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

Ivermectin (with Propylene Glycol) Formulation

Version 2.0 Revision Date: 08/23/2019 SDS Number: 4710801-00002 Date of last issue: 30.07.2019
Date of first issue: 30.07.2019

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

1.1 Product identifier
Trade name: Ivermectin (with Propylene Glycol) 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
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone: 908-740-4000
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)
Flammable liquids, Category 2 H225: Highly flammable liquid and vapour.
Eye irritation, Category 2 H319: Causes serious eye irritation.
Specific target organ toxicity - single exposure, Category 2 H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.
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: Danger
Hazard statements :  
H225  Highly flammable liquid and vapour.
H319  Causes serious eye irritation.
H371  May cause damage to organs.
H373  May cause damage to organs through prolonged or repeated exposure.
H410  Very toxic to aquatic life with long lasting effects.

Precautionary statements :  
Prevention:  
P210  Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233  Keep container tightly closed.
P273  Avoid release to the environment.
P280  Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:  
P308 + P311  IF exposed or concerned: Call a POISON CENTER/doctor.
P391  Collect spillage.

Hazardous components which must be listed on the label:  
Ivermectin

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. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,3-Dioxan-5-ol</td>
<td>4740-78-7</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>225-248-9</td>
<td>Flam. Liq. 2; H225</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE 3; H336</td>
<td></td>
</tr>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>201-159-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>606-002-00-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>Acute Tox. 2; H300</td>
<td>&gt;= 1 - &lt; 2.5</td>
</tr>
<tr>
<td></td>
<td>274-536-0</td>
<td>Acute Tox. 3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE 1; H370</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Acute)</td>
<td></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.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure.

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.
- Ventilate the area.
- 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
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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 dyking or other appropriate contain-
ment 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 absorb-
ent.
Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-
mine 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 ventila-
tion.

Advice on safe handling:
Avoid inhalation of vapour or mist.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

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 contami-

nated clothing before re-use.
The effective operation of a facility should include review of
engineering controls, proper personal protective equipment, appropriate 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

### Occupational Exposure Limits

<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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particles)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TWA (Total vapour and particles)</td>
<td>150 ppm 474 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Butanone 78-93-3 TWA 200 ppm 600 mg/m³ 2000/39/EC

Further information: Indicative

<table>
<thead>
<tr>
<th></th>
<th>STEL</th>
<th>300 ppm 900 mg/m³</th>
<th>2000/39/EC</th>
</tr>
</thead>
</table>

Butanone TWA 200 ppm 600 mg/m³ GB EH40

Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.
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<thead>
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</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Ivermectin</th>
<th>70288-86-7</th>
<th>TWA</th>
<th>0.05 mg/m³ (OEB 3)</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further information</td>
<td>Skin</td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Biological occupational exposure limits**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butanone</td>
<td>78-93-3</td>
<td>butan-2-one: 70 micromol per litre (Urine)</td>
<td>After shift</td>
<td>GB EH40 BAT</td>
</tr>
</tbody>
</table>

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<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>Butanone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>600 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1161 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>106 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>412 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>31 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</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>Butanone</td>
<td>Fresh water</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>55.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>709 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>284.74 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>284.7 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>22.5 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>1000 mg/kg food</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Environmental fate</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td>Soil</td>
<td>50 mg/kg</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**
- 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.

**Respiratory protection**
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type: Combined particulates and organic vapour type (A-P)

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

- **Appearance**: liquid
- **Colour**: Colorless to pale yellow
- **Odour**: characteristic
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: < -66 °C
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Initial boiling point and boiling range: 81.5 °C
Flash point: 16 °C
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: 1.04 - 1.08
Density: No data available
Solubility(ies)
   Water solubility: slightly soluble
   Partition coefficient: n-octanol/water: Not applicable
   Auto-ignition temperature: No data available
   Decomposition temperature: No data available
Viscosity
   Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.

9.2 Other information
Flammability (liquids): Not applicable
Molecular weight: No data available
Particle size: Not applicable

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: Highly 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:
1,3-Dioxan-5-ol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Remarks: Based on data from similar materials

Butanone:
- Acute oral toxicity: LD50 (Rat): > 2,000 - 5,000 mg/kg
  Remarks: Based on data from similar materials
- Acute inhalation toxicity: LC50 (Rat): > 25.5 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour
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Method: OECD Test Guideline 436
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

Ivermectin:
Acute oral toxicity: LD50 (Rat): 50 mg/kg
LD50 (Mouse): 25 mg/kg
LD50 (Monkey): > 24 mg/kg
Target Organs: Central nervous system
Symptoms: Vomiting, Dilatation of the pupil
Remarks: No mortality observed at this dose.

