SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin Liquid Formulation

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
              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)
   
   Skin irritation, Category 2
   Eye irritation, Category 2
   Reproductive toxicity, Category 1B
   Specific target organ toxicity - single exposure, Category 2
   Specific target organ toxicity - single exposure, Category 3
   Specific target organ toxicity - repeated exposure, Category 2
   Short-term (acute) aquatic hazard, Category 1
   Long-term (chronic) aquatic hazard, Category 1

   Classification (REGULATION (EC) No 1272/2008)
   
   H315: Causes skin irritation.
   H319: Causes serious eye irritation.
   H360D: May damage the unborn child.
   H371: May cause damage to organs.
   H335: May cause respiratory irritation.
   H373: May cause damage to organs through prolonged or repeated exposure.
   H400: Very toxic to aquatic life.
   H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

- Danger
- Exclamation mark
- Flammable

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

<table>
<thead>
<tr>
<th>Components</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 Repr. 1B; H360D STOT SE 3; 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</td>
<td>&gt;= 1 - &lt; 2.5</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. 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.

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.
SAFETY DATA SHEET
guaranteed to Regulation (EC) No. 1907/2006

Ivermectin 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>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>23.03.2020</td>
<td>1204465-00010</td>
<td>13.09.2019</td>
<td>09.01.2017</td>
</tr>
</tbody>
</table>

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 dyeing or other appropriate containment to keep material from spreading. If dyed 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/PERSOONAL 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>10 ppm</td>
<td></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></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 mg/m³</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Identifies the possibility of significant uptake through the skin, Indicative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(OEB 3)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</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>
</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>
</tbody>
</table>
Ivermectin Liquid Formulation

Consumers Ingestion Long-term systemic effects 0.85 mg/kg bw/day

## 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

- 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

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

Equipment should conform to I.S. EN 14387

#### Filter type

Combined particulates and organic vapour type (A-P)
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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 range</td>
<td>No data available</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>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.90 - 0.92 g/cm³</td>
</tr>
<tr>
<td>Solubility (ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Ivermectin:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>Humans</td>
<td>Does not cause skin sensitisation</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

Genotoxicity in vitro:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 471</td>
<td>negative</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></td>
<td>negative</td>
</tr>
</tbody>
</table>

Ivermectin:

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>Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>

Ivermectin:

Genotoxicity in vitro:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 471</td>
<td>negative</td>
</tr>
</tbody>
</table>
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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
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.
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Components:

N-Methyl-2-pyrrolidone:
Assessment: May cause respiratory irritation.

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

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:

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

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

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

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

M-Factor (Chronic aquatic toxicity):

- 10,000

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

12.3 Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:

- Partition coefficient: n-octanol/water:
  - log Pow: -0.46
  - Method: OECD Test Guideline 107
Ivermectin Liquid Formulation

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

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

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<tr>
<th>Code</th>
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<tr>
<td>ADN</td>
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<td>ADR</td>
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<td>IATA</td>
<td>UN 3082</td>
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14.2 UN proper shipping name

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<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
</tr>
<tr>
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<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
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<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin)</td>
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14.3 Transport hazard class(es)

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<td>IATA</td>
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</tbody>
</table>

14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Ivermectin Liquid Formulation

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 N-Methyl-2-pyrrolidone (Number on list 72, 71, 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).  
REACH - List of substances subject to authorisation (Annex XIV) : N-Methyl-2-pyrrolidone
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

E1 ENVIROMENTAL HAZARDS  

Quantity 1 : 100 t  
Quantity 2 : 200 t

Other regulations:  
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Ivermectin Liquid Formulation

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information:

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

Full text of H-Statements

- H300: Fatal if swallowed.
- H311: Toxic in contact with skin.
- H315: Causes skin irritation.
- H319: Causes serious eye irritation.
- 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
- IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- 2009/161/EU / TWA: Limit Value - eight hours
- 2009/161/EU / STEL: Short term exposure limit
- IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
- IE OEL / OELV - 15 min: Occupational exposure limit value (15-minute reference period)
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin Liquid Formulation

Version 3.3
Revision Date: 23.03.2020
SDS Number: 1204465-00010
Date of last issue: 13.09.2019
Date of first issue: 09.01.2017

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 Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCIS - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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.

IE / EN