## 1. PRODUCT AND COMPANY IDENTIFICATION

**Product name** : Florfenicol (with Triacetin) Liquid Formulation

**Manufacturer or supplier’s details**

- **Company** : MSD
- **Address** : JL Raya Pandaan KM. 48
  Pandaan, Jawa Timur - Indonesia
- **Telephone** : 908-740-4000
- **Emergency telephone number** : 1-908-423-6000
- **E-mail address** : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

- **Recommended use** : Veterinary product

## 2. HAZARDS IDENTIFICATION

**GHS Classification**

- **Serious eye damage/eye irritation** : Category 2B
- **Reproductive toxicity** : Category 1B
- **Specific target organ toxicity - repeated exposure** : Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)
- **Short-term (acute) aquatic hazard** : Category 1
- **Long-term (chronic) aquatic hazard** : Category 1

**GHS label elements**

- **Hazard pictograms** :
  - ![Pictogram]
  - ![Pictogram]
- **Signal word** : Danger
- **Hazard statements** :
  - H320 Causes eye irritation.
  - H360FD May damage fertility. May damage the unborn child.
  - H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.
  - H410 Very toxic to aquatic life with long lasting effects.
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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- 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.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P391 Collect spillage.

**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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
</tbody>
</table>

### 4. 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.

**If inhaled**

If inhaled, remove to fresh air. Get medical attention.

**In case of skin contact**

In case of contact, immediately flush skin with soap and plenty of water. Remove 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 eye irritation.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aider:
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.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Methods and materials for:
Soak up with inert absorbent material.
containment and cleaning up

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.

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 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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

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

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>
</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

**Hand protection**
- 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.

**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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance**: liquid
- **Colour**: yellow
- **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
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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute toxicity:
Not classified based on available information.

Components:
2-Pyrrolidone:
Florfenicol (with Triacetin) Liquid Formulation

Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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

Skin corrosion/irritation
Not classified based on available information.

Components:

2-Pyrrolidone:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Florfenicol:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation
Causes eye irritation.

Components:

2-Pyrrolidone:
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days
Florfenicol (with Triacetin) Liquid Formulation

Florfenicol:
Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

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

Carcinogenicity:

Not classified based on available information.

**Components:**

2-Pyrrolidone:

- **Species:** Mouse
- **Application Route:** Ingestion
- **Exposure time:** 18 month(s)
- **Result:** negative
- **Remarks:** Based on data from similar materials

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

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Components:**

2-Pyrrolidone:

- **Effects on fertility:** Test Type: One-generation reproduction toxicity study
**SPECIES:** Rat  
**APPLICATION ROUTE:** Ingestion  
**RESULT:** positive  
**REMARKS:** Based on data from similar materials

### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>positive</td>
</tr>
</tbody>
</table>

### Reproductive toxicity - Assessment

Clear evidence of adverse effects on sexual function and fertility, based on animal experiments. Clear evidence of adverse effects on development, based on animal experiments.

### Florfenicol

#### Effects on fertility

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Fertility</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 12 mg/kg body weight</td>
<td>decreased pup survival, reduced lactation</td>
</tr>
</tbody>
</table>

#### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>General Toxicity Maternal</th>
<th>Embryo-foetal toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>NOAEL: 4 mg/kg body weight</td>
<td>LOAEL: 40 mg/kg body weight</td>
<td>No teratogenic effects, Fetotoxicity</td>
</tr>
</tbody>
</table>

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.

### STOT - single exposure

Not classified based on available information.

### 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:

2-Pyrrolidone:
- Species: Rat
- NOAEL: 207 mg/kg
- Application Route: Ingestion
- Exposure time: 3 Months
- Method: OECD Test Guideline 408

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: 30 mg/kg
- Exposure time: 13 Weeks
- Target Organs: Liver, Testis
- Species: Dog
- NOAEL: 3 mg/kg
- LOAEL: 12 mg/kg
- Exposure time: 52 Weeks
- Target Organs: Liver, gallbladder
- Species: Rat
- NOAEL: 1 mg/kg
- LOAEL: 3 mg/kg
- Exposure time: 52 Weeks
- Target Organs: Testis

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

2-Pyrrolidone:
- Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
- Exposure time: 96 h
- Method: OECD Test Guideline 203
# Safety Data Sheet

## Florfenicol (with Triacetin) Liquid Formulation

### Toxicity to daphnia and other aquatic invertebrates

**EC50** *(Daphnia magna (Water flea))*: > 500 mg/l  
Exposure time: 48 h

### Toxicity to algae/aquatic plants

**ErC50** *(Desmodesmus subspicatus (green algae))*: > 500 mg/l  
Exposure time: 72 h  
**EC10** *(Desmodesmus subspicatus (green algae))*: 22.2 mg/l  
Exposure time: 72 h

### Toxicity to microorganisms

**EC50** : > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

---

**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** *(Lehna gibba (gibbous duckweed))*: 0.76 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

**NOEC** *(Lemna 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

M-Factor (Acute aquatic toxicity): 10
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

M-Factor (Chronic aquatic toxicity): 10

### Persistence and degradability

#### Components:

**2-Pyrrolidone:**

Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

**2-Pyrrolidone:**

Partition coefficient: n-octanol/water: log Pow: -0.71
Method: OECD Test Guideline 107

**Florfenicol:**

Partition coefficient: n-octanol/water: log Pow: 0.373

### Mobility in soil

No data available

### Other adverse effects

No data available
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.

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)
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.

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.
15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information


Date format : yyyy/mm/dd

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or 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;
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.