SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Version 6.2  Revision Date: 16.10.2020  SDS Number: 28057-00017  Date of last issue: 23.03.2020

Date of first issue: 04.11.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Florfenicol / Flunixin Formulation

Manufacturer or supplier's details

Company: MSD

Address: 50 Tuas West Drive
Singapore - Singapore 638408

Telephone: +1-908-740-4000

Emergency telephone number: 65 6697 2111 (24/7/365)

E-mail address: EHSDATASTeward@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Inhalation): Category 4
Serious eye damage/eye irritation: Category 2
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)
Specific target organ toxicity - repeated exposure: Category 2 (Gastrointestinal tract, Kidney)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements

Hazard pictograms:

Signal word: Danger
Hazard statements: H319 Causes serious eye irritation. H332 Harmful if inhaled.
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor 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.
- 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

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td></td>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Malic Acid</td>
<td>6915-15-7</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>&gt;= 1 - &lt; 2.5</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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with 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. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation. Harmful if inhaled. May damage fertility. May damage the unborn child. 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.

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 Fluorine compounds 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
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 containment and cleaning up | Soak up with inert absorbent material. | For large spills, provide dyeing or other appropriate containment to keep material from spreading. If dyed 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. |
| | Keep in a cool, well-ventilated place. |
Materials to avoid: Store in accordance with the particular national regulations.
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>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Wipe limit: 400 µg/100 cm² Internal

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

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: 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.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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 decontamination and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.22</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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.

Particle size: Not applicable

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: Harmful if inhaled.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 2.28 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Version 6.2  Revision Date: 16.10.2020  SDS Number: 28057-00017  Date of last issue: 23.03.2020
Date of first issue: 04.11.2014

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

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

Malic Acid:

Acute oral toxicity: LD50 (Rat): 3,500 mg/kg

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Acute oral toxicity: LD50 (Rat): 53 - 157 mg/kg
LD50 (Mouse): 176 - 249 mg/kg
LD50 (Guinea pig): 488.3 mg/kg
LD50 (Monkey): 300 mg/kg

Acute inhalation toxicity: LC50 (Rat): < 0.52 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration):
LD50 (Rat): 59.4 - 185.3 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 164 - 363 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation
Not classified based on available information.

Components:

Florfenicol:
Species: Rabbit

8 / 22
### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### Malic Acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

#### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### Florfenicol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

#### 2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 7 days</td>
</tr>
</tbody>
</table>

#### Malic Acid:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irreversible effects on the eye</td>
</tr>
</tbody>
</table>

### 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

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

Malic Acid:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative

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

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

Malic Acid:

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
Result: negative
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Genotoxicity in vitro

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

Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: positive

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: in vitro assay
Test system: Escherichia coli
Result: positive

Genotoxicity in vivo:
  Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative

Germ cell mutagenicity - Assessment:
  Weight of evidence does not support classification as a germ cell mutagen.

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

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

**1-Deoxy-1-(methy lamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**
- Species: Rat
- Application Route: oral (feed)
- Exposure time: 104 w
- LOAEL: 2 mg/kg body weight
- Result: negative
- Target Organs: Gastrointestinal tract
- Remarks: Significant toxicity observed in testing

**Species:**
- Application Route: oral (feed)
- Exposure time: 97 w
- NOAEL: 0.6 mg/kg body weight
- Result: negative
- Target Organs: Gastrointestinal tract
- Remarks: Significant toxicity observed in testing
Reproductive toxicity
May damage fertility. May damage the unborn child.

**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.

**Reproductive toxicity - Assessment**
- Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
  - Based on data from similar materials

**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

**Malic Acid:**

**Effects on fertility**
- Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative
## Effects on foetal development

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

### 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

**Effects on fertility**  
**Test Type:** Two-generation reproduction toxicity study  
**Species:** Rat  
**Application Route:** Oral  
**General Toxicity - Parent:** LOAEL: 1 - 1.5 mg/kg body weight  
**Symptoms:** No foetal abnormalities  
**Result:** No effects on fertility and early embryonic development were detected.

