SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Version 7.0 Revision Date: 2020/03/23 SDS Number: 28047-00016 Date of last issue: 2019/12/12 Date of first issue: 2014/11/04

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Florfenicol / Flunixin Formulation

Supplier's company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTeward@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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.
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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 20 - &lt; 30</td>
<td>5-112</td>
</tr>
<tr>
<td></td>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 20 - &lt; 25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Malic Acid</td>
<td>6915-15-7</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-1442</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 method: Use extinguishing measures that are appropriate to local cir-
6. ACCIDENTAL RELEASE MEASURES

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

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

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide drying 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

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.

Avoidance of contact: Oxidizing agents

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.

### Storage

**Conditions for safe storage:**
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.

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

**Packaging material:**
- Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

<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>

**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.
- 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
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity : No data available

Viscosity, kinematic : No data available
**Solubility(ies)**
- Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Vapour pressure: No data available
- Density and/or relative density:
  - Relative density: 1.22
  - Density: No data available
  - Relative vapour density: