

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

SECTION 1: IDENTIFICATION

Product name : Ivermectin (with Propylene Glycol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : 91-105 Harpin Street
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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 2

Serious eye damage/eye irritation : Category 2A

Specific target organ toxicity - single exposure (Oral) : Category 2 (Central nervous system)

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Central nervous system)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H371 May cause damage to organs (Central nervous system) if swallowed.
H373 May cause damage to organs (Central nervous system)

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
 Date of first issue: 30.07.2019

through prolonged or repeated exposure if swallowed.

Precautionary statements :

Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ ventilating/ lighting equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.

P260 Do not breathe mist or vapours.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

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.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol	57-55-6	>= 30 -< 60
1,3-Dioxan-5-ol	4740-78-7	>= 30 -< 60
Butanone	78-93-3	>= 10 -< 20
Ivermectin	70288-86-7	>= 1 -< 10

Ivermectin (with Propylene Glycol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.4	30.09.2023	4710365-00017	Date of first issue: 30.07.2019

SECTION 4. FIRST AID MEASURES

- | | | |
|---|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air.
Get medical attention if symptoms occur. |
| In case of skin contact | : | Remove contaminated clothing and shoes. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | Causes serious eye irritation.
May cause damage to organs if swallowed.
May cause damage to organs through prolonged or repeated exposure if swallowed. |
| 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. FIREFIGHTING MEASURES

- | | | |
|---------------------------------------|---|---|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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. |

Ivermectin (with Propylene Glycol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.4	30.09.2023	4710365-00017	Date of first issue: 30.07.2019

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

Hazchem Code : •2YE

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Remove all sources of ignition.
Ventilate the area.
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 be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling : Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety

Ivermectin (with Propylene Glycol) Formula- tion

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

- 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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash 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 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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA (particulate)	10 mg/m ³	AU OEL
		TWA (Total vapour and particles))	150 ppm 474 mg/m ³	AU OEL
Butanone	78-93-3	TWA	150 ppm	AU OEL

Ivermectin (with Propylene Glycol) Formula- tion

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

			445 mg/m ³	
		STEL	300 ppm 890 mg/m ³	AU OEL
		TWA	200 ppm	ACGIH
		STEL	300 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	Sam-pling time	Permissible concentra-tion	Basis
Butanone	78-93-3	methyl ethyl ketone	Urine	End of shift (As soon as possible after exposure ceases)	2 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 : Combined particulates and organic vapour 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

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Skin and body protection : potential for direct contact to the face with dusts, mists, or aerosols.
: 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

Colour : Colorless to pale yellow

Odour : characteristic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : < -66 °C

Initial boiling point and boiling range : 81.5 °C

Flash point : 16 °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

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : 1.04 - 1.08

Density : No data available

Solubility(ies)
Water solubility : slightly soluble

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Highly 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Components:

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

1,3-Dioxan-5-ol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Butanone:

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

Acute inhalation toxicity : LC50 (Rat): > 25.5 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 436
Remarks: Based on data from similar materials

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

Ivermectin:

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

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

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

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Skin corrosion/irritation

Not classified based on available information.

Components:

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

1,3-Dioxan-5-ol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Butanone:

Assessment : Repeated exposure may cause skin dryness or cracking.

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Ivermectin:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Propylene glycol:

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

1,3-Dioxan-5-ol:

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

Butanone:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Method : OECD Test Guideline 405

Ivermectin:

Species : Rabbit
Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Propylene glycol:

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

1,3-Dioxan-5-ol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Butanone:

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

Ivermectin:

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

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Ivermectin (with Propylene Glycol) Formula- tion

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Components:

Propylene glycol:

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

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

1,3-Dioxan-5-ol:

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

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

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Result: negative
Remarks: Based on data from similar materials

Butanone:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay
(in vitro)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Ivermectin:

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

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

Test Type: Mouse Lymphoma
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
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:

Propylene glycol:

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

Ivermectin (with Propylene Glycol) Formula- tion

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Result: negative

Effects on foetal develop-
ment : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Butanone:

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

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

Ivermectin:

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

Effects on foetal 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 off-
spring were detected.
Remarks: The mechanism or mode of action may not be rele-
vant 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

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

toxic doses

STOT - single exposure

May cause damage to organs (Central nervous system) if swallowed.

Components:

Butanone:

Assessment : May cause drowsiness or dizziness.

Ivermectin:

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

STOT - repeated exposure

May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

Ivermectin:

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

Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Butanone:

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

Ivermectin:

Species : Dog
NOAEL : 0.5 mg/kg
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Target Organs : Central nervous system
Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey
NOAEL : 1.2 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 0.4 mg/kg
LOAEL : 0.8 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : spleen, Bone marrow, Kidney

Aspiration toxicity

Not classified based on available information.

Components:

Butanone:

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

Experience with human exposure

Components:

Ivermectin:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h

Ivermectin (with Propylene Glycol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.4	30.09.2023	4710365-00017	Date of first issue: 30.07.2019

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

1,3-Dioxan-5-ol:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

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

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

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

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

Butanone:

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

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

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 1,240 mg/l
Exposure time: 96 h

**Ivermectin (with Propylene Glycol) Formula-
tion**

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Method: OECD Test Guideline 201

Ivermectin:

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

Persistence and degradability**Components:****Propylene glycol:**

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

1,3-Dioxan-5-ol:

- Biodegradability : Result: Inherently biodegradable.
Remarks: Based on data from similar materials

Butanone:

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

Ivermectin:

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

Ivermectin (with Propylene Glycol) Formula- tion

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Bioaccumulative potential

Components:

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

1,3-Dioxan-5-ol:

Partition coefficient: n-octanol/water : log Pow: -0.65

Butanone:

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

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

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

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.
Dispose of in accordance with local regulations.

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 1193
Proper shipping name : METHYL ETHYL KETONE SOLUTION
Class : 3
Packing group : II

Ivermectin (with Propylene Glycol) Formulation

Version 5.4 Revision Date: 30.09.2023 SDS Number: 4710365-00017 Date of last issue: 04.04.2023
Date of first issue: 30.07.2019

Labels : 3
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1193
Proper shipping name : Ethyl methyl ketone solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

IMDG-Code

UN number : UN 1193
Proper shipping name : ETHYL METHYL KETONE SOLUTION (Ivermectin)
Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

ADG

UN number : UN 1193
Proper shipping name : METHYL ETHYL KETONE SOLUTION
Class : 3
Packing group : II
Labels : 3
Hazchem Code : •2YE
Environmentally hazardous : no

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcino-

Ivermectin (with Propylene Glycol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.4	30.09.2023	4710365-00017	Date of first issue: 30.07.2019

gens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date	:	30.09.2023
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/
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
AU OEL / TWA	:	Exposure standard - time weighted average
AU OEL / STEL	:	Exposure standard - short term exposure limit

AIC - 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 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

Ivermectin (with Propylene Glycol) Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.4	30.09.2023	4710365-00017	Date of first issue: 30.07.2019

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.

AU / EN