

Ivermectin / Abamectin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	1210018-00024	Date of first issue: 10.01.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Ivermectin / Abamectin Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Acute toxicity, Category 4	H302: Harmful if swallowed.
Acute toxicity, Category 4	H332: Harmful if inhaled.
Skin irritation, Category 2	H315: Causes skin irritation.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 2	H371: May cause damage to organs.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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- Hazard pictograms : 
- Signal word : Danger
- Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.
 H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H360D May damage the unborn child.
 H371 May cause damage to organs.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**
 P201 Obtain special instructions before use.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**
 P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
 P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
 P391 Collect spillage.

Hazardous components which must be listed on the label:

N-Methyl-2-pyrrolidone
 Ivermectin
 abamectin (combination of avermectin B1a and avermectin B1b) (ISO)

Additional Labelling

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

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N-Methyl-2-pyrrolidone	872-50-4 212-828-1 606-021-00-7	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D STOT SE 3; H335	>= 20 - < 30
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	>= 1 - < 2,5
abamectin (combination of avermectin B1a and avermectin B1b) (ISO)	71751-41-2 606-143-00-0	Acute Tox. 2; H300 Acute Tox. 1; H330 Acute Tox. 3; H311 Repr. 2; H361fd STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	>= 1 - < 2,5
(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		< 0,1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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

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- advice.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed or if inhaled.
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.
May damage the unborn child.
May cause damage to organs.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

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5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- 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.
- 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 use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : 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.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

- Specific use(s) : No data available

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SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
N-Methyl-2-pyrrolidone	872-50-4	TWA	10 ppm 40 mg/m ³	2009/161/EU
		STEL	20 ppm 80 mg/m ³	2009/161/EU
		TWA	10 ppm 40 mg/m ³	2004/37/EC
		STEL	20 ppm 80 mg/m ³	2004/37/EC
Ivermectin	70288-86-7	TWA	30 µg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	300 µg/100 cm ²	Internal
abamectin (combination of avermectin B1a and avermectin B1b) (ISO)	71751-41-2	TWA	15 µg/m ³ (OEB 3)	Internal
		Wipe limit	150 µg/100 cm ²	Internal
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 µg/m ³ (OEB 1)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
N-Methyl-2-pyrrolidone	Workers	Inhalation	Long-term systemic effects	14,4 mg/m ³
		Inhalation	Long-term local effects	40 mg/m ³
		Skin contact	Long-term systemic effects	4,8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3,6 mg/m ³
		Inhalation	Long-term local effects	4,5 mg/m ³
		Skin contact	Long-term systemic effects	2,4 mg/kg bw/day
		Ingestion	Long-term systemic effects	0,85 mg/kg bw/day
(dl)-a-Tocopheryl acetate	Workers	Inhalation	Long-term systemic effects	73,5 mg/m ³
		Skin contact	Long-term systemic effects	416,6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	21,7 mg/m ³
		Skin contact	Long-term systemic effects	250 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic	12,5 mg/kg

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			effects	bw/day
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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
N-Methyl-2-pyrrolidone	Fresh water	0,25 mg/l
	Freshwater - intermittent	5 mg/l
	Marine water	0,025 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	1,09 mg/kg dry weight (d.w.)
	Marine sediment	1,09 mg/kg dry weight (d.w.)
	Soil	0,07 mg/kg dry weight (d.w.)
(dl)-a-Tocopheryl acetate	Fresh water	0,27 mg/l
	Marine water	0,027 mg/l
	Intermittent use/release	0,27 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	212000 mg/kg
	Marine sediment	21200 mg/kg
	Soil	74800 mg/kg

8.2 Exposure controls**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

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

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Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties**9.1 Information on basic 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

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

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

9.2 Other information

Flammability (liquids) : No data available

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Molecular weight : No data available

Particle size : Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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: 1.031 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: > 2.000 mg/kg
Method: Calculation method

Components:

N-Methyl-2-pyrrolidone:

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Acute oral toxicity : LD50 (Rat): 4.150 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg
LD50 (Mouse): 25 mg/kg
LD50 (Monkey): > 24 mg/kg
Target Organs: Central nervous system
Symptoms: Vomiting, Dilatation of the pupil
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5,11 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg
LD50 (Rat): > 660 mg/kg

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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Components:**N-Methyl-2-pyrrolidone:**

Result : Skin irritation

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
Result : Irritation to eyes, reversing within 21 days

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.

Respiratory sensitisation

Not classified based on available information.

