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

1.1 Product identifier
Trade name: Ivermectin / Abamectin Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4
Acute toxicity, Category 4
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

H302: Harmful if swallowed.
H332: Harmful if inhaled.
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)
Ivermectin / Abamectin Liquid Formulation

Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled. H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. H360D May damage the unborn child. H371 May cause damage to organs. H373 May cause damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.


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. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4 212-828-1</td>
<td>Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
</tbody>
</table>
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 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 fire-fighting : 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</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>(dl)-a-Tocopheryl acetate</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>0.85 mg/kg bw/day</td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate</td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic</td>
<td>0.85 mg/kg bw/day</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>73.5 mg/m³</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>21.7 mg/m³</td>
</tr>
<tr>
<td>Abamectin (combination of avermectin B1a and avermectin B1b)</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>73.5 mg/m3</td>
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<tr>
<td>Abamectin (combination of avermectin B1a and avermectin B1b)</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>416.6 mg/kg bw/day</td>
</tr>
<tr>
<td>Abamectin (combination of avermectin B1a and avermectin B1b)</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic</td>
<td>416.6 mg/kg bw/day</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
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<tr>
<td>N-Methyl-2-pyrrolidone</td>
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<td>Skin contact</td>
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<td>2009/161/EU</td>
</tr>
<tr>
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<td>Skin contact</td>
<td>Long-term systemic</td>
<td>2009/161/EU</td>
</tr>
<tr>
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<td>2009/161/EU</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic</td>
<td>2009/161/EU</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin / Abamectin Liquid Formulation

Version: 4.2
Revision Date: 10.10.2020
SDS Number: 1212762-00011
Date of last issue: 23.03.2020
Date of first issue: 10.01.2017

| Consumers | Skin contact | Long-term systemic effects | 250 mg/kg bw/day |
| Consumers | Ingestion | Long-term systemic effects | 12.5 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>
<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>21200 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 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. Equipment should conform to I.S. EN 14387

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
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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

- **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 (Rabbit): 330 mg/kg
    - LD50 (Rat): 2,000 mg/kg

**(dl)-a-Tocopheryl acetate:**
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Date of first issue: 10.01.2017

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
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Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative
Remarks: Based on data from similar materials

Ivermectin:
Exposure routes: Dermal
Species: Humans
Result: Does not cause skin sensitisation.

Abamectin (combination of avermectin B1a and avermectin B1b):
Test Type: Maximisation Test
Exposure routes: Skin contact
Result: Not a skin sensitizer.

(dl)-a-Tocopheryl acetate:
Test Type: Draize Test
Exposure routes: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:
Genotoxicity in vitro
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative
Genotoxicity in vivo:

- **Ivermectin**: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
  Species: Mouse  
  Application Route: Ingestion  
  Method: OECD Test Guideline 474  
  Result: negative

- **Ivermectin**: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
  Species: Hamster  
  Application Route: Ingestion  
  Method: OECD Test Guideline 475  
  Result: negative

Genotoxicity in vitro:

- **Ivermectin**: Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

- **Ivermectin**: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
  Test system: human diploid fibroblasts  
  Result: negative

- **Ivermectin**: Test Type: Mouse Lymphoma  
  Result: negative

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

- **Genotoxicity in vitro**: Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

- **Abamectin (combination of avermectin B1a and avermectin B1b)**: Test Type: In vitro mammalian cell gene mutation test  
  Test system: Chinese hamster lung cells  
  Result: negative

- **Abamectin (combination of avermectin B1a and avermectin B1b)**: Test Type: Alkaline elution assay  
  Result: negative

Genotoxicity in vivo:

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

- **(dl)-a-Tocopheryl acetate**: Test Type: Bacterial reverse mutation assay (AMES)  
  Method: OECD Test Guideline 471  
  Result: negative
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<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>4.2</td>
<td>10.10.2020</td>
<td>1212762-00011</td>
<td>23.03.2020</td>
<td>10.01.2017</td>
</tr>
</tbody>
</table>

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

**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

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.

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

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Inhalation (dust/mist/fume)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 Days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 413</td>
</tr>
</tbody>
</table>

### 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
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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

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
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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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>EC50/NOEC</th>
<th>Exposure Time</th>
<th>Species/Strain</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Americamysis): 0.022 µg/l</td>
<td>96 h</td>
<td></td>
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<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): 0.34 µg/l</td>
<td>48 h</td>
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</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 100 mg/l</td>
<td>72 h</td>
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<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>10,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 1,000 mg/l</td>
<td>3 h</td>
<td></td>
<td>Respiration inhibition</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC: 0.52 µg/l</td>
<td>32 d</td>
<td>Pimephales promelas (fathead minnow)</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC: 0.03 µg/l</td>
<td>21 d</td>
<td>Daphnia magna (Water flea)</td>
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</tr>
<tr>
<td></td>
<td>NOEC: 0.0035 µg/l</td>
<td>28 d</td>
<td>Mysidopsis bahia (opossum shrimp)</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(dl)-a-Tocopheryl acetate:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 927 mg/l</td>
<td>30 min</td>
<td>ISO 8192</td>
<td></td>
</tr>
</tbody>
</table>
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

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.
(Asamewellin (combination of avermectin B1a and avermectin B1b), Ivermectin)

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

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

IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
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according to Regulation (EC) No. 1907/2006

Ivermectin / Abamectin Liquid Formulation

Version 4.2  Revision Date: 10.10.2020  SDS Number: 1212762-00011  Date of last issue: 23.03.2020
Date of first issue: 10.01.2017

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
  - Packing group: III
  - Labels: Miscellaneous

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

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<thead>
<tr>
<th>Adverse Classification</th>
<th>Hazardous</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
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</tr>
<tr>
<td>ADR</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IATA (Passenger)</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>IATA (Cargo)</td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

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):
  - N-Methyl-2-pyrrolidone

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

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

- Regulation (EU) 2019/1021 on persistent organic pollutants (recast):
  - Not applicable

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

  - Quantity 1: 100 t
  - Quantity 2: 200 t

Other regulations:
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according to Regulation (EC) No. 1907/2006

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<thead>
<tr>
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</tbody>
</table>

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
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.
- **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
- **IE OEL**: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- **2009/161/EU / TWA**: Limit Value - eight hours
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<thead>
<tr>
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</tr>
</tbody>
</table>

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 (STEL): Occupational exposure limit value (15-minute reference period)

Further information:


Classification of the mixture:

<table>
<thead>
<tr>
<th>Acute Tox. 4</th>
<th>H302</th>
<th>Calculation method</th>
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</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H332</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
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<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
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<tr>
<td>STOT SE 2</td>
<td>H371</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H335</td>
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</tr>
</tbody>
</table>

Classification procedure:

Calculation method.
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</tbody>
</table>

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.

IE / EN