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

1.1 Product identifier
Trade name : Florfenicol 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

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)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation, Category 2</td>
<td>H315: Causes skin irritation.</td>
</tr>
<tr>
<td>Eye irritation, Category 2</td>
<td>H319: Causes serious eye irritation.</td>
</tr>
<tr>
<td>Reproductive toxicity, Category 1B</td>
<td>H380Df: May damage the unborn child. Suspected of damaging fertility.</td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure, Category 3</td>
<td>H335: May cause respiratory irritation.</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure, Category 1</td>
<td>H372: Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Short-term (acute) aquatic hazard, Category 1</td>
<td>H400: Very toxic to aquatic life.</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td>H410: Very toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
<th>Signal word</th>
<th>Hazard statements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Danger</td>
<td>H315: Causes skin irritation.</td>
</tr>
</tbody>
</table>
H319   Causes serious eye irritation.
H335   May cause respiratory irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H372   Causes 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 + P313   IF exposed or concerned: Get medical advice/attention.
P391   Collect spillage.

Hazardous components which must be listed on the label:
Florfenicol
N-Methyl-2-pyrrolidone

Additional Labelling

Restricted to professional users.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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>Florfenicol</td>
<td>73231-34-2</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 2; H361fd STOT RE 1; H372 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
# SAFETY DATA SHEET

**Florfenicol Liquid Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<th>SDS Number:</th>
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<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
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<td>09.04.2021</td>
<td>29.10.2014</td>
</tr>
</tbody>
</table>

## M-Factor (Chronic aquatic toxicity): 10

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Number</th>
<th>Skin Irrit.</th>
<th>Eye Irrit.</th>
<th>Repir.</th>
<th>STOT SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>H315</td>
<td>H319</td>
<td>H360D</td>
<td>H335</td>
</tr>
<tr>
<td></td>
<td>212-828-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>606-021-00-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

### 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. Suspected of damaging fertility.
- Causes 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.

---

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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 (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 spills cannot be contained.

6.3 Methods and material for containment and cleaning up

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

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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

Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours.
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

### 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>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>TWA OEL-RL</td>
<td>100 ppm 400 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Recommended Limit

<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></td>
<td>TWA</td>
<td>10 ppm 40 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>20 ppm 80 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA OEL-RL (particulate)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Recommended Limit

<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>Propylene glycol</td>
<td></td>
<td>TWA OEL-RL (Vapour + particulates)</td>
<td>150 ppm 470 mg/m³</td>
<td>ZA OEL</td>
</tr>
</tbody>
</table>

Further information: Recommended Limit

### 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>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2,4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0,85 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>
Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Fresh water</td>
<td>0.25 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.025 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.07 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 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.

Laboratory operations do not require special containment.

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

Skin and body protection

: Work uniform or laboratory coat.

Respiratory protection

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

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Viscous

Colour: Gold

Odour: No data available
SAFETY DATA SHEET

Florfenicol 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>2.6</td>
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<td>26292-00019</td>
<td>09.04.2021</td>
<td>29.10.2014</td>
</tr>
</tbody>
</table>

- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **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**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
  - **Partition coefficient: n-octanol/water**: Not applicable
  - **Auto-ignition temperature**: No data available
  - **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.

**9.2 Other information**

- **Flammability (liquids)**: 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
Not classified based on available information.

Components:

Florfenicol:
- Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
- LD50 (Mouse): > 2.000 mg/kg
- LD50 (Dog): > 1.280 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 0,28 mg/l
  Exposure time: 4 h
- Acute dermal toxicity: Remarks: No data available
- Acute toxicity (other routes of administration): LD50 (Rat): 1.913 - 2.253 mg/kg
  Application Route: Intraperitoneal
  LD50 (Mouse): 100 mg/kg
  Application Route: Intravenous

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
SAFETY DATA SHEET
Florfenicol Liquid Formulation

Method: OECD Test Guideline 403

Acute dermal toxicity: LD50 (Rat): > 5.000 mg/kg

Skin corrosion/irritation
Causes skin irritation.

Components:
Florfenicol:
Species: Rabbit
Result: No skin irritation

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
Florfenicol:
Species: Rabbit
Result: Mild eye irritation

N-Methyl-2-pyrrolidone:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Florfenicol:
Test Type: Maximisation Test
Species: Guinea pig
Result: negative

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
Germ cell mutagenicity
Not classified based on available information.

