

Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ivermectin (with Isopropyl Alcohol) Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Flammable liquids : Category 3

Serious eye damage/eye irri-

tation

Category 2A

Skin sensitisation : Category 1

Germ cell mutagenicity : Category 2

Specific target organ toxicity - : Category 3

single exposure

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Hazard pictograms :









Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H341 Suspected of causing genetic defects.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

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.

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.

P261 Avoid breathing mist or vapours.

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.

P273 Avoid release to the environment.

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 person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor 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.

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ at-

P362 + P364 Take off contaminated clothing and wash it before reuse.



Ivermectin (with Isopropyl Alcohol) Formulation

SDS Number: Date of last issue: 2024/07/06 Version Revision Date: 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

P391 Collect spillage.

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

lines of the emergency as-

sumed

Important symptoms and out- : Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
2-(2-Butoxyethoxy)ethanol	112-34-5	52.27	2-422, 7-97
Propan-2-ol	67-63-0	34.091	2-207
7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate	2386-87-0	>= 1 - < 2.5	3-2452
2,6-Di-tert-butyl-p-cresol	128-37-0	>= 0.1 - < 1	3-540, 9-1805
Ivermectin	70288-86-7	>= 0.25 - < 1	-

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.



Ivermectin (with Isopropyl Alcohol) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

delayed

Causes serious eye irritation.

May cause drowsiness or dizziness. Suspected of causing genetic defects.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

Do not use a solid water stream as it may scatter and spread

fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion 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

SO.

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency procedures

Remove all sources of ignition. Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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 get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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.

Avoidance of contact : Oxidizing agents



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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.

Storage

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:

Oxidizing solids Oxidizing liquids

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis
2-(2-Butoxyethoxy)ethanol	112-34-5	8h-OEL-M	60 mg/m3	JP ISHL OEL 577-2(2)
		TWA (Inhalable fraction and vapor)	10 ppm	ACGIH
Propan-2-ol	67-63-0	ACL	200 ppm	JP OEL ISHL
		OEL-C	400 ppm 980 mg/m3	JP OEL JSOH
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	300 µg/100 cm2	Internal
2,6-Di-tert-butyl-p-cresol	128-37-0	8h-OEL-M	10 mg/m3	JP ISHL OEL 577-2(2)



Ivermectin (with Isopropyl Alcohol) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2024/07/06

 10.1
 2024/09/28
 1496912-00025
 Date of first issue: 2017/03/29

TWA (Inhalable fraction	2 mg/m3	ACGIH
and vapor)		

Biological occupational exposure limits

Components	CAS-No.	Target sub- stance	Biological specimen	Sam- pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face con-

tainment devices). Minimize open handling.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

Organic vapour type

Material : Chemical-resistant gloves

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

mable, 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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025 Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

contaminated clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state liquid

Colour yellow

Odour solvent-like

Odour Threshold No data available

No data available Melting point/freezing point

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

Flash point 28 °C

No data available Decomposition temperature

No data available рΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Relative density : No data available

Density : 0.855 - 0.905 g/cm³

Relative vapour density : 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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Flammable liquid and vapour.

tions 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 : No hazardous dec

products

: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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 Isopropyl Alcohol) Formulation

Version F 10.1 2

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

Components:

2-(2-Butoxyethoxy)ethanol:

Acute oral toxicity : LD50 (Mouse): 2,410 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 2,764 mg/kg

Propan-2-ol:

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

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l

Exposure time: 6 h
Test atmosphere: vapour

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

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): >= 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 inhala-

tion 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

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

Acute oral toxicity : LD50 (Rat): > 6,000 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Ivermectin:

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

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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

Not classified based on available information.

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

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

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

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Ivermectin:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

2-(2-Butoxyethoxy)ethanol:

Species : Rabbit



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Result : Irritation to eyes, reversing within 21 days

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

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

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

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Ivermectin:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-(2-Butoxyethoxy)ethanol:

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

Propan-2-ol:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

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

Test Type : Maximisation Test



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Exposure routes : Skin contact
Species : Guinea pig
Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

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

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : negative

Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

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

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Ingestion

Result: negative

Propan-2-ol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

Application Route: Intraperitoneal injection

Result: negative

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

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

Method: OECD Test Guideline 471

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: positive

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

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

thesis in mammalian cells (in vitro)

Result: positive

Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 486

Result: negative

Test Type: Micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Transgenic rodent somatic cell gene mutation as-

say

Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 488

Result: positive

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

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

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Ivermectin:

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

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:

Propan-2-ol:

Species : Rat

Application Route : inhalation (vapour)

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

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

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

Ivermectin:

Species : Rat Application Route : Oral

NOAEL : 1.5 mg/kg body weight



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

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

toxic doses

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

Ivermectin:

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



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

STOT - repeated exposure

Not classified based on available information.

