SAFETY DATA SHEET
generated in accordance with Regulation (EC) No. 1907/2006

Ivermectin / Abamectin Liquid Formulation

Version 4.0 Revision Date: 09/13/2019 SDS Number: 1212766-00009 Date of last issue: 24.04.2019
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 Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
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)
Ivermectin / Abamectin Liquid Formulation

Hazard pictograms : [signal word and 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)

Additional Labelling
Restricted to professional users.

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>212-828-1</td>
<td></td>
<td>Skin Irrit.2; H315 Eye Irrit.2; H319</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
</tbody>
</table>
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 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 soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. 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 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.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
 Nitrogen oxides (NOx)
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 and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided. 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOLOG 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 vapours or spray mist. Do not swallow. Do not get in eyes. 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 should consult their physician regarding working with respiratory irritants or sensitisers. 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, Organic peroxides, Explosives, Gases.

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>TWA</td>
<td>5 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>20 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Short Term Value is a value for the average concentration of a chemical in the breathing zone of a worker not to be exceeded in a specified reference peri-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
According to Regulation (EC) No. 1907/2006, the reference period is 15 minutes if no other reference periods are given. The EU has set an indicative limit value for this substance, Substances considered to be reprotoxic, Chemicals that can be absorbed through the skin.

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>TWA</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>10 ppm</td>
<td>40 mg/m³ 2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
</tr>
<tr>
<td></td>
<td>Further information</td>
<td>Identifies the possibility of significant uptake through the skin, Indicative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Further information</td>
<td>Identifies the possibility of significant uptake through the skin, Indicative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ivermectin 70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Further information</td>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Abamectin (combination of avermectin B1a and avermectin B1b) 71751-41-2</td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>30 μg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>300 μg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>(dl)-a-Tocopheryl acetate 7695-91-2</td>
<td>TWA</td>
<td>5000 μg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Fresh water</td>
<td>0.25 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>5 mg/l</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Fresh water</td>
<td>0.25 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>5 mg/l</td>
</tr>
</tbody>
</table>
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 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.

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
- Not applicable

### 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)
- Not applicable

### 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:
- Acute oral toxicity: LD50 (Rat): 4.150 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 5,1 mg/l
  Exposure time: 4 h
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Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

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):

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.
Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Skin irritation</td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>Abamectin (combination of avermectin B1a and avermectin B1b)</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>No skin irritation</td>
<td></td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Irritation to eyes, reversing within 21 days</td>
<td>Based on harmonised classification in EU regulation 1272/2008, Annex VI</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Mild eye irritation</td>
<td></td>
</tr>
<tr>
<td>Abamectin (combination of avermectin B1a and avermectin B1b)</td>
<td>Mild eye irritation</td>
<td></td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>No eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.
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):
- 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

Ivermectin:
- 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
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):
- 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.

Components:

N-Methyl-2-pyrrolidone:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
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**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)**:

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

- **Species**: Mouse
- **Application Route**: Oral
- **Exposure time**: 93 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  
  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
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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):
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
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.

Components:

N-Methyl-2-pyrrolidone:

Assessment: May cause respiratory irritation.

Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
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Version: 4.0
Revision Date: 09/13/2019
SDS Number: 1212766-00009
Date of last issue: 24.04.2019
Date of first issue: 10.01.2017

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):
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

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):

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
Exposure time: 90 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

Abamectin (combination of avermectin B1a and avermectin B1b):
- Ingestion: Symptoms: May cause, Tremors, Diarrhoea, central nervous
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
- **Toxicity to algae/aquatic plants (Chronic toxicity):**
  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
  LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0048 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 0,000025 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,1 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
  NOEC (Pseudokirchneriella subcapitata (green algae)): 9,1 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- **M-Factor (Acute aquatic toxicity):** 10,000
### Abamectin (combination of avermectin B1a and avermectin B1b):

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 3.2 µg/l Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.6 µg/l Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>LC50 (Ictalurus punctatus (channel catfish)): 24 µg/l Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinus carpio (Carp)): 42 µg/l Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinodon variegatus (sheepshead minnow)): 15 µg/l Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Americamysis): 0.022 µg/l Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): 0.34 µg/l Exposure time: 48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC: 0.52 µg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC: 0.03 µg/l Exposure time: 21 d Species: Daphnia magna (Water flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC: 0.0035 µg/l Exposure time: 28 d Species: Mysis bahia (opossum shrimp)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic aquatic toxicity)</th>
<th>10.000</th>
</tr>
</thead>
</table>

### (dl)-a-Tocopheryl acetate:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l Exposure time: 96 h</th>
</tr>
</thead>
</table>
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): \( > 100 \text{ mg/l} \)
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): \( > 100 \text{ mg/l} \)
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): \( \geq 100 \text{ mg/l} \)
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms

EC50: \( > 927 \text{ mg/l} \)
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:**

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

**Abamectin (combination of avermectin B1a and avermectin B1b):**

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-octanol/water : log Pow: -0.46

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

Abamectin (combination of avermectin B1a and avermectin B1b):
 Bioaccumulation : Bioconcentration factor (BCF): 52
 Partition coefficient: n-octanol/water : log Pow: 4

12.4 Mobility in soil

Components:

Abamectin (combination of avermectin B1a and avermectin B1b):
 Distribution among environmental compartments : log Koc: > 3.6

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

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.
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

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 3082</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>
## Ivermectin / Abamectin Liquid Formulation

### 14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Abamectin (combination of avermectin B1a and avermectin B1b), Ivermectin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Abamectin (combination of avermectin B1a and avermectin B1b), Ivermectin)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Abamectin (combination of avermectin B1a and avermectin B1b), Ivermectin)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Abamectin (combination of avermectin B1a and avermectin B1b), Ivermectin)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Abamectin (combination of avermectin B1a and avermectin B1b), Ivermectin)</td>
</tr>
</tbody>
</table>

### 14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

### 14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>Packing group: III, Classification Code: M6, Hazard Identification Number: 90, Labels: 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Packing group: III, Classification Code: M6, Hazard Identification Number: 90, Labels: 9, Tunnel restriction code: (-)</td>
</tr>
<tr>
<td>RID</td>
<td>Packing group: III, Classification Code: M6, Hazard Identification Number: 90</td>
</tr>
</tbody>
</table>
Ivermectin / Abamectin Liquid Formulation

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
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according to Regulation (EC) No. 1907/2006

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Date of first issue: 10.01.2017

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59):
- N-Methyl-2-pyrrolidone

REACH - List of substances subject to authorisation (Annex XIV):
- Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:
- Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants:
- Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:
- Not applicable


Environmental Hazards:

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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.
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H370 : Causes damage to organs if swallowed.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
2009/161/EU / TWA : Limit Value - eight hours
2009/161/EU / STEL : Short term exposure limit
FOR-2011-12-06-1358 / TWA : Long term exposure limit
FOR-2011-12-06-1358 / STEL : Short term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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; ICAR - 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;
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according to Regulation (EC) No. 1907/2006

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SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

Further information

Classification of the mixture:

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

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

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.

NO / EN