

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1497023-00020 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin (with Isopropyl Alcohol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Highly flammable liquids

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 sensitisation : Category 1

Germ cell mutagenicity : Category 2

Specific target organ toxicity - single exposure : Category 3

Short-term (acute) aquatic : Category 1

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hazard

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.
 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.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P203 Obtain, read and follow all safety instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P261 Avoid breathing mist or vapours.
 P264+P265 Wash hands thoroughly after handling. Do not touch eyes.
 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:

P301 + P333 + P317 IF SWALLOWED or if skin irritation or rash occurs: Get medical help.
 P303 + P361 + P353 + P317 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Get medical help.
 P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help 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.
 P318 IF exposed or concerned, get medical advice.
 P337 + P317 If eye irritation persists: Get medical help.
 P362 + P364 Take off contaminated clothing and wash it before reuse.

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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

Vapours may form explosive mixture with air.

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 - < 2.5
Ivermectin	70288-86-7	>= 0.25 - < 1
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.25 - < 1

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.

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Protection of first-aiders : May cause drowsiness or dizziness.
Suspected of causing genetic defects.
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Use personal protective equipment.
Follow safe handling advice (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/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can

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be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

- | | | |
|-----------------------------|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe mist or vapours.
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. |
| Conditions for safe storage | : | Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition. |
| Materials to avoid | : | Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives |

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
2,6-Di-tert-butyl-p-cresol	128-37-0	TWA (Inhalable fraction and vapor)	2 mg/m ³	ACGIH
Ivermectin	70288-86-7	TWA	30 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	300 µg/100 cm ²	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	ACGIH BEI

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.
 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 vapour type

Hand protection

Material : Chemical-resistant gloves

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	yellow
Odour	:	solvent-like
Odour 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	:	No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour 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

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.

Molecular weight : No data available

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

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

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

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Acute toxicity

May be harmful if swallowed or in contact with skin.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,985 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: vapour

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): \geq 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

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Acute oral toxicity : LD50 (Rat): 50 mg/kg
 LD50 (Mouse): 25 mg/kg

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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

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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[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
Method : OECD Test Guideline 405
Result : No eye irritation

Ivermectin:

Species : Rabbit
Result : Mild eye irritation

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

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

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Test Type : Maximisation Test
 Exposure routes : Skin contact
 Species : Guinea pig
 Result : negative

Propan-2-ol:

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

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

Test Type : Human repeat insult patch test (HRIPT)
 Exposure routes : Skin contact
 Result : negative

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

Test Type : Maximisation Test
 Exposure routes : Skin contact
 Species : Guinea pig
 Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

Ivermectin:

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

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

Test Type : Human repeat insult patch test (HRIPT)
 Exposure routes : Skin contact
 Species : Humans
 Result : negative

Germ cell mutagenicity

Suspected of causing genetic defects.

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

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Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
 Species: Mouse
 Application Route: Ingestion
 Result: negative

Propan-2-ol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Result: negative

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

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: Bacterial reverse mutation assay (AMES)
 Method: OECD Test Guideline 471
 Result: positive

Test Type: In vitro mammalian cell gene mutation test
 Result: positive

Test Type: In vitro sister chromatid exchange assay in mammalian cells
 Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
 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

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Test Type: Transgenic rodent somatic cell gene mutation assay
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 488
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)
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts
Result: negative

Test Type: Mouse Lymphoma
Result: negative

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

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Propan-2-ol:

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 104 weeks
Method : OECD Test Guideline 451
Result : negative

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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

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

Species : Rat
 Application Route : Ingestion
 Exposure time : 22 Months
 Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 415
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 Result: negative

Propan-2-ol:

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

Effects on foetal development : Test Type: Embryo-foetal development

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Species: Rat
Application Route: Ingestion
Result: negative

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

Effects on foetal develop-
ment : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Ivermectin:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 0.6 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-
ment : Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.4 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected.
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Development
Species: Rabbit
Application Route: Oral
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

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

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

Effects on foetal develop-
ment : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion

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||| 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:

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

||| Exposure routes : 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.

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

||| Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

2-(2-Butoxyethoxy)ethanol:

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

||| Species : Rat
||| NOAEL : >= 0.094 mg/l
||| Application Route : inhalation (vapour)
||| Exposure time : 90 Days

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Method : OECD Test Guideline 413

Species : Rat
 NOAEL : >= 2,000 mg/kg
 Application Route : Skin contact
 Exposure time : 90 Days

Propan-2-ol:

Species : Rat
 NOAEL : 12.5 mg/l
 Application Route : inhalation (vapour)
 Exposure time : 104 Weeks

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

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

Species : Rat
 NOAEL : 25 mg/kg
 Application Route : Ingestion
 Exposure time : 22 Months

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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ivermectin:

Skin contact	: Remarks: Can be absorbed through skin.
Eye contact	: Remarks: May irritate eyes.
Ingestion	: Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,300 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
	NOEC (Desmodesmus subspicatus (green algae)): >= 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 201
Toxicity to microorganisms	: EC10: > 1,995 mg/l Exposure time: 30 min

Propan-2-ol:

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

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

Toxicity to fish	: LC50: 540 mg/l
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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 (Raphidocelis subcapitata (freshwater green alga)): > 110 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 30 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (activated sludge): 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

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l

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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
 Method: Directive 67/548/EEC, Annex V, C.1.

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

Toxicity to fish (Chronic toxicity) : NOEC: 0.053 mg/l
 Exposure time: 30 d
 Species: Oryzias latipes (Japanese medaka)
 Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.316 mg/l
 Exposure time: 21 d
 Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 1

Persistence and degradability

Components:

2-(2-Butoxyethoxy)ethanol:

Biodegradability : Result: Readily biodegradable.

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Biodegradation: 85 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301C

Propan-2-ol:

Biodegradability : Result: rapidly degradable
 BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

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

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

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
 Method: OECD Test Guideline 107

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-octanol/water : log Pow: 3.22

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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

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous.
Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1993
Proper shipping name : FLAMMABLE LIQUID, N.O.S.
(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.

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(Propan-2-ol, Ivermectin, 2,6-Di-tert-butyl-p-cresol)

Class	: 3
Packing group	: III
Labels	: 3
EmS Code	: F-E, <u>S-E</u>
Marine pollutant	: yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS	: not determined
DSL	: not determined
IECSC	: not determined

16. OTHER INFORMATION

Revision Date : 04.04.2023

Further information

Sources of key data used to compile the 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.

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	: ACGIH - Biological Exposure Indices (BEI)

ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit

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

Ivermectin (with Isopropyl Alcohol) Formula- tion

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Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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

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

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