according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

### **SECTION 1. IDENTIFICATION**

Product name : Ivermectin (with Propylene Glycol) Formulation

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations

Flammable liquids : Category 2

Eye irritation : Category 2A

Specific target organ toxicity

- single exposure (Oral)

Category 1 (Central nervous system)

Specific target organ toxicity

- repeated exposure (Oral)

: Category 1 (Central nervous system)

#### **GHS** label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation.

H370 Causes damage to organs (Central nervous system) if

swallowed.

H372 Causes damage to organs (Central nervous system) 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.

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

P260 Do not breathe mist or vapors.

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

and 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 doctor. P337 + P313 If eye irritation persists: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

#### Other hazards

Vapors may form explosive mixture with air.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Propylene glycol	1,2-Propanediol		>= 30 - < 60 *
1,3-Dioxan-5-ol	No data availa- ble	4740-78-7	>= 30 - < 60 *
Butanone	Ethyl methyl ketone	78-93-3	>= 10 - < 30 *
Ivermectin	No data availa- ble	70288-86-7	>= 1 - < 5 *

\* Actual concentration or concentration range is withheld as a trade secret

# **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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: Date of last issue: 04/14/2025 SDS Number: 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

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 center immediately.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and Causes serious eye irritation.

Causes damage to organs if swallowed.

delayed

Causes 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. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

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 prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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, protec: : tive equipment and emer-

gency procedures

Remove all sources of ignition.

Ventilate the area.

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers)

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Non-sparking tools should be used. Soak up with inert absorbent material.

Suppress (knock down) gases/vapors/mists with a water spray

jet.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

# **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Advice on safe handling : Do not breathe mist or vapors.

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 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.

Materials to avoid

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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. 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

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis			
Propylene glycol	57-55-6	TWA (Va- pour and aerosols)	50 ppm 155 mg/m³	CA ON OEL			
		TWA (aero- sol)	10 mg/m³	CA ON OEL			
Butanone	78-93-3	TWA	200 ppm 590 mg/m³	CA AB OEL			
		STEL	300 ppm 885 mg/m³	CA AB OEL			
		TWA	50 ppm	CA BC OEL			
		STEL	100 ppm	CA BC OEL			
		TWAEV	50 ppm 150 mg/m <sup>3</sup>	CA QC OEL			
		STEV	100 ppm 300 mg/m³	CA QC OEL			
		TWA	75 ppm	ACGIH			
		STEL	150 ppm	ACGIH			
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal			
	Further information: Skin						
		Wipe limit	300 μg/100 cm2	Internal			

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

#### **Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	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. Combined particulates and organic vapor type

Filter type

Material

Hand protection

: Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is

flammable, which may impact the selection of hand

protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : Colorless to pale yellow

Odor : characteristic

Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : 1.04 - 1.08

Density : No data available

Solubility(ies)

Water solubility : slightly soluble

Partition coefficient: n- : Not applicable

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

octanol/water

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, kinematic No data available

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle characteristics

Particle size Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Possibility of hazardous reac-

tions

Highly 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 No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### Information on likely routes of exposure

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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

**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: vapor

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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

### 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

Method : OECD Test Guideline 405

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

Ivermectin:

Species Rabbit

Result Mild eye irritation

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### **Components:**

#### Propylene glycol:

Test Type : Maximization Test Routes of exposure : Skin contact Species : Guinea pig Result : negative

# 1,3-Dioxan-5-ol:

Test Type : Maximization Test Routes of exposure Species Method : Skin contact : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks Based on data from similar materials

### **Butanone:**

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

: OECD Test Guideline 406 Method

Result : negative

## Ivermectin:

Routes of exposure : Dermal Species Humans

Result Does not cause skin sensitization.

## Germ cell mutagenicity

Not classified based on available information.

# **Components:**

#### Propylene glycol:

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

Result: negative

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Ivermectin:

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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: Date of last issue: 04/14/2025 SDS Number: 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis 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

Based on data from similar materials Remarks

Species Mouse Application Route NOAEL Oral

: 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

Result: negative

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

Species: Mouse

Application Route: Ingestion

Result: negative

#### **Butanone:**

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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 fetal development : Test Type: Embryo-fetal 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 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 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

toxic doses

#### STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

### **Components:**

## **Butanone:**

Assessment : May cause drowsiness or dizziness.