Acute inhalation toxicity: LC50 (Rat): 5.11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): 406 mg/kg
LD50 (Rat): > 660 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Butanone:
Assessment: Repeated exposure may cause skin dryness or cracking.
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Ivermectin:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.
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Components:

1,3-Dioxan-5-ol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

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

Ivermectin:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

1,3-Dioxan-5-ol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Butanone:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

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

Germ cell mutagenicity
Not classified based on available information.
Components:

1,3-Dioxan-5-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  
Result: negative  
Remarks: Based on data from similar materials

Butanone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Test Type: Chromosome aberration test in vitro  
Result: negative  
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

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

Ivermectin:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: human diploid fibroblasts  
Result: negative

Test Type: Mouse Lymphoma  
Result: negative
Carcinogenicity
Not classified based on available information.

**Components:**

**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:**

**Butanone:**
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Inhalation
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

STOT - single exposure
May cause damage to organs.

Components:
Butanone:
Assessment : May cause drowsiness or dizziness.

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

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

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

Repeated dose toxicity

Components:
Butanone:
Species : Rat
NOAEL : 14.84 mg/l
Application Route : inhalation (vapour)
Exposure time : 90 Days
Method : OECD Test Guideline 413

Ivermectin:
Species : Dog
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<thead>
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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.

Components:

Butanone:  
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:

Ivermectin:  
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:

1,3-Dioxan-5-ol:  
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h
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Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants**
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Remarks: Based on data from similar materials

- NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Remarks: Based on data from similar materials

**Toxicity to microorganisms**
- EC10: > 1,000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - Remarks: Based on data from similar materials

**Butanone**

**Toxicity to fish**
- LC50 (Pimephales promelas (fathead minnow)): 2,993 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): 308 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants**
- ErC50 (Pseudokirchneriella subcapitata (green algae)): 2,029 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 1,240 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 201

**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
Ivermectin (with Propylene Glycol) Formula-
tion

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

12.2 Persistence and degradability

Components:

1,3-Dioxan-5-ol:
Biodegradability: Result: Inherently biodegradable.
Remarks: Based on data from similar materials

Butanone:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 98 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

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

12.3 Bioaccumulative potential

Components:

1,3-Dioxan-5-ol:
Partition coefficient: n-octanol/water: log Pow: -0.65

Butanone:
Partition coefficient: n-octanol/water: log Pow: 0.3

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

12.4 Mobility in soil
No data available
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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

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1193</th>
</tr>
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<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
<td>UN 1193</td>
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<tr>
<td>IMDG</td>
<td>UN 1193</td>
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<tr>
<td>IATA</td>
<td>UN 1193</td>
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</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ETHYL METHYL KETONE, SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ETHYL METHYL KETONE, SOLUTION</td>
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<tr>
<td>RID</td>
<td>ETHYL METHYL KETONE, SOLUTION</td>
</tr>
<tr>
<td>IMDG</td>
<td>ETHYL METHYL KETONE, SOLUTION (Ivermectin)</td>
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<tr>
<td>IATA</td>
<td>Ethyl methyl ketone, solution</td>
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</table>

14.3 Transport hazard class(es)

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>ADR</td>
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<td>RID</td>
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</table>
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14.4 Packing group

<table>
<thead>
<tr>
<th>Packing group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel restriction code</th>
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<tbody>
<tr>
<td>ADN</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td>(D/E)</td>
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<tr>
<td>ADR</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>F1</td>
<td>33</td>
<td>3</td>
<td></td>
</tr>
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<td>IATA (Cargo)</td>
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<tr>
<td>IATA (Passenger)</td>
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14.5 Environmental hazards

<table>
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<th>Packing group</th>
<th>Environmentally hazardous</th>
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<tbody>
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<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
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</tr>
<tr>
<td>IMDG</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

EmS Code: F-E, S-D

Marine pollutant: yes
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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 - 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 (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
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


<table>
<thead>
<tr>
<th>Entry</th>
<th>Environmental Hazards</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>ENVIRONMENTAL HAZARDS</td>
<td>100 t</td>
<td>200 t</td>
</tr>
<tr>
<td>P5c</td>
<td>FLAMMABLE LIQUIDS</td>
<td>5,000 t</td>
<td>50,000 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
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.
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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.
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
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
GB EH40: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 BAT: UK. Biological monitoring guidance values
2000/39/EC / TWA: Limit Value - eight hours
2000/39/EC / STEL: Short term exposure limit
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL: Short-term exposure limit (15-minute reference period)

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 Organisa-
Further information

Classification of the mixture:

- Flam. Liq. 2: H225
- Eye Irrit. 2: H319
- STOT SE 2: H371
- STOT RE 2: H373
- Aquatic Acute 1: H400
- Aquatic Chronic 1: H410

Classification procedure:
- Based on product data or assessment
- Calculation method
- Calculation method
- Calculation method
- Calculation method
- Calculation method

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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.

GB / EN