Components:

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

Exposure routes : Ingestion
Target Organs : nasal cavity

Assessment : Shown to produce significant health effects in animals at con-

centrations of >10 to 100 mg/kg bw.

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

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

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 (vapour)

Exposure time : 90 Days

Method : OECD Test Guideline 413

Species : Rat

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

Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

Application Route : inhalation (vapour)



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Exposure time : 104 Weeks

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

Species : Rat

NOAEL : 5 mg/kg

LOAEL : 50 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Method : OECD Test Guideline 408

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

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

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.



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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

iting, anorexia, Lack of coordination

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-(2-Butoxyethoxy)ethanol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1,300 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): >= 100

mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10: > 1,995 mg/l

Exposure time: 30 min

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h

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



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

110 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 30

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (activated sludge): 409 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

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

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0.57 mg/l

Exposure time: 96 h

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

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.48 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

: 1

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): 0.053 mg/l

Exposure time: 30 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.316 mg/l

Exposure time: 21 d

M-Factor (Chronic aquatic

toxicity)

: 1

Toxicity to microorganisms

: EC50: > 10,000 mg/l Exposure time: 3 h

Method: OECD Test Guideline 209

Ivermectin:



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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

M-Factor (Acute aquatic tox-

icity)

M-Factor (Chronic aquatic

toxicity)

10,000

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: 2,23 BOD/COD: 53 %

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

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 71 % Exposure time: 28 d

Method: OECD Test Guideline 301B

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

Biodegradability : Result: Not readily biodegradable.



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

Biodegradation: 4.5 % Exposure time: 28 d

Method: OECD Test Guideline 301C

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- : log Pow: 1.34

octanol/water Method: OECD Test Guideline 107

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

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 330 - 1,800

Partition coefficient: n-

octanol/water

log Pow: 5.1

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

log Pow: 3.22

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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 han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 1993

Proper shipping name FLAMMABLE LIQUID, N.O.S.

(Propan-2-ol)

Class 3 Ш Packing group 3 Labels Environmentally hazardous no

IATA-DGR

UN/ID No. UN 1993

Proper shipping name Flammable liquid, n.o.s.

(Propan-2-ol)

3 Class Packing group Ш

Labels Flammable Liquids

Packing instruction (cargo 366

aircraft)

Packing instruction (passen-

ger aircraft)

355

IMDG-Code

UN number UN 1993

FLAMMABLE LIQUID, N.O.S. Proper shipping name

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

Class 3 Packing group Ш Labels 3 **EmS Code** F-E, S-E Marine pollutant yes

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

Not applicable for product as supplied.



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1

Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 128

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Group 4, Type 2 petroleums, Water insoluble liquid, (1000 litre), Hazardous rank III

Chemical Substance Control Law

Priority Assessment Chemical Substance

Chemical name	Number
2-(2-Butoxyethoxy)ethan-1-ol	276
Isopropyl alcohol	102
2,6-Di-tert-butyl-4-methylphenol	64

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Diethylene glycol monobutyl ether	>=50 - <60	-
Propyl alcohol	34.091	-
2,6-Di-tert-butyl-4-cresol	>=0.1 - <1	-



Ivermectin (with Isopropyl Alcohol) Formulation

Version 10.1 Revision Date: 2024/09/28

SDS Number: 1496912-00025

Date of last issue: 2024/07/06 Date of first issue: 2017/03/29

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Diethylene glycol monobutyl ether	-
Propyl alcohol	-

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Inflammable Substance

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class I Designated Chemical Substances

Chemical name	Administration number	Concentration (%)
Diethylene glycol monobutyl ether	627	52

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Specially Controlled Industrial Waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

Further information

Sources of key data used to

compile the Safety Data

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

Sheet

Date format : yyyy/mm/dd

Full text of other abbreviations

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

JP ISHL OEL 577-2(2) : Concentration standard (Value set by the Minister of Health,

Labour and Welfare stipulated under the Ministerial Ordinance

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

Article 577-2(2))

JP OEL ISHL : Japan. Administrative Control Levels

JP OEL JSOH : Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

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

JP ISHL OEL 577-2(2) / 8h-

: 8-hour Occupational Exposure Limit-Mean

OEL-M

JP OEL ISHL / ACL : Administrative Control level

JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling



Ivermectin (with Isopropyl Alcohol) Formulation

Version Revision Date: SDS Number: Date of last issue: 2024/07/06 10.1 2024/09/28 1496912-00025 Date of first issue: 2017/03/29

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

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.

JP / EN