SAFETY DATA SHEET

Florfenicol Liquid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Florfenicol Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 91-105 Harpin Street
         Bendigo 3550, Victoria Australia
Telephone: 908-740-4000
Emergency telephone number: 1 800 033 461
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 1 800 817 414

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - single exposure: Category 3
Specific target organ toxicity - repeated exposure: Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements:
H315 Causes skin irritation.
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 (Liver, Brain, Testis, Spinal
cord, Blood, gallbladder) through prolonged or repeated exposure.

Precautionary statements:
- **Prevention:**
  - P201 Obtain special instructions before use.
  - P202 Do not handle until all safety precautions have been read and understood.
  - P260 Do not breathe mist or vapours.
  - P264 Wash skin thoroughly after handling.
  - P270 Do not eat, drink or smoke when using this product.
  - P271 Use only outdoors or in a well-ventilated area.
  - P280 Wear protective gloves/ eye protection/ face protection.
  - P281 Use personal protective equipment as required.

**Response:**
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P332 + P313 If skin irritation occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P362 Take off contaminated clothing and wash before reuse.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>N-Methyl-2-pyrroldone</td>
<td>872-50-4</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
</tbody>
</table>

### SECTION 4. FIRST AID MEASURES

**General advice:** In the case of accident or if you feel unwell, seek medical ad-
vice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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.

Most important symptoms and effects, both acute and delayed:
- 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.

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).

Notes to physician:
- Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

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.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Hazchem Code:
- 3Z

SECTION 6. ACCIDENTAL RELEASE MEASURES
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Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

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

Methods and materials for containment and 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.

SECTION 7. HANDLING AND STORAGE

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

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

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

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

Conditions for safe storage:
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.

Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</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</td>
<td>25 ppm 103 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: Skin absorption

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>STEL</td>
<td>75 ppm 309 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: Skin absorption

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>TWA (particulate)</td>
<td>10 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>5-Hydroxy-N-methyl-2-pyrrolidone</td>
<td>Urine</td>
<td>End of shift (As soon as possible after exposure ceases)</td>
<td>100 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

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
Material : Chemical-resistant gloves

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.

Skin and body protection : Work uniform or laboratory coat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : viscous
Colour : gold
Odour : No data available
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
Flammability (liquids) : No data available
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**: No data available

**Explosive properties**: Not explosive

**Oxidizing properties**: The substance or mixture is not classified as oxidizing.

**Particle size**: Not applicable

### SECTION 10. STABILITY AND REACTIVITY

**Reactivity**: Not classified as a reactivity hazard.

**Chemical stability**: Stable under normal conditions.

**Possibility of hazardous reactions**: Can react with strong oxidizing agents.

**Conditions to avoid**: None known.

**Incompatible materials**: Oxidizing agents

**Hazardous decomposition products**: No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

**Exposure routes**: 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:**
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Version: 8.0  Revision Date: 23.03.2020  SDS Number: 26257-00016  Date of last issue: 13.09.2019
Date of first issue: 29.10.2014

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

Propylene glycol:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Causes skin irritation.

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

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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No 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
Propylene glycol:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405

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

**Propylene glycol**:
- **Test Type**: Maximisation Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Result**: negative

**Chronic toxicity**

**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
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<table>
<thead>
<tr>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>positive</td>
</tr>
<tr>
<td>Chinese hamster ovary cells</td>
<td></td>
</tr>
</tbody>
</table>

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

N-Methyl-2-pyrrolidone:
- 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

Propylene glycol:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

- 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**: Ingestion
- **Exposure time**: 2 Years
- **Result**: negative

Propylene glycol:
- **Species**: Rat
- **Application Route**: Ingestion
- **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.

Propylene glycol:

Effects on fertility

: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development

: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

|| May cause respiratory irritation.
Components:

N-Methyl-2-pyrrolidone:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) 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:

Species: Dog
NOAEL: 3 mg/kg
Exposure time: 13 Weeks
Target Organs: Liver, Testis, Brain, Spinal cord

Species: Mouse
NOAEL: 200 mg/kg
Exposure time: 13 Weeks
Target Organs: Liver, Testis

Species: Rat
NOAEL: 1 mg/kg
LOAEL: 3 mg/kg
Exposure time: 52 Weeks
Target Organs: Liver, gallbladder

Species: Dog
NOAEL: 3 mg/kg
LOAEL: 12 mg/kg
Exposure time: 52 Weeks
Target Organs: Liver, Testis

Species: Rat
NOAEL: 1 mg/kg
LOAEL: 3 mg/kg
Exposure time: 52 Weeks
Target Organs: Testis

N-Methyl-2-pyrrolidone:

Species: Rat, male
NOAEL: 169 mg/kg
LOAEL: 433 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
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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

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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

Ecotoxicity

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

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

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

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

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
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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 daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 12.5 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Toxicity to microorganisms:
- EC50: > 600 mg/l
  Exposure time: 30 min
  Method: ISO 8192

Propylene glycol:
Toxicity to fish:
- LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants:
- ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d

Toxicity to microorganisms:
- NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:
Biodegradability:
- Result: Readily biodegradable.
  Biodegradation: 73%
  Exposure time: 28 d
  Method: OECD Test Guideline 301C

Propylene glycol:
Biodegradability:
- Result: Readily biodegradable.
  Biodegradation: 98.3%
  Exposure time: 28 d
  Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Florfenicol:
- Partition coefficient: n-log Pow: 0.373
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**Octanol/water**

**N-Methyl-2-pyrrolidone:**
- Partition coefficient: \( n\)-octanol/water: \( \log \text{Pow} = -0.46 \)
- Method: OECD Test Guideline 107

**Propylene glycol:**
- Partition coefficient: \( n\)-octanol/water: \( \log \text{Pow} = -1.07 \)

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: Dispose of in accordance with local regulations.
- 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

**International Regulations**

**UNRTDG**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**IATA-DGR**
- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (Florfenicol)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 964
- **Packing instruction (passenger aircraft)**: 964
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
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Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

ADG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

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

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 23.03.2020
SAFETY DATA SHEET

Florfenicol Liquid Formulation

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

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average
AU OEL / STEL : Exposure standard - short term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen, Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.
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