Components:

Florfenicol:
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: rat hepatocytes
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

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
Carcinogenicity
Not classified based on available information.

Components:

Florfenicol:
Species: Rat
Application Route: oral (gavage)
Exposure time: 2 Years
Result: negative
Target Organs: Liver, Testes

Species: Mouse
Application Route: oral (gavage)
Exposure time: 2 Years
Result: negative
Target Organs: Testes, Blood

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

Reproductive toxicity
May damage the unborn child. Suspected of damaging fertility.

Components:

Florfenicol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 12 mg/kg body weight
Result: decreased pup survival, reduced lactation

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
General Toxicity Maternal: NOAEL: 4 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight
Result: No teratogenic effects, Fetotoxicity
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-foetal development
Species: Mouse
Application Route: oral (gavage)
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity

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.

**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.

**STOT - single exposure**

May cause respiratory irritation.

**Components:**

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

- Assessment: May cause respiratory irritation.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:**

**Florfenicol:**

- **Target Organs**
  - Liver, Brain, Testis, Spinal cord, Blood, gallbladder
- **Assessment**
  - Causes damage to organs through prolonged or repeated exposure.
### Repeated dose toxicity

#### Components:

**Florfenicol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>13 Weeks</td>
<td>Liver, Testis, Brain, Spinal cord</td>
</tr>
<tr>
<td>Mouse</td>
<td>200 mg/kg</td>
<td>13 Weeks</td>
<td>Liver, Testis</td>
</tr>
<tr>
<td>Rat</td>
<td>30 mg/kg</td>
<td>13 Weeks</td>
<td>Liver, Testis</td>
</tr>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>52 Weeks</td>
<td>Liver, gallbladder</td>
</tr>
<tr>
<td>Rat</td>
<td>1 mg/kg</td>
<td>52 Weeks</td>
<td>Testis</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, male</td>
<td>169 mg/kg</td>
<td>433 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>OECD Test Guideline 408</td>
</tr>
<tr>
<td>Rat</td>
<td>0,5 mg/l</td>
<td>1 mg/l</td>
<td>Inhalation (dust/mist/fume)</td>
<td>96 Days</td>
<td>OECD Test Guideline 413</td>
</tr>
<tr>
<td>Rabbit</td>
<td>826 mg/kg</td>
<td>1.653 mg/kg</td>
<td>Skin contact</td>
<td>20 Days</td>
<td></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

SECTION 12: Ecological information

12.1 Toxicty

Components:

Florfenicol:
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l
Exposure time: 96 h
Method: FDA 4.11
LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 330 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 2,9 mg/l
Exposure time: 14 d
Method: FDA 4.01

NOEC (Pseudokirchneriella subcapitata (green algae)): 2,9 mg/l
Exposure time: 14 d
Method: FDA 4.01

IC50 (Skeletonema costatum (marine diatom)): 0,0336 mg/l
Exposure time: 72 h
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 0,00423 mg/l
Exposure time: 72 h
Method: ISO 10253

EC50 (Lemma gibba (gibbous duckweed)): 0,76 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221

NOEC (Lemma gibba (gibbous duckweed)): 0,39 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221
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Version 2.6 Revision Date: 27.08.2021 SDS Number: 26292-00019 Date of last issue: 09.04.2021 Date of first issue: 29.10.2014

EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.066 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.051 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10

Toxicity to fish (Chronic toxicity):
NOEC: 5.5 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 1.5 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

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
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

12.3 Bioaccumulative potential

**Components:**

**Florfenicol:**
Partition coefficient: n-octanol/water: log Pow: 0,373

**N-Methyl-2-pyrrolidone:**
Partition coefficient: n-octanol/water: log Pow: -0,46 Method: OECD Test Guideline 107

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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. (Florfenicol) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol) |
| IMDG| : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol) |
| IATA| : Environmentally hazardous substance, liquid, n.o.s. (Florfenicol) |

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  | |

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
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H360D: May damage the unborn child.
H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
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; AIIC - Australian Inventory of Industrial Chemicals; 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 -
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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; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Classification</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360Df</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H335</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN