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

Florfenicol (with Triacetin) 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>
</table>

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

1.1 Product identifier
Trade name : Florfenicol (with Triacetin) Liquid Formulation

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

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

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008)**
- Eye irritation, Category 2
- Reproductive toxicity, Category 1B
- Specific target organ toxicity - repeated exposure, Category 1
- Short-term (acute) aquatic hazard, Category 1
- Long-term (chronic) aquatic hazard, Category 1

**Hazard statements**
- H319: Causes serious eye irritation.
- H360FD: May damage fertility. May damage 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.

2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008)**

**Hazard pictograms**

**Signal word** : Danger

**Hazard statements** : H319 Causes serious eye irritation.
H360FD  May damage fertility. May damage the unborn child.
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.
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.
P337 + P313  If eye irritation persists: Get medical advice/ attention.
P391   Collect spillage.

Hazardous components which must be listed on the label:
2-Pyrrolidone
Florfenicol

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>210-483-1</td>
<td></td>
<td>Eye Irrit.2; H319 Repr.1B; H360FD</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td></td>
<td></td>
<td>Repr.2; H361fd STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 30 - &lt; 50</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 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. May damage fertility. May damage the unborn child. 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.
5.2 Special hazards arising from the substance or mixture

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

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

5.3 Advice for firefighters

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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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

Advice on safe handling: Do not get on skin or clothing. Do not breathe 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. 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. Store in accordance with the particular national regulations.

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

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

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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>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57,8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17,1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>167 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5,2 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>33,3 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Triacetin</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>35,275 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>8,7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2,5 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>2,5 mg/kg bw/day</td>
<td></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>2-Pyrrolidone</td>
<td>Fresh water</td>
<td>0,5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0,5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,05 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>0,4205 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,0612 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Triacetin</td>
<td>Fresh water</td>
<td>1,88 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0,188 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1088 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>4,73 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0,47 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0,57 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>69,9 mg/kg food</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.
Equipment should conform to NS EN 14387
Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : 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
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:

**2-Pyrrolidone:**

**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 serious eye irritation.

Components:

2-Pyrrolidone:
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days

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
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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 : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive  

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.  

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.
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Date of first issue: 16.09.2016

STOT - single exposure
Not classified based on available information.

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:

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.

SECTION 12: Ecological information

12.1 Toxicity

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

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

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 (Lemna 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: 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

12.2 Persistence and degradability

Components:

2-Pyrrolidone:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials
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Date of first issue: 16.09.2016

12.3 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

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
          According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

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

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

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Florfenicol (with Triacetin) Liquid Formulation

Packing group: III
Labels: Miscellaneous

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

E1 ENVIRONMENTAL HAZARDS
Quantity 1: 100 t
Quantity 2: 200 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-statements

- H319: Causes serious eye irritation.
- H360FD: May damage fertility. 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
- STOT RE: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Mari-
Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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

NO / EN