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

1.1 Product identifier
   Trade name : Ivermectin 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)
   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 : [images of caution and warning symbols]
SAFETY DATA SHEET
Ivermectin Liquid Formulation

Signal word : Danger

Hazard statements : 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.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
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

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>Registration number</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>606-021-00-7</td>
<td></td>
<td>Skin Irrit.2; H315 Eye Irrit.2; H319 Rep.1B; H360D STOT SE3; H335</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td></td>
<td></td>
<td>Acute Tox.2; H300 Acute Tox.3; H311 STOT SE1; H370 STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Ivermectin Liquid Formulation

Version 3.3  Revision Date: 23.03.2020  SDS Number: 1204380-00010  Date of last issue: 13.09.2019
Date of first issue: 09.01.2017

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 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. 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: 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.
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)
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</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>400 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Further information:</strong></td>
<td>Recommended Limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 ppm</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 mg/m³</td>
<td></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><strong>Further information:</strong></td>
<td>Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>0.5 mg/100 cm²</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 local 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>
</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>
</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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>light yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>characteristic</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 100 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
### 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
- 0.90 - 0.92 g/cm³

### Water solubility
- insoluble

### Partition coefficient: n-octanol/water
- Not applicable

### Auto-ignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity, kinematic
- No data available

### Explosive properties
- Not explosive

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

### 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
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2.000 mg/kg
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

Acute dermal toxicity: LD50 (Rabbit): 406 mg/kg
LD50 (Rat): > 660 mg/kg
Skin corrosion/irritation
Causes skin irritation.

**Components:**

**N-Methyl-2-pyrrolidone:**
Result: Skin irritation

**Ivermectin:**
Species: Rabbit
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

**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.

**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 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

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: 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

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

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.

Repeated dose toxicity

Components:

N-Methyl-2-pyrrolidone:
SAFETY DATA SHEET

Ivermectin Liquid Formulation

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rat, male</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 169 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>: 433 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>: Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 90 Days</td>
</tr>
<tr>
<td>Method</td>
<td>: OECD Test Guideline 408</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 0,5 mg/l</td>
</tr>
<tr>
<td>LOAEL</td>
<td>: 1 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>: inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 96 Days</td>
</tr>
<tr>
<td>Method</td>
<td>: OECD Test Guideline 413</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 826 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>: 1.653 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>: Skin contact</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 20 Days</td>
</tr>
</tbody>
</table>

**Ivermectin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>: Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 0,5 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>: 1 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>: Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 14 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>: Central nervous system</td>
</tr>
<tr>
<td>Symptoms</td>
<td>: Dilatation of the pupil, Tremors, Lack of coordination, anorexia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>: Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 1,2 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>: Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 2 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>: No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>: Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>: 0,4 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>: 0,8 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>: Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>: spleen, Bone marrow, Kidney</td>
</tr>
</tbody>
</table>

**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.
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Eye contact: Remarks: May irritate eyes.
Ingestion: Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

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
  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
### 12.2 Persistence and degradability

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Result: Readily biodegradable. 73% degradation, Exposure time: 28 days Method: OECD Test Guideline 301C</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Result: Not readily biodegradable. 50% degradation, Exposure time: 240 days</td>
<td></td>
</tr>
</tbody>
</table>

### 12.3 Bioaccumulative potential

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Bioconcentration factor (BCF)</th>
<th>log Pow</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td></td>
<td>-0.46</td>
<td>OECD Test Guideline 107</td>
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<tr>
<td>Ivermectin</td>
<td></td>
<td>3.22</td>
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</tr>
</tbody>
</table>

### 12.4 Mobility in soil

No data available

### 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></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN number</td>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
<td>UN 3082</td>
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</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Ivermectin)</td>
</tr>
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</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport hazard class(es)</td>
<td>9</td>
<td>9</td>
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<td>9</td>
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</table>

14.4 Packing group

<table>
<thead>
<tr>
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<th>ADR</th>
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<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
<td>III</td>
</tr>
<tr>
<td>Classification Code</td>
<td>M6</td>
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</tr>
<tr>
<td>Hazard Identification Number</td>
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<tr>
<td>Labels</td>
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<td>9</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
<td>(-)</td>
<td></td>
</tr>
</tbody>
</table>
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
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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.
H335: May cause respiratory irritation.
H360D: May damage 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;
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Version 3.3 Revision Date: 23.03.2020 SDS Number: 1204380-00010 Date of last issue: 13.09.2019

Further information


Classification of the mixture:

| 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 |

Classification procedure:

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.