

Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

SECTION 1. IDENTIFICATION

Product identifier : Ivermectin (0.50%) Liquid Formulation

Other means of identification : COOPERS PARAMAX POUR-ON FOR BEEF AND DAIRY

CATTLE (50558)

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Skin irritation : Category 3

Eye irritation : Category 2A

Skin sensitization : Category 1

Germ cell mutagenicity : Category 2

Specific target organ toxicity - :

single exposure

Category 3

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard



Ivermectin (0.50%) Liquid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 20.02.2024 28.09.2024 10874507-00007 Date of first issue: 20.10.2022 3.0

Hazard pictograms







Signal Word Warning

H316 Causes mild skin irritation. Hazard Statements

> H317 May cause an allergic skin reaction. H319 Causes serious eve 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. 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 protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of 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 ad-

vice/ attention.

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

P391 Collect spillage.

Storage:

P405 Store locked up.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---------------|---------|-------------------------------|-----------------------|
| Propan-2-ol | 67-63-0 | Flam. Liq., 2 Eve Irrit 2A | >= 70 -< 90 |
| <u>II</u> | | Eye IIII., ZA | |



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

| | | STOT SE, 3 | |
|---|------------|---|--------------|
| Cetyl octanoate | 59130-69-7 | Skin Irrit., 3 | >= 10 -< 20 |
| Hexanoic acid, 2-ethyl-, octa- decyl ester | 59130-70-0 | Skin Irrit., 3 | >= 10 -< 20 |
| 7-Oxabicyclo[4.1.0]hept-3- ylmethyl 7- oxabicyclo[4.1.0]heptane-3- carboxylate | 2386-87-0 | Acute Tox. (Oral), 5 Skin Sens., 1 Muta., 2 STOT RE, (nasal cavity), 2 Aquatic Acute, 3 Aquatic Chronic, 3 | >= 1 -< 2,5 |
| Ivermectin | 70288-86-7 | Acute Tox. (Oral), 2 Acute Tox. (Dermal), 3 STOT SE, (Oral)(Central nervous system), 1 STOT RE, (Oral)(Central nervous system), 1 Aquatic Acute, 1 Aquatic Chronic, 1 | >= 0,25 -< 1 |

SECTION 4. FIRST AID MEASURES

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

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

for at least 15 minutes.

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

Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and delayed

Causes mild skin irritation.

May cause an allergic skin reaction.

Causes serious eye irritation.

May cause drowsiness or dizziness.

Suspected of causing genetic defects.

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).



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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

None known.

Specific hazards during fire

fighting

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 fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

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

Soak up with inert absorbent material.

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.



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapors.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

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

assessment

Take care to prevent spills, waste and minimize release to the

environment.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis | |
|-------------|---|------------|-----------------------|----------|--|
| | | (Form of | ters / Permissible | | |
| | | exposure) | concentration | | |
| Propan-2-ol | 67-63-0 | LT | 310 ppm | BR OEL | |
| | | | 765 mg/m ³ | | |
| | Further information: Absorption through the skin, Degree of harm- | | | | |
| | fulness: medium | | | | |
| | | TWA | 200 ppm | ACGIH | |
| | | STEL | 400 ppm | ACGIH | |
| Ivermectin | 70288-86-7 | TWA | 30 μg/m3 (OEB 3) | Internal | |



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

| Further information: Skin | | | | |
|---------------------------|------------|----------------|----------|--|
| | Wipe limit | 300 µg/100 cm2 | Internal | |

Biological occupational exposure limits

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

Engineering measures : Use appropriate engineering controls and manufacturing

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

less quick connections).

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

protect products, workers, and the environment.

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

containment devices).
Minimize open handling.

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

Hand protection

Organic vapor Type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

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

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

Physical state : liquid

Color : clear

Straw-colored

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

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 : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 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: > 5.000 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Components:

Propan-2-ol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

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

Exposure time: 6 h
Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Cetyl octanoate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 401

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity : LC50 (Rat): > 5,7 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

Method: OECD Test Guideline 436

Remarks: Based on data from similar materials

Hexanoic acid, 2-ethyl-, octadecyl ester:

Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg

Remarks: Based on data from similar materials

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

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

Skin corrosion/irritation

Causes mild skin irritation.

Components:

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

Cetyl octanoate:

Species : Rabbit



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

Method : OECD Test Guideline 404

Result : Mild skin irritation

Hexanoic acid, 2-ethyl-, octadecyl ester:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

Remarks : Based on data from similar materials

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

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Ivermectin:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Cetyl octanoate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Hexanoic acid, 2-ethyl-, octadecyl ester:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

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

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Ivermectin:

Species : Rabbit

Result : Mild eye irritation



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Propan-2-ol:

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

Method : OECD Test Guideline 406

Result : negative

Cetyl octanoate:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact Result : negative

Remarks : Based on data from similar materials

Hexanoic acid, 2-ethyl-, octadecyl ester:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact
Species : Humans
Result : negative

Remarks : Based on data from similar materials

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

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

Assessment : Probability or evidence of skin sensitization in humans

Ivermectin:

Routes of exposure : Dermal Species : Humans

Result : Does not cause skin sensitization.

