SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

SECTION 1. IDENTIFICATION

Product name : Ivermectin (with Isopropyl Alcohol) Formulation

Manufacturer or supplier's details
Company : MSD
Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids : Category 3
Acute toxicity (Oral) : Category 5
Acute toxicity (Dermal) : Category 5
Skin irritation : Category 3
Eye irritation : Category 2A
Skin sensitization : 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 : 

[Image of hazard pictograms]
Signal Word : Warning

Hazard Statements : H226 Flammable liquid and vapor.
H303 + H313 May be harmful if swallowed or in contact with skin.
H316 Causes mild skin irritation.
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.
P261 Avoid breathing mist or vapors.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 Call a POISON CENTER/ doctor if you feel unwell.
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:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS
**SAFETY DATA SHEET**

**Ivermectin (with Isopropyl Alcohol) Formulation**

**Version** 3.6  
**Revision Date:** 27.08.2021  
**SDS Number:** 1497034-00011  
**Date of last issue:** 09.04.2021  
**Date of first issue:** 29.03.2017

### Substances / Mixtures

**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;= 50 -&lt; 70</td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 -&lt; 50</td>
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<tr>
<td>Poly[oxy(methyl-1,2-ethanediyl)]-α-(1-oxotetradecyl)-ω-(phenylmethoxy)-</td>
<td>642443-86-5</td>
<td>&gt;= 10 -&lt; 20</td>
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<tr>
<td>7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate</td>
<td>2386-87-0</td>
<td>&gt;= 1 -&lt; 2,5</td>
</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; 1</td>
</tr>
</tbody>
</table>

### SECTION 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 be harmful if swallowed or in contact with skin. Causes mild skin irritation. 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.

### SECTION 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media**

Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

**Unsuitable extinguishing media**

High volume water jet

**Specific hazards during fire**

Do not use a solid water stream as it may scatter and spread.
fighting fire.
Flash back possible over considerable distance.
Vapors 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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. Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling: Do not get on skin or clothing. Avoid breathing mist or vapors. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment.


Materials to avoid: 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Ingredients with workplace control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>2-(2-Butoxyethoxy)ethanol</td>
</tr>
<tr>
<td>Propan-2-ol</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
</tr>
</tbody>
</table>
Further information: Skin

<table>
<thead>
<tr>
<th></th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-Di-tert-butyl-p-cresol</td>
<td>0.5 mg/100 cm²</td>
</tr>
</tbody>
</table>

Further information: A4 - Not classifiable as a human carcinogen

<table>
<thead>
<tr>
<th></th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (Inhalable fraction and vapor)</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

**Biological occupational exposure limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>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>2 mg/g Creatinine</td>
<td>AR BEI</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equipment.

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Organic vapor Type

**Material**: 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.
- Contaminated work clothing should not be allowed out of the workplace.
- Wash contaminated clothing before re-use.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** liquid
- **Color:** yellow
- **Odor:** solvent
- **Odor Threshold:** No data available
- **pH:** No data available
- **Melting point/freezing point:** No data available
- **Initial boiling point and boiling range:** No data available
- **Flash point:** 28 °C
- **Evaporation rate:** No data available
- **Flammability (solid, gas):** Not applicable
- **Flammability (liquids):** Not applicable
- **Upper explosion limit / Upper flammability limit:** No data available
- **Lower explosion limit / Lower:** No data available
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flammmability limit
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : 0.855 - 0.905 g/cm³
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition 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.
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
  : Flammable liquid and vapor.
    Vapors 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
  Skin contact
  Ingestion
  Eye contact

Acute toxicity
May be harmful if swallowed or in contact with skin.

Product:
Acute oral toxicity: Acute toxicity estimate: 2.992 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: 4.924 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
Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
Exposure time: 6 h
Test atmosphere: vapor
Acute dermal toxicity: LD50 (Rabbit): > 5.000 mg/kg

Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:
Acute oral toxicity: LD50 (Rat): > 16.000 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
Causes mild skin irritation.

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

Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:
   Species: Rabbit
   Result: Mild 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

**Poly[oxymethyl-1,2-ethanediyl], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**
Species : Rabbit
Result : No eye irritation

**Ivermectin:**
Species : Rabbit
Result : Mild eye irritation

**2,6-Di-tert-buty1-p-cresol:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitization

**Skin sensitization**
May cause an allergic skin reaction.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**2-(2-Butoxyethoxy)ethanol:**
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
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tion

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Propan-2-ol:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Result: negative

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: positive
Assessment: Probability or evidence of skin sensitization in humans

Ivermectin:
Routes of exposure: Dermal
Species: Humans
Result: Does not cause skin sensitization.

2,6-Di-tert-butyl-p-cresol:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
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
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

Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) 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 (vapor) 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 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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal 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 fetal 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
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<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>3.6</td>
<td>27.08.2021</td>
<td>1497034-00011</td>
<td>09.04.2021</td>
<td>29.03.2017</td>
</tr>
</tbody>
</table>

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 fetal development | Test Type: Embryo-fetal 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 (vapor)
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 (vapor)
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:
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

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

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
Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)-:

Toxicity to fish  :  LC50: 540 mg/l  
                          Exposure time: 96 h  
                          Test substance: Water Accommodated Fraction

Toxicity to daphnia and other aquatic invertebrates :  EC50 (Ceriodaphnia dubia (water flea)): 221 mg/l  
                                                     Exposure time: 48 h  
                                                     Test substance: Water Accommodated Fraction

Toxicity to algae/aquatic plants  :  NOEC (Selenastrum capricornutum (fresh water algae)): 78 mg/l  
                                          Exposure time: 72 h  
                                          Method: OECD Test Guideline 201

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
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formula-
tion

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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
Method: OECD Test Guideline 201

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: 2.23 BOD/COD: 53 %

7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:
Biodegradability: Biodegradation: 71 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Stability in water: Degradation half life (DT50): 2 d

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
SAFETY DATA SHEET

Ivermectin (with Isopropyl Alcohol) Formulation

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

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

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

IMDG-Code
UN number: UN 1993
Proper shipping name: FLAMMABLE LIQUID, N.O.S. (Propan-2-ol, Ivermectin, 2,6-Di-tert-butyl-p-cresol)
Class: 3
Packing group: III
Labels: 3
EmS Code: F-E, S-E
Marine pollutant: yes
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Propan-2-ol

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
AR BEI: Argentina. Biological Exposure Indices
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
AR OEL / CMP: TLV (Threshold Limit Value)
AR OEL / CMP - CPT: STEL (Short Term Limit Value)

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;
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.