

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Ivermectin / Abamectin Liquid Formulation

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

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

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

Specific target organ toxicity - single exposure : Category 3

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

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Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

| | | |
|--------------------------|---|--|
| Hazard pictograms | : | Three red diamond hazard pictograms. The first shows a person with a splash on their head. The second shows a large exclamation mark. The third shows a dead tree and fish in a body of water. |
| Signal word | : | Danger |
| Hazard statements | : | <p>H302 + H332 Harmful if swallowed or if inhaled. H315 + H319 Causes skin irritation and serious eye irritation. H335 May cause respiratory irritation. H360D May damage the unborn child. H371 May cause damage to organs (Central nervous system) if swallowed. H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.</p> |
| Precautionary statements | : | <p>Prevention: P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe mist or vapours. P264+P265 Wash hands thoroughly after handling. Do not touch eyes. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or with adequate ventilation. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>Response: P301 + P317 + P330 IF SWALLOWED: Get medical help. Rinse mouth. P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 + P317 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help. 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 + P316 IF exposed or concerned: Get emergency medical help immediately. P332 + P317 If skin irritation 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.</p> <p>Storage: P405 Store locked up.</p> |

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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

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| N-Methyl-2-pyrrolidone | 872-50-4 | >= 20 - < 30 |
| Ivermectin | 70288-86-7 | >= 1 - < 2.5 |
| abamectin (combination of avermectin B1a and avermectin B1b) (ISO) | 71751-41-2 | >= 1 - < 2.5 |
| (dl)-a-Tocopheryl acetate | 7695-91-2 | < 0.1 |

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.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing 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.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed or if inhaled.
Causes skin irritation and serious eye irritation.
May cause respiratory irritation.
May damage the unborn child.
May cause damage to organs if swallowed.
May cause damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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Notes to physician : when the potential for exposure exists (see section 8).
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.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)

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.

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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.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.
Do not eat, drink or smoke when using this product.
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 tightly closed.
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 parame- ters / Permissible concentration | Basis |
|--|---------------------------|-------------------------------------|--|----------|
| Ivermectin | 70288-86-7 | TWA | 30 µg/m ³ (OEB 3) | Internal |
| | Further information: Skin | | | |
| abamectin (combination of avermectin B1a and avermectin B1b) (ISO) | 71751-41-2 | Wipe limit | 300 µg/100 cm ² | Internal |
| | | TWA | 15 µg/m ³ (OEB 3) | Internal |
| (dl)-a-Tocopheryl acetate | 7695-91-2 | Wipe limit | 150 µg/100 cm ² | Internal |
| | | TWA | 5000 µg/m ³ (OEB 1) | Internal |

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Version
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Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampli- ng time | Permissible concentra- tion | Basis |
|------------------------|----------|--|---------------------|--|-----------------------------------|--------------|
| N-Methyl-2-pyrrolidone | 872-50-4 | 5-Hydroxy- N-methyl-2- pyrrolidone | Urine | End of shift (As soon as possible after exposure ceases) | 100 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 | : Combined particulates and organic vapour type |
| Material | : Chemical-resistant gloves |
| Remarks | |
| Eye protection | : Consider double gloving. : 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. 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 |

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use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------|
| Appearance | : | liquid |
| Colour | : | light yellow |
| 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 | : | > 100 °C |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | 0.91 - 1.00 mg/l |
| Solubility(ies) | | |
| Water solubility | : | insoluble |
| 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 |

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Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

| | |
|--------------------------|--|
| 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 Eye contact |
|--|--|

Acute toxicity

Harmful if swallowed or if inhaled.

Product:

| | |
|---------------------------|--|
| Acute oral toxicity | : Acute toxicity estimate: 981.33 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : Acute toxicity estimate: 1.84 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |
| Acute dermal toxicity | : Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method |

Components:

N-Methyl-2-pyrrolidone:

| | |
|---------------------------|--|
| Acute oral toxicity | : LD50 (Rat): 4,150 mg/kg Method: OECD Test Guideline 401 Remarks: The test was conducted equivalent or similar to guideline |
| Acute inhalation toxicity | : LC50 (Rat): > 5.1 mg/l Exposure time: 4 h Test atmosphere: dust/mist |

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Version
8.0

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SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

Method: OECD Test Guideline 403

Remarks: The test was conducted according to guideline

Acute dermal toxicity

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

Method: OECD Test Guideline 402

Remarks: The test was conducted equivalent or similar to guideline

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Acute oral toxicity

: LD50 (Rat): 24 mg/kg

LD50 (Mouse): 10 mg/kg

LDLo (Monkey): 24 mg/kg

Symptoms: Dilatation of the pupil

Acute inhalation toxicity

: LC50 (Rat): 0.023 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity

: LD50 (Rat): 330 mg/kg

LD50 (Rabbit): 2,000 mg/kg

(dl)-a-Tocopheryl acetate:

Acute oral toxicity

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

Acute dermal toxicity

: LD50 (Rat): > 3,000 mg/kg

Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Causes skin irritation.