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

Propan-2-ol:

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

Result: negative



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Cetyl octanoate:

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

Method: OECD Test Guideline 471

Result: negative

Hexanoic acid, 2-ethyl-, octadecyl ester:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

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



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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

mutagenicity tests.

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 (vapor)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

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

Species: MouseApplication Route: Skin contactExposure time: 29 MonthsResult: negative

Ivermectin:

Species : Rat Application Route : Oral

NOAEL : 1,5 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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:

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

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

Species: Rat

Application Route: Ingestion

Result: negative

Hexanoic acid, 2-ethyl-, octadecyl ester:

Effects on fertility : Test Type: Fertility/early embryonic development

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: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

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

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

Species: Rat

Application Route: Ingestion
Method: OECD Test Guideline 414

Result: negative

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0,6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Development

Species: Mouse



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

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.

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:

Routes of exposure : Ingestion
Target Organs : nasal cavity

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

centrations of >10 to 100 mg/kg bw.

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

Repeated dose toxicity

Components:

Propan-2-ol:

Species : Rat NOAEL : 12,5 mg/l

Application Route : inhalation (vapor)
Exposure time : 104 Weeks

Cetyl octanoate:

Species : Rat

NOAEL : 1.000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Remarks : Based on data from similar materials

Hexanoic acid, 2-ethyl-, octadecyl ester:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Remarks : Based on data from similar materials

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

Species: RatNOAEL: 5 mg/kgLOAEL: 50 mg/kgApplication Route: IngestionExposure time: 90 Days

Method : OECD Test Guideline 408

Ivermectin:

Species: DogNOAEL: 0,5 mg/kgLOAEL: 1 mg/kgApplication Route: OralExposure 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



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 28.09.2024 10874507-00007 Date of first issue: 20.10.2022 3.0

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.

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

iting, anorexia, Lack of coordination

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Propan-2-ol:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): 9.640 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 10.000 mg/l

Exposure time: 24 h

: EC50 (Pseudomonas putida): > 1.050 mg/l Toxicity to microorganisms

Exposure time: 16 h

Cetyl octanoate:

: LL50 (Danio rerio (zebra fish)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

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

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 110

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Daphnia magna (Water flea)): > 1 mg/l

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Remarks: Based on data from similar materials

17/23



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

II

Hexanoic acid, 2-ethyl-, octadecyl ester:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 203

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

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

EL10 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOELR (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 21 d

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to microorganisms : EL50 (activated sludge): > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

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

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 24 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 40 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

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

110 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

na/l

Exposure time: 72 h

Method: OECD Test Guideline 201



Ivermectin (0.50%) Liquid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 20.02.2024 28.09.2024 10874507-00007 Date of first issue: 20.10.2022 3.0

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

Exposure time: 3 h

Method: OECD Test Guideline 209

Ivermectin:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9,1

10.000

10.000

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

M-Factor (Chronic aquatic

toxicity)

Persistence and degradability

Components:

Propan-2-ol:

Biodegradability Result: rapidly degradable

BOD/COD BOD: 1,19 (BOD5)

COD: 2.23 **BOD/COD: 53 %**

Cetyl octanoate:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 89,8 % Exposure time: 29 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

Hexanoic acid, 2-ethyl-, octadecyl ester:

Result: Readily biodegradable. Biodegradability

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

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

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 71 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

Bioaccumulative potential

Components:

Propan-2-ol:

Partition coefficient: n- : log Pow: 0,05

octanol/water

Cetyl octanoate:

Partition coefficient: n-

octanol/water

: log Pow: 6,15

Hexanoic acid, 2-ethyl-, octadecyl ester:

Partition coefficient: n- : log Pow: > 4

octanol/water Method: OECD Test Guideline 123

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

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.

If not otherwise specified: Dispose of as unused product.



Ivermectin (0.50%) Liquid Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 20.02.2024

 3.0
 28.09.2024
 10874507-00007
 Date of first issue: 20.10.2022

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Ivermectin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Ivermectin)

964

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
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

ANTT

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S. (Ivermectin)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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



Ivermectin (0.50%) Liquid Formulation

Version **Revision Date:** SDS Number: Date of last issue: 20.02.2024 28.09.2024 10874507-00007 Date of first issue: 20.10.2022 3.0

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

National List of Carcinogenic Agents for Humans -

Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

Police

Propan-2-ol

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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

not determined

DSL not determined

IECSC not determined

SECTION 16. OTHER INFORMATION

Revision Date 28.09.2024 Date format dd.mm.yyyy

Further information

Sources of key data used to

compile the Material Safety **Data Sheet**

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

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

Full text of other abbreviations

ACGIH USA, ACGIH Threshold Limit Values (TLV) **ACGIH BEI** ACGIH - Biological Exposure Indices (BEI)

BR BEI Brazil. NR7. Parameters for Biological Control of Occupational

Exposure to Some Chemical Agents

BR OEL Brazil. NR 15 - Unhealthy activities and operations

ACGIH / TWA 8-hour, time-weighted average ACGIH / STEL Short-term exposure limit BR OEL / LT Up to 48 hours /week

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 Sys-



Ivermectin (0.50%) Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 20.02.2024 3.0 28.09.2024 10874507-00007 Date of first issue: 20.10.2022

tem; 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.

BR / Z8