024-00008</td>
<td>13.09.2019</td>
<td>29.03.2017</td>
</tr>
</tbody>
</table>

<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>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>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

**9.2 Other information**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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
Ivermectin (with Isopropyl Alcohol) Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 25 mg/l Exposure time: 6 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: vapour</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:</td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat, male): 2,959 - 5,000 mg/kg Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt;= 5.19 mg/l Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist Method: OECD Test Guideline 436</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td>Ivermectin:</td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 50 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 25 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Monkey): &gt; 24 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Target Organs: Central nervous system</td>
</tr>
<tr>
<td></td>
<td>Symptoms: Vomiting, Dilatation of the pupil</td>
</tr>
<tr>
<td></td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 5.11 mg/l Exposure time: 1 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): 406 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 660 mg/kg</td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol:</td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 6,000 mg/kg Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>
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: 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
Method: OECD Test Guideline 405
Result: No eye irritation
Ivermectin (with Isopropyl Alcohol) Formulation

Version | Revision Date: | SDS Number: | Date of last issue: | Date of first issue:
---------|----------------|-------------|---------------------|---------------------
3.3      | 23.03.2020     | 1497024-00008 | 13.09.2019          | 29.03.2017          

Ivermectin:
Species: Rabbit
Result: Mild eye irritation

2,6-Di-tert-butyl-p-cresol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formula-
tion

Species: Humans
Result: negative

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
Ivermectin (with Isopropyl Alcohol) Formulation

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
Ivermectin (with Isopropyl Alcohol) Formula-
tion

Version 3.3  Revision Date: 23.03.2020  SDS Number: 1497024-00008  Date of last issue: 13.09.2019  Date of first issue: 29.03.2017

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

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
Ivermectin (with Isopropyl Alcohol) Formula-
tion

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
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Ivermectin (with Isopropyl Alcohol) Formula-**

**Version** 3.3  
**Revision Date:** 23.03.2020  
**SDS Number:** 1497024-00008  
**Date of last issue:** 13.09.2019  
**Date of first issue:** 29.03.2017

**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

**SECTION 12: Ecological information**

**12.1 Toxicity**

**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
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formulation

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

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
**Safety Data Sheet**


**Ivermectin (with Isopropyl Alcohol) Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>23.03.2020</td>
<td>1497024-00008</td>
<td>13.09.2019</td>
<td>29.03.2017</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 9.1 mg/l</td>
<td>9.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

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

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

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

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>LC50 (Danio rerio (zebra fish))</th>
<th>NOEC (Oryzias latipes (Japanese medaka))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 0.57 mg/l</td>
<td>0.053 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 30 d</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>NOEC (Daphnia magna (Water flea))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.48 mg/l</td>
<td>0.316 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ErC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 0.24 mg/l</td>
<td>0.24 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**M-Factor (Acute aquatic toxicity)**: 1

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>EC50</th>
<th>NOEC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 10,000 mg/l</td>
<td>0.053 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
<td>Exposure time: 30 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>NOEC</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.053 mg/l</td>
<td>Oryzias latipes (Japanese medaka)</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 30 d</td>
<td>Method: OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>NOEC</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.316 mg/l</td>
<td>Daphnia magna (Water flea)</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
</tbody>
</table>

**M-Factor (Chronic aquatic toxicity)**: 1
Ivermectin (with Isopropyl Alcohol) Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td>Result: Readily biodegradable. Biodegradation: 85 %</td>
<td>28 d</td>
<td>OECD Test Guideline 301C</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Result: rapidly degradable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>Biodegradation: 71 %</td>
<td>28 d</td>
<td>OECD Test Guideline 301B</td>
</tr>
<tr>
<td></td>
<td>Stability in water</td>
<td>Degradation half life (DT50): 2 d</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Result: Not readily biodegradable. Biodegradation: 50 %</td>
<td>240 d</td>
<td></td>
</tr>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>Result: Not readily biodegradable. Biodegradation: 4.5 %</td>
<td>28 d</td>
<td>OECD Test Guideline 301C</td>
</tr>
</tbody>
</table>

12.3 Bioaccumulative potential

<table>
<thead>
<tr>
<th>Component</th>
<th>Partition coefficient: n-octanol/water</th>
<th>log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td></td>
<td>0.05</td>
</tr>
<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ivermectin (with Isopropyl Alcohol) Formulation

Partition coefficient: n-octanol/water

**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

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product** : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**Contaminated packaging** : Empty containers should be taken to an approved waste handling site for recycling or disposal.

Empty containers retain residue and can be dangerous.

Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

**ADN** : UN 1993

**ADR** : UN 1993

**RID** : UN 1993

**IMDG** : UN 1993

**IATA** : UN 1993
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin (with Isopropyl Alcohol) Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1497024-00008
Date of last issue: 13.09.2019
Date of first issue: 29.03.2017

14.2 UN proper shipping name

| ADN       | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol) |
| ADR       | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol) |
| RID       | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol) |
| IMDG      | FLAMMABLE LIQUID, N.O.S. (Propan-2-ol, Ivermectin, 2,6-Di-tert-butyl-p-cresol) |
| IATA      | Flammable liquid, n.o.s. (Propan-2-ol) |

14.3 Transport hazard class(es)

| ADN | 3 |
| ADR | 3 |
| RID | 3 |
| IMDG| 3 |
| IATA| 3 |

14.4 Packing group

| ADN             | III |
| Classification Code | F1 |
| Hazard Identification Number | 30 |
| Labels          | 3  |

| ADR             | III |
| Classification Code | F1 |
| Hazard Identification Number | 30 |
| Labels          | 3  |

| RID             | III |
| Classification Code | F1 |
| Hazard Identification Number | 30 |
| Labels          | 3  |

| IMDG            | III |
| Labels          | 3  |
| EmS Code        | F-E, S-E |

| IATA (Cargo)    | III |
| Packing instruction (cargo aircraft) | 366 |
| Packing instruction (LQ) | Y344 |
| Packing group   | III |
Ivermectin (with Isopropyl Alcohol) Formulation

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3
2-(2-Butoxyethoxy)ethanol (Number on list 55)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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P5c  FLAMMABLE LIQUIDS
  Quantity 1: 5,000 t  Quantity 2: 50,000 t
E1  ENVIRONMENTAL HAZARDS
  Quantity: 100 t  200 t

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H225: Highly flammable liquid and vapour.
H300: Fatal if swallowed.
H311: Toxic in contact with skin.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H336: May cause drowsiness or dizziness.
H370: Causes damage to organs if swallowed.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Irrit.: Eye irritation
Flam. Liq.: Flammable liquids
Skin Sens.: Skin sensitisation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
2006/15/EC: Europe. Indicative occupational exposure limit values
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2006/15/EC / TWA: Limit Value - eight hours
Ivermectin (with Isopropyl Alcohol) Formulation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; KECl - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCIS - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture: Classification procedure:

| Flam. Liq. 3 | H226 | Based on product data or assessment |
| Eye Irrit. 2 | H319 | Calculation method |
| Skin Sens. 1 | H317 | Calculation method |
| STOT SE 3 | H336 | Calculation method |
| Aquatic Acute 1 | H400 | Calculation method |
| Aquatic Chronic 1 | H410 | Calculation method |
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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