

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : 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 : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Skin corrosion/irritation : Category 3

Serious eye damage/eye irritation : Category 2A

Skin sensitisation : 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

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GHS label elements

Hazard pictograms



Signal word

: Warning

Hazard statements

: H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H341 Suspected of causing genetic defects.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P203 Obtain, read and follow all safety instructions before use.
P261 Avoid breathing mist or vapours.
P264+P265 Wash hands thoroughly after handling. Do not touch eyes.
P271 Use only outdoors or with adequate ventilation.
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:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help 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.
P318 IF exposed or concerned, get medical advice.
P333 + P317 If skin irritation or rash occurs: Get medical help.
P337 + P317 If eye irritation persists: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| Propan-2-ol | 67-63-0 | $\geq 70 - < 90$ |
| Cetyl octanoate | 59130-69-7 | $\geq 10 - < 20$ |
| Octadecyl 2-ethylhexanoate | 59130-70-0 | $\geq 10 - < 20$ |
| 7-Oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo[4.1.0]heptane-3-carboxylate | 2386-87-0 | $\geq 1 - < 2.5$ |
| Ivermectin | 70288-86-7 | $\geq 0.25 - < 1$ |

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).
- 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 : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

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| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency 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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.

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Version 5.0 Revision Date: 14.04.2025 SDS Number: 10874501-00008 Date of last issue: 28.09.2024
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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.

Conditions for safe storage : Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|---------------------------|----------------------------------|--|----------|
| Propan-2-ol | 67-63-0 | TWA | 200 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| Ivermectin | 70288-86-7 | TWA | 30 µg/m ³ (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 300 µg/100 cm ² | Internal |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|-------------|---------|--------------------|---------------------|----------------------------------|---------------------------|-----------|
| Propan-2-ol | 67-63-0 | Acetone | Urine | End of shift at end of work-week | 40 mg/l | 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 : Organic vapour type

Hand protection

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| | | |
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| 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. |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|-----------------------------|
| Appearance | : | liquid |
| Colour | : | clear Straw-coloured |
| Odour | : | characteristic |
| Odour 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 |

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| | | |
|--|---|--|
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle 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 reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

| | | |
|--|---|---|
| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion |
|--|---|---|

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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: vapour

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 toxicity

Acute inhalation toxicity : LC50 (Rat): > 5.7 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
Remarks: Based on data from similar materials

Octadecyl 2-ethylhexanoate:

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 inhalation toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402

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| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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 |
| Method | : OECD Test Guideline 404 |
| Result | : Mild skin irritation |

Octadecyl 2-ethylhexanoate:

| | |
|---------|--|
| 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 |

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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 |
| Method | : OECD Test Guideline 405 |
| Result | : No eye irritation |

Octadecyl 2-ethylhexanoate:

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

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:

Propan-2-ol:

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

Cetyl octanoate:

| | |
|-----------------|--|
| Test Type | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact |
| Result | : negative |
| Remarks | : Based on data from similar materials |

SAFETY DATA SHEET

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

Octadecyl 2-ethylhexanoate:

| | |
|-----------------|--|
| Test Type | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : 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 | : Maximisation Test |
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Result | : positive |

| | |
|------------|---|
| Assessment | : Probability or evidence of skin sensitisation in humans |
|------------|---|

Ivermectin:

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

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

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 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 |
|-----------------------|---|

Octadecyl 2-ethylhexanoate:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials |
|-----------------------|--|

SAFETY DATA SHEET

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| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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 mammalian cells Result: positive |
| | Test Type: DNA damage and repair, unscheduled DNA synthesis 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 assay 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- |

SAFETY DATA SHEET

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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 |

Ivermectin:

| | |
|-------------------|--|
| Species | : Rat |
| Application Route | : Oral |
| NOAEL | : 1.5 mg/kg body weight |
| Result | : negative |
| Remarks | : Based on data from similar materials |

| | |
|-------------------|--|
| Species | : Mouse |
| Application Route | : Oral |
| NOAEL | : 2.0 mg/kg body weight |
| Result | : negative |
| Remarks | : Based on data from similar materials |

Reproductive toxicity

Not classified based on available information.

Components:

Propan-2-ol:

| | |
|----------------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
| Effects on foetal develop- | : Test Type: Embryo-foetal development |

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ment

Species: Rat
Application Route: Ingestion
Result: negative

Octadecyl 2-ethylhexanoate:

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 foetal development : Test Type: Embryo-foetal 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 foetal development : Test Type: Embryo-foetal 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 foetal development : Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.4 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected.
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Development
Species: Rabbit
Application Route: Oral

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| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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:

Exposure routes : Ingestion
Target Organs : nasal cavity
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Ivermectin:

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

Repeated dose toxicity

Components:

Propan-2-ol:

Species : Rat
NOAEL : 12.5 mg/l
Application Route : inhalation (vapour)
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

Octadecyl 2-ethylhexanoate:

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

| | |
|-------------------|--|
| 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 | : Rat |
| NOAEL | : 5 mg/kg |
| LOAEL | : 50 mg/kg |
| Application Route | : Ingestion |
| Exposure time | : 90 Days |
| Method | : OECD Test Guideline 408 |

Ivermectin:

| | |
|-------------------|--|
| Species | : Dog |
| NOAEL | : 0.5 mg/kg |
| LOAEL | : 1 mg/kg |
| Application Route | : Oral |
| Exposure time | : 14 Weeks |
| Target Organs | : Central nervous system |
| Symptoms | : Dilatation of the pupil, Tremors, Lack of coordination, anorexia |

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

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Ivermectin:

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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 |

Cetyl octanoate:

| | |
|--|--|
| 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)): > 110 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: > 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials |

Octadecyl 2-ethylhexanoate:

| | |
|---|---|
| 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 |

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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 microorganisms : EL50 (activated sludge): > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOELR: > 1 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Test substance: Water Accommodated Fraction
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 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (activated sludge): 409 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

| | |
|---|---|
| | 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 toxicity) | : 10,000 |
| M-Factor (Chronic aquatic toxicity) | : 10,000 |

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 |
|------------------|--|

Octadecyl 2-ethylhexanoate:

| | |
|------------------|---|
| Biodegradability | : Result: Readily biodegradable. Method: OECD Test Guideline 301B Remarks: Based on data from similar materials |
|------------------|---|

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:

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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

Bioaccumulative potential

Components:

Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

Cetyl octanoate:

Partition coefficient: n-octanol/water : log Pow: 6.15

Octadecyl 2-ethylhexanoate:

Partition coefficient: n-octanol/water : log Pow: > 4
Method: OECD Test Guideline 123

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

Partition coefficient: n-octanol/water : log Pow: 1.34
Method: OECD Test Guideline 107

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

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

Mobility in soil

No data available

Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
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 IMO instruments

Not applicable for product as supplied.

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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

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

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

16. OTHER INFORMATION

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

Revision Date : 14.04.2025

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

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

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

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 mate-

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin (0.50%) Liquid Formulation

| | | | |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024 |
| 5.0 | 14.04.2025 | 10874501-00008 | Date of first issue: 20.10.2022 |

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.

IN / EN