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Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

Components:

N-Methyl-2-pyrrolidone:

| | | |
|---------|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 404 |
| Result | : | Skin irritation |
| Remarks | : | The test was conducted equivalent or similar to guideline |

Ivermectin:

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

(dl)-a-Tocopheryl acetate:

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

N-Methyl-2-pyrrolidone:

| | | |
|---------|---|---|
| Species | : | Rabbit |
| Method | : | OECD Test Guideline 405 |
| Result | : | Irritation to eyes, reversing within 21 days |
| Remarks | : | The test was conducted equivalent or similar to guideline |

Ivermectin:

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|---------|---|---------------------|
| Species | : | Rabbit |
| Result | : | Mild eye irritation |

(dl)-a-Tocopheryl acetate:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
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Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

Respiratory sensitisation

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

| | | |
|-----------------|---|--------------------------------------|
| Test Type | : | Local lymph node assay (LLNA) |
| Exposure routes | : | Skin contact |
| Species | : | Mouse |
| Method | : | OECD Test Guideline 429 |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

Ivermectin:

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|-----------------|---|------------------------|
| Test Type | : | Maximisation Test |
| Exposure routes | : | Skin contact |
| Result | : | Not a skin sensitizer. |

(dl)-a-Tocopheryl acetate:

| | | |
|-----------------|---|--------------|
| Test Type | : | Draize Test |
| Exposure routes | : | Skin contact |
| Species | : | Humans |
| Result | : | negative |

Germ cell mutagenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: The test was conducted according to guideline |
| | | Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: The test was conducted according to guideline |
| | | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Method: OECD Test Guideline 482 Result: negative Remarks: The test was conducted equivalent or similar to guideline |

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: The test was conducted according to guideline

Ivermectin:

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

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

Test Type: Mouse Lymphoma
Result: negative

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Result: negative

Test Type: Alkaline elution assay
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

(dl)-a-Tocopheryl acetate:

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

Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

Carcinogenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

| | | |
|-------------------|---|---|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 2 Years |
| Method | : | OECD Test Guideline 451 |
| Result | : | negative |
| Remarks | : | The test was conducted according to guideline |

| | | |
|-------------------|---|---|
| Species | : | Rat |
| Application Route | : | Inhalation |
| Exposure time | : | 2 Years |
| Method | : | OECD Test Guideline 453 |
| Result | : | negative |
| Remarks | : | The test was conducted equivalent or similar to guideline |

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 |

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 105 weeks |
| Result | : | negative |

| | | |
|-------------------|---|----------|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 93 weeks |
| Result | : | negative |

(dl)-a-Tocopheryl acetate:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| Application Route | : | Ingestion |
| Exposure time | : | 104 weeks |

SAFETY DATA SHEET

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Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

N-Methyl-2-pyrrolidone:

| | |
|------------------------------------|---|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: The test was conducted according to guideline |
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted according to guideline |
| | Test Type: Fertility/early embryonic development Species: Rat Application Route: inhalation (vapour) Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted equivalent or similar to guideline |
| | Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted equivalent or similar to guideline |
| Reproductive toxicity - Assessment | : Clear evidence of adverse effects on development, based on animal experiments. |

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 |

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24.03.2025

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Date of last issue: 03.02.2025
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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
Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Effects on fertility

: Test Type: Fertility
Species: Rat, male
Application Route: Oral
Result: Effects on fertility

Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Early Embryonic Development: NOAEL: 0.12 mg/kg body weight
Result: Fetotoxicity

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
General Toxicity Maternal: NOAEL: 0.05 mg/kg body weight
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight
Result: Cleft palate
Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 2 mg/kg body weight
Result: Cleft palate, Teratogenic effects, Reduced embryonic survival
Remarks: Adverse developmental effects were observed

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 1.6 mg/kg body weight
Result: Teratogenic effects

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

(dl)-a-Tocopheryl acetate:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

STOT - single exposure

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

Components:

N-Methyl-2-pyrrolidone:

Assessment : May cause respiratory irritation.

Ivermectin:

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

STOT - repeated exposure

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

Components:

Ivermectin:

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

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

Repeated dose toxicity

Components:

N-Methyl-2-pyrrolidone:

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

| | | |
|-------------------|---|---|
| Species | : | Rat, male |
| NOAEL | : | 169 mg/kg |
| LOAEL | : | 433 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 408 |
| Remarks | : | The test was conducted according to guideline |

| | | |
|-------------------|---|---|
| Species | : | Rat |
| NOAEL | : | 0.5 mg/l |
| LOAEL | : | 1 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 96 Days |
| Method | : | OECD Test Guideline 413 |
| Remarks | : | The test was conducted according to guideline |

| | | |
|-------------------|---|---|
| Species | : | Rabbit, male |
| NOAEL | : | 826 mg/kg |
| LOAEL | : | 1,653 mg/kg |
| Application Route | : | Skin contact |
| Exposure time | : | 20 Days |
| Method | : | OECD Test Guideline 410 |
| Remarks | : | The test was conducted equivalent or similar to guideline |