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

Ivermectin:

Target Organs Central nervous system Assessment Causes damage to organs.

# STOT-repeated exposure

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

### **Components:**

#### Ivermectin:

: Central nervous system Target Organs

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

# Propylene glycol:

Species : Rat, male NOAEL : >= 1,700 mg/kg
Application Route : Ingestion
Exposure time : 2 v

Exposure time : 2 y

### **Butanone:**

Species : Rat

NOAEL : 14.84 mg/l

Application Route : inhalation (vapor)

Exposure time : 90 Days

OECD Test Guide

: OECD Test Guideline 413 Method

#### Ivermectin:

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

: Central nervous system

: Dilatation of the pupil, Tremors, Lack of coordination, anorexia Symptoms

Species : Monkey NOAEL : 1.2 mg/kg Application Route : Oral Exposure time

Remarks : No significant adverse effects were reported

Species Rat NOAEL 0.4 mg/kg LOAEL 0.8 mg/kg

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

Application Route Exposure time : Oral 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.

Remarks: May irritate eyes. Eye contact

Ingestion Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, 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

aquatic invertebrates

Toxicity to daphnia and other : 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

Method: OECD Test Guideline 201

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic 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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

aquatic invertebrates

Toxicity to daphnia and other : 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

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

mq/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Ivermectin:

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l Toxicity to fish

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

mq/l

Exposure time: 72 h

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: Date of last issue: 04/14/2025 SDS Number: 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

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:** 

Result: Readily biodegradable. Biodegradability

Biodegradation: 98 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Ivermectin:

Result: Not readily biodegradable. Biodegradability

> Biodegradation: 50 % Exposure time: 240 d

#### Bioaccumulative potential

# **Components:**

Propylene glycol:

Partition coefficient: n-: log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

1,3-Dioxan-5-ol:

Partition coefficient: nlog Pow: -0.65

octanol/water

**Butanone:** 

Partition coefficient: n-

: log Pow: 0.3

octanol/water

Ivermectin:

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: Date of last issue: 04/14/2025 SDS Number: 06/18/2025 4710379-00020 Date of first issue: 07/30/2019 7.0

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 Ш 3 Labels Environmentally hazardous nο

**IATA-DGR** 

UN 1193 UN/ID No.

Proper shipping name Ethyl methyl ketone solution

Class Packing group Ш

Labels Flammable Liquids

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

353

364

**IMDG-Code** 

**UN** number

Proper shipping name ETHYL METHYL KETONE SOLUTION

(Ivermectin)

Class 3

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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.

### **Domestic regulation**

**TDG** 

UN number : UN 1193

Proper shipping name : ETHYL METHYL KETONE SOLUTION

Class : 3
Packing group : II
Labels : 3
ERG Code : 127

Marine pollutant : yes(Ivermectin)

# 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**

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

AICS : not determined

DSL : not determined

IECSC : not determined

# **SECTION 16. OTHER INFORMATION**

Full text of other abbreviations

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

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA ON OEL : Ontario Table of Occupational Exposure Limits made under

the Occupational Health and Safety Act.

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

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

CA AB OEL / TWA : 8-hour Occupational exposure limit

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04/14/2025

 7.0
 06/18/2025
 4710379-00020
 Date of first issue: 07/30/2019

CA AB OEL / STEL : 15-minute occupational exposure limit

CA BC OEL / TWA : 8-hour time weighted average CA BC OEL / STEL : short-term exposure limit

CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value

CA QC OEL / STEV : Short-term exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal 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; 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

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Revision Date : 06/18/2025 Date format : mm/dd/yyyy

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

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

according to the Hazardous Products Regulations



# Ivermectin (with Propylene Glycol) Formulation

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 7.0 06/18/2025 4710379-00020 Date of first issue: 07/30/2019

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.

CA / Z8