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
20 Spartan Road
1619 Spartan, South Africa

Telephone: +27119239300
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)**
Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or 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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>Skin Irrit.2; H315</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>212-828-1</td>
<td>Eye Irrit.2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td>606-021-00-7</td>
<td>Repr.1B; H360D</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ivermectin / Abamectin Liquid Formulation

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 plenty of water.

For explanation of abbreviations see section 16.
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.

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/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 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 OEL-RL</td>
<td>100 ppm 400 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm 40 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm 80 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Abamectin (combination of avermec-</td>
<td>71751-41-2</td>
<td>TWA</td>
<td>30 µg/m³ (OEB 3)</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>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>40 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4.8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3.6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>4.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.85 mg/kg bw/day</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>73.5 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>416.6 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>21.7 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>250 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>12.5 mg/kg bw/day</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>
<tr>
<td></td>
<td>Marine water</td>
<td>0.025 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.07 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Fresh water</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.027 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.27 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>212000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>212000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>74800 mg/kg</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 facesheild 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*

*Material*: 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*

*Material*: 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
  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
**SAFETY DATA SHEET**

**Ivermectin / Abamectin Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>4.1</td>
<td>23.03.2020</td>
<td>1210018-00010</td>
<td>13.09.2019</td>
<td>10.01.2017</td>
</tr>
</tbody>
</table>

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:**

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

Result: Skin irritation

**Ivermectin:**

Species: Rabbit  
Result: No skin irritation

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

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):
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.

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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 471</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
</tr>
<tr>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>OECD Test Guideline 474</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>OECD Test Guideline 475</td>
<td>negative</td>
</tr>
<tr>
<td>Species: Hamster</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ivermectin:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Test system: human diploid fibroblasts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mouse Lymphoma</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Test system: Chinese hamster lung cells</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Genotoxicity in vivo:
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
Result: negative

Species: Rat
Application Route: Inhilation (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):
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
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):

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.

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):
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
- **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:

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

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

M-Factor (Chronic aquatic toxicity) : 10.000
Abamectin (combination of avermectin B1a and avermectin B1b):

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: Mysisopsis 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:
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
Method: OECD Test Guideline 107
SAFETY DATA SHEET

Ivermectin / Abamectin Liquid Formulation

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

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), Ivermectin)
SAFETY DATA SHEET

Ivermectin / Abamectin Liquid Formulation

Version 4.1  Revision Date: 23.03.2020  SDS Number: 1210018-00010  Date of last issue: 13.09.2019
Date of first issue: 10.01.2017

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

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

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

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

14.3 Transport hazard class(es)

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
SAFETY DATA SHEET

Ivermectin / Abamectin Liquid Formulation

Version 4.1
Revision Date: 23.03.2020
SDS Number: 1210018-00010
Date of last issue: 13.09.2019
Date of first issue: 10.01.2017

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
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
SAFETY DATA SHEET
Ivermectin / Abamectin Liquid Formulation

Version 4.1
Revision Date: 23.03.2020
SDS Number: 1210018-00010
Date of last issue: 13.09.2019
Date of first issue: 10.01.2017

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.
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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
2009/161/EU / TWA : Limit Value - eight hours
2009/161/EU / STEL : Short term exposure limit
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended 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; 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
SAFETY DATA SHEET

Ivermectin / Abamectin Liquid Formulation

Version 4.1
Revision Date: 23.03.2020
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Further information
Sources of key data used to compile the Safety Data Sheet:

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 |

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.

ZA / EN