

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
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

Ivermectin (with Isopropyl Alcohol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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 : High volume water jet

Ivermectin (with Isopropyl Alcohol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

media

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.
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

Ivermectin (with Isopropyl Alcohol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

- | | | |
|-----------------------------|---|--|
| 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 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. |
| 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. |
| Conditions for safe storage | : | Keep in properly labeled 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:
Strong oxidizing agents
Self-reactive substances and mixtures
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
Very acutely toxic substances and mixtures |

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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/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	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., 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

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

Filter type	:	exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Hand protection	:	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.

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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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 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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

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: 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): \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

Ivermectin:

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

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

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

Skin corrosion/irritation

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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

||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)
 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 cyto-genetic 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 cyto-genetic 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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

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

Ivermectin:

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

Not classified based on available information.

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

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
 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

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

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
 Result: Embryotoxic effects and adverse effects on the offspring were detected.
 Remarks: The mechanism or mode of action may not be relevant in humans.

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

STOT-single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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 : $\geq 2,000$ 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 (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
 Date of first issue: 29.03.2017

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
 Exposure time: 96 h

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

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 (Raphidocelis subcapitata (freshwater green alga)): >

Ivermectin (with Isopropyl Alcohol) Formulation

Version 7.0 Revision Date: 04.04.2023 SDS Number: 1496910-00019 Date of last issue: 09.02.2023
Date of first issue: 29.03.2017

plants 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
Exposure time: 72 h
Method: OECD Test Guideline 201

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: 2.23BOD/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 %

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

Exposure time: 28 d
Method: OECD Test Guideline 301B

Ivermectin:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
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
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 : 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.

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

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, <u>S-E</u>
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.

Ivermectin (with Isopropyl Alcohol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

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 : 04.04.2023
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- : Time weighted average limit value
PPT
NOM-010-STPS-2014 / VLE- : Short term exposure limit value
CT

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-

Ivermectin (with Isopropyl Alcohol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 09.02.2023
7.0	04.04.2023	1496910-00019	Date of first issue: 29.03.2017

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.

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