# SAFETY DATA SHEET

## Ivermectin (with Isopropyl Alcohol) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---|---|---|---|
| 8.0 | 06.07.2024 | 1496910-00022 | Date of first issue: 29.03.2017 |

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin (with Isopropyl Alcohol) Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

**GHS Classification**

Flammable liquids : Category 3

Acute toxicity (Oral) : Category 5

Acute toxicity (Dermal) : Category 5

Skin corrosion/irritation : Category 3

Serious eye damage/eye irritation : Category 2A

Skin sensitization : Category 1

Germ cell mutagenicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Specific target organ toxicity - repeated exposure : Category 2 (nasal cavity)

**GHS label elements**

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.
H341 Suspected of causing genetic defects.
H373 May cause damage to organs (nasal cavity) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe 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.
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 victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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 or doctor/ physician 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.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| 2-(2-Butoxyethoxy)ethanol | 112-34-5 | >= 50 -< 70 |
| Propan-2-ol | 67-63-0 | >= 30 -< 50 |
| Poly[oxy(methyl-1,2-ethanediyl)], α-(1-oxotetradecyl)-ω-(phenylmethoxy)- | 642443-86-5 | >= 10 -< 20 |
| 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate | 2386-87-0 | >= 1 -< 5 |
| Ivermectin | 70288-86-7 | >= 0.1 -< 1 |

## 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.

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.
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.
Suspected of causing genetic defects.
May cause damage to organs through prolonged or repeated exposure.

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.<br>Flash back possible over considerable distance.<br>Vapors may form explosive mixtures with air.<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Remove all sources of ignition.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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.<br>Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>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.<br>When using do not eat, drink or smoke.<br>Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.<br>Keep away from heat and sources of ignition. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Flammable solids<br>Pyrophoric liquids<br>Pyrophoric solids<br>Self-heating substances and mixtures<br>Substances and mixtures which in contact with water emit flammable gases<br>Explosives<br>Gases<br>Very acutely toxic substances and mixtures |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| 2-(2-Butoxyethoxy)ethanol | 112-34-5 | TWA (Inhalable fraction and vapor) | 10 ppm | ACGIH |
| Propan-2-ol | 67-63-0 | VLE-PPT | 200 ppm | NOM-010-STPS-2014 |
| | | VLE-CT | 400 ppm | NOM-010-STPS-2014 |
| | | TWA | 200 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| Ivermectin | 70288-86-7 | TWA | 30 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 300 µg/100 cm2 | Internal |

**Biological occupational exposure limits**

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|---|---|---|---|---|---|---|
| Propan-2-ol | 67-63-0 | Acetone | Urine | End of shift at end of work-week | 40 mg/l | MX BEI |
| | | Acetone | Urine | End of shift at end of work-week | 40 mg/l | ACGIH BEI |

**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

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.

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.

## 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) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |

| | | |
|---|---|---|
| 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 | : | Not applicable |
| 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. |
| Molecular weight | : | No data available |
| Particle characteristics | | |
| 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.<br>Vapors may form explosive mixture with air.<br>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: 2,985 mg/kg<br>Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: 4,924 mg/kg<br>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<br>Exposure time: 6 h<br>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<br>Method: OECD Test Guideline 401 |
| Acute inhalation toxicity | : | LC50 (Rat): >= 5.19 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 436<br>Assessment: The substance or mixture has no acute inhalation toxicity |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Ivermectin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 50 mg/kg<br><br>LD50 (Mouse): 25 mg/kg |

| | | |
|---|---|---|
| | | LD50 (Monkey): > 24 mg/kg<br>Target Organs: Central nervous system<br>Symptoms: Vomiting, Dilatation of the pupil<br>Remarks: No mortality observed at this dose. |
| Acute inhalation toxicity | : | LC50 (Rat): 5.11 mg/l<br>Exposure time: 1 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): 406 mg/kg<br><br>LD50 (Rat): > 660 mg/kg |

**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 |

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

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No eye irritation |
| Method | : | OECD Test Guideline 405 |

**Ivermectin:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

**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 |

**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. |

**Germ cell mutagenicity**

Suspected of causing genetic defects.

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Propan-2-ol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

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

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471 |

| | | |
|---|---|---|
| | | Result: positive<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Result: positive<br><br>Test Type: In vitro sister chromatid exchange assay in mammalian cells<br>Result: positive<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: positive |
| Genotoxicity in vivo | : | Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 486<br>Result: negative<br><br>Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative<br><br>Test Type: Transgenic rodent somatic cell gene mutation assay<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 488<br>Result: positive |
| Germ cell mutagenicity - Assessment | : | Positive result(s) from in vivo mammalian somatic cell mutagenicity tests. |

**Ivermectin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Test system: human diploid fibroblasts<br>Result: negative<br><br>Test Type: Mouse Lymphoma<br>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 |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Skin contact |
| Exposure time | : | 29 Months |
| Result | : | negative |

**Ivermectin:**

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

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

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 415<br>Result: negative |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Propan-2-ol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

| | | |
|---|---|---|
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: negative |

**Ivermectin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 0.6 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility. |
| Effects on fetal development | : | Test Type: Development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 0.2 mg/kg body weight<br>Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 0.4 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected.<br>Remarks: The mechanism or mode of action may not be relevant in humans.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses |

**STOT-single exposure**

May cause drowsiness or dizziness.

**Components:**

**Propan-2-ol:**

| | | |
|---|---|---|
| Assessment | : | May cause drowsiness or dizziness. |

**Ivermectin:**

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

**STOT-repeated exposure**

May cause damage to organs (nasal cavity) through prolonged or repeated exposure.

**Components:**

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Routes of exposure | : | Ingestion |
| Target Organs | : | nasal cavity |
| Assessment | : | Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw. |

**Ivermectin:**

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

**Repeated dose toxicity**

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 250 mg/kg |
| LOAEL | : | 1,000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 408 |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | >= 0.094 mg/l |
| Application Route | : | inhalation (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 |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 5 mg/kg |
| LOAEL | : | 50 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 408 |

**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 |

**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<br>Exposure time: 96 h |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Desmodesmus subspicatus (green algae)): >= 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC10: > 1,995 mg/l<br>Exposure time: 30 min |

**Propan-2-ol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l<br>Exposure time: 24 h |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): > 1,050 mg/l<br>Exposure time: 16 h |

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

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 : 540 mg/l<br>Exposure time: 96 h<br>Test substance: Water Accommodated Fraction |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 221 mg/l<br>Exposure time: 48 h<br>Test substance: Water Accommodated Fraction |
| Toxicity to algae/aquatic plants | : | NOEC (Selenastrum capricornutum (fresh water algae)): 78 mg/l<br>Exposure time: 72 h<br>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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 40 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic | : | ErC50 (Raphidocelis subcapitata (freshwater green alga)): > |

| | | |
|---|---|---|
| plants | | 110 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Raphidocelis subcapitata (freshwater green alga)): 30 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC10 (activated sludge): 409 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209 |

**Ivermectin:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l<br>Exposure time: 96 h<br><br>LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0.000025 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

**Persistence and degradability**

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 85 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301C |

**Propan-2-ol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: rapidly degradable |
| BOD/COD | : | BOD: 1,19 (BOD5)<br>COD: 2,23<br>BOD/COD: 53 % |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 71 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |

**Ivermectin:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 240 d |

**Bioaccumulative potential**

**Components:**

**2-(2-Butoxyethoxy)ethanol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 1 |

**Propan-2-ol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 0.05 |

**7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 1.34<br>Method: OECD Test Guideline 107 |

**Ivermectin:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>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.<br>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 |
| Environmentally hazardous | : | no |

**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.

**Domestic regulation**

**NOM-002-SCT**

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

**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.

## SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

Revision Date : 06.07.2024
Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value
NOM-010-STPS-2014 / VLE-CT : Short term exposure limit value

AIIC - 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; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

| | | |
|---|---|---|
| Sources of key data used to compile the Material Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8