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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

Test Type: In vitro mammalian cell gene mutation test
 Method: OECD Test Guideline 476
 Result: negative

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

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

Test Type: Mutagenicity (in vivo mammalian bone-marrow

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cytogenetic test, chromosomal analysis)
Species: Hamster
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative

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

Carcinogenicity

Not classified based on available information.

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Components:**N-Methyl-2-pyrrolidone:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Species : Rat
Application Route : inhalation (vapour)
Exposure time : 2 Years
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

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
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

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- Method: OECD Test Guideline 416
Result: negative
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: positive
- Test Type: Fertility/early embryonic development
Species: Rat
Application Route: inhalation (vapour)
Result: positive
- Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: positive
- 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 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):

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- 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
- 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.

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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 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:**

Species : Rat, male
 NOAEL : 169 mg/kg
 LOAEL : 433 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Method : OECD Test Guideline 408

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

Species : Rabbit
 NOAEL : 826 mg/kg
 LOAEL : 1.653 mg/kg
 Application Route : Skin contact
 Exposure time : 20 Days

Ivermectin:

Species : Dog

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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

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

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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

SECTION 12: Ecological information**12.1 Toxicity****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

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 : > 600 mg/l
Exposure time: 30 min
Method: ISO 8192

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

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,003 mg/l
Exposure time: 96 h

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		LC50 (<i>Lepomis macrochirus</i> (Bluegill sunfish)): 0,0048 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): 0,000025 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 9,1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (<i>Pseudokirchneriella subcapitata</i> (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
abamectin (combination of avermectin B1a and avermectin B1b) (ISO):		
Toxicity to fish	:	LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): 3,2 µg/l Exposure time: 96 h
		LC50 (<i>Lepomis macrochirus</i> (Bluegill sunfish)): 9,6 µg/l Exposure time: 96 h
		LC50 (<i>Ictalurus punctatus</i> (channel catfish)): 24 µg/l Exposure time: 96 h
		LC50 (<i>Cyprinus carpio</i> (Carp)): 42 µg/l Exposure time: 96 h
		LC50 (<i>Cyprinodon variegatus</i> (sheepshead minnow)): 15 µg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Americamysis</i>): 0,022 µg/l Exposure time: 96 h
		EC50 (<i>Daphnia magna</i> (Water flea)): 0,34 µg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (<i>Pseudokirchneriella subcapitata</i> (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

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- 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
- (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)

12.2 Persistence and degradability**Components:****N-Methyl-2-pyrrolidone:**

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 73 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Ivermectin:

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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

12.3 Bioaccumulative potential**Components:****N-Methyl-2-pyrrolidone:**

Partition coefficient: n- : log Pow: -0,46
octanol/water : Method: OECD Test Guideline 107

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n- : log Pow: 3,22
octanol/water

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

Bioaccumulation : Bioconcentration factor (BCF): 52

Partition coefficient: n- : log Pow: 4
octanol/water

12.4 Mobility in soil**Components:****abamectin (combination of avermectin B1a and avermectin B1b) (ISO):**

Distribution among environ- : log Koc: > 3,6
mental compartments

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects**Product:**

Endocrine disrupting poten- : The substance/mixture does not contain components consid-

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ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.

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.

SECTION 14: Transport information**14.1 UN number**

ADN : UN 3082

ADR : UN 3082

RID : UN 3082

IMDG : UN 3082

IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), Ivermectin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), Ivermectin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), Ivermectin)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(abamectin (combination of avermectin B1a and avermectin B1b) (ISO), Ivermectin)

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14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous
IATA (Passenger)	
Packing instruction (passenger aircraft)	: 964
Packing instruction (LQ)	: Y964
Packing group	: III
Labels	: Miscellaneous

14.5 Environmental hazards

ADN	
Environmentally hazardous	: yes
ADR	
Environmentally hazardous	: yes
RID	

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Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : 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 H-Statements

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin.

H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H330 : Fatal if inhaled.

H335 : May cause respiratory irritation.

H360D : May damage the unborn child.

H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.

H370 : Causes damage to organs if swallowed.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

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H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
2009/161/EU : Europe. COMMISSION DIRECTIVE 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
2004/37/EC / STEL : Short term exposure limit
2004/37/EC / TWA : Long term exposure limit
2009/161/EU / TWA : Limit Value - eight hours
2009/161/EU / STEL : Short term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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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/>

Classification of the mixture:

Acute Tox. 4	H302
Acute Tox. 4	H332
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Repr. 1B	H360D
STOT SE 2	H371
STOT SE 3	H335
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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.

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