**Effects on foetal development**  
**Test Type:** Development  
**Species:** Rat  
**Application Route:** Oral  
**General Toxicity Maternal:** LOAEL: 2 mg/kg body weight  
**Embryo-foetal toxicity:** NOAEL: 2 mg/kg body weight  
**Result:** Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses.

**Test Type:** Embryo-foetal development  
**Species:** Rabbit  
**Application Route:** Oral  
**General Toxicity Maternal:** LOAEL: 3 mg/kg body weight  
**Embryo-foetal toxicity:** NOAEL: 3 mg/kg body weight  
**Result:** Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

## STOT - single exposure

Not classified based on available information.

### Components:

**1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**  
**Assessment:** May cause respiratory irritation.

## STOT - repeated exposure

Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.  
May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

### Components:

**Florfenicol:**  
**Target Organs**  
**Assessment:** Causes damage to organs through prolonged or repeated exposure.

**1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**  
**Target Organs**  
Gastrointestinal tract, Kidney, Blood
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**: 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

**2-Pyrrolidone:**

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

**Malic Acid:**

- **Species**: Rat  
- **NOAEL**: > 250 mg/kg  
- **Application Route**: Ingestion  
- **Exposure time**: 104 Weeks

**1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

- **Species**: Rat  
- **NOAEL**: 2 mg/kg  
- **LOAEL**: < 4 mg/kg
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Application Route: Oral
Exposure time: 6 w
Target Organs: Gastrointestinal tract

Species: Rat
NOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 1 y
Target Organs: Gastrointestinal tract, Kidney

Species: Monkey
NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organs: Gastrointestinal tract, Blood

Species: Rabbit
LOAEL: 80 mg/kg
Application Route: Dermal
Exposure time: 21 d
Symptoms: Severe irritation

Species: Dog
LOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 9 d
Target Organs: Gastrointestinal tract
Symptoms: Vomiting

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Inhalation: Symptoms: respiratory tract irritation
Skin contact: Symptoms: Skin irritation
Eye contact: Symptoms: Severe irritation
Ingestion: Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Florfenicol:
Toxicity to fish: LC50 (Lepomis macrochirius (Bluegill sunfish)): > 830 mg/l
Exposure time: 96 h
Method: FDA 4.11

LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l
### 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

### M-Factor (Acute aquatic toxicity)

- **M-Factor**: 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)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>1.5 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Factor (Chronic aquatic toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>10</td>
</tr>
</tbody>
</table>

### Toxicity to Fish

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Danio rerio (zebra fish))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>&gt; 4,600 - 10,000 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicity to Daphnia and Other Aquatic Invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>&gt; 500 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicity to Algae/Aquatic Plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>ErC50 (Desmodesmus subspicatus (green algae))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>&gt; 500 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC10 (Desmodesmus subspicatus (green algae))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>22.2 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Toxicity to Microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>&gt; 1,000 mg/l</td>
<td>30 min</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Malic Acid

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Danio rerio (zebra fish))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malic Acid</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malic Acid</td>
<td>240 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

### Remarks

Based on data from similar materials.

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Toxicity to fish:
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l
  Exposure time: 96 h
  Method: FDA 4.11
- LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l
  Exposure time: 96 h
  Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 15 mg/l
  Exposure time: 48 h
  Method: FDA 4.08

Toxicity to algae/aquatic plants:
- NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l
  Exposure time: 13 d
  Method: FDA 4.01
- NOEC (Selenastrum capricornutum (green algae)): 96 mg/l
  Exposure time: 12 d

Persistence and degradability

Components:
2-Pyrrolidone:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

Malic Acid:
Biodegradability: Result: Readily biodegradable.
Method: OECD Test Guideline 107
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Stability in water: Hydrolysis: 0 % (28 d)

Bioaccumulative potential

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

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

Malic Acid:
Partition coefficient: n-octanol/water: log Pow: -1.26

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Partition coefficient: n-octanol/water: log Pow: 1.34
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Components:
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Distribution among environmental compartments: log Koc: 1.92

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: 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: dd.mm.yyyy

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; 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.

SG / EN