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 |

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|-------------------|---|------------------------|
| Species | : | Rat |
| NOAEL | : | 1.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 24 Months |
| Target Organs | : | Central nervous system |
| Symptoms | : | Tremors, ataxia |

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

| | | |
|-------------------|---|------------------------|
| Species | : | Mouse |
| NOAEL | : | 4.0 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 24 Months |
| Target Organs | : | Central nervous system |
| Symptoms | : | Tremors, ataxia |

| | | |
|-------------------|---|------------------------|
| Species | : | Dog |
| NOAEL | : | 0.25 mg/kg |
| LOAEL | : | 0.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 53 Weeks |
| Target Organs | : | Central nervous system |
| Symptoms | : | Tremors, weight loss |
| Remarks | : | mortality observed |

| | | |
|-------------------|---|------------------------|
| Species | : | Monkey |
| NOAEL | : | 1.0 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 14 Weeks |
| Target Organs | : | Central nervous system |

(dl)-a-Tocopheryl acetate:

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| NOAEL | : | 500 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

| | | |
|--------------|---|---------------------------|
| Skin contact | : | Symptoms: Skin irritation |
|--------------|---|---------------------------|

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 |

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|-----------|---|--|
| Ingestion | : | Symptoms: May cause, Tremors, Diarrhoea, central nervous system effects, Salivation, tearing |
|-----------|---|--|

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Methyl-2-pyrrolidone:

| | |
|--|--|
| Toxicity to fish | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: DIN 38412 Remarks: The test was conducted according to guideline |
| Toxicity to algae/aquatic plants | : ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : EC50 (activated sludge): > 600 mg/l Exposure time: 30 min Method: ISO 8192 Remarks: The test was conducted according to guideline |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 12.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: The test was conducted according to guideline |

Ivermectin:

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

M-Factor (Acute aquatic toxicity) : 10,000

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3.2 µg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.6 µg/l
Exposure time: 96 h

LC50 (Ictalurus punctatus (channel catfish)): 24 µg/l
Exposure time: 96 h

LC50 (Cyprinus carpio (Carp)): 42 µg/l
Exposure time: 96 h

LC50 (Cyprinodon variegatus (sheepshead minnow)): 15 µg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): 0.022 µg/l
Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 0.34 µg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 10,000

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition

Toxicity to fish (Chronic toxicity) : NOEC: 0.52 µg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.03 µg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

NOEC: 0.0035 µg/l
Exposure time: 28 d
Species: Mysidopsis bahia (opossum shrimp)

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

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

(dl)-a-Tocopheryl acetate:

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| 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 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC50: > 927 mg/l Exposure time: 30 min Method: ISO 8192 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 100 mg/l Exposure time: 28 d Species: Oncorhynchus mykiss (rainbow trout) |

Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:

| | | |
|------------------|---|---|
| Biodegradability | : | Result: Readily biodegradable. Biodegradation: 73 % Exposure time: 28 d Method: OECD Test Guideline 301C Remarks: The test was conducted according to guideline |
|------------------|---|---|

Ivermectin:

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

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

| | | |
|--------------------|---|--------------------------|
| Stability in water | : | Hydrolysis: 50 %(< 12 h) |
|--------------------|---|--------------------------|

(dl)-a-Tocopheryl acetate:

| | | |
|------------------|---|--|
| Biodegradability | : | Result: Not readily biodegradable. Biodegradation: 21.7 - 31 % Exposure time: 28 d Method: OECD Test Guideline 301C |
|------------------|---|--|

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

II

Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0.46
Method: OECD Test Guideline 107
Remarks: The test was conducted according to guideline

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74
Partition coefficient: n-octanol/water : log Pow: 3.22

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Bioaccumulation : Bioconcentration factor (BCF): 52
Partition coefficient: n-octanol/water : log Pow: 4

Mobility in soil

Components:

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Distribution among environmental compartments : log Koc: > 3.6

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

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(abamectin (combination of avermectin B1a and avermectin

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version 8.0 Revision Date: 24.03.2025 SDS Number: 1212763-00026 Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

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

B1b) (ISO), Ivermectin

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), 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.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), 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 / Abamectin Liquid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 8.0 | Revision Date: 24.03.2025 | SDS Number: 1212763-00026 | Date of last issue: 03.02.2025 Date of first issue: 10.01.2017 |
|----------------|------------------------------|------------------------------|---|

Revision Date : 24.03.2025

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 BEI : ACGIH - Biological Exposure Indices (BEI)

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; KECL - 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

SAFETY DATA SHEET

according to the Globally Harmonized System



Ivermectin / Abamectin Liquid Formulation

Version
8.0

Revision Date:
24.03.2025

SDS Number:
1212763-00026

Date of last issue: 03.02.2025
Date of first issue: 10.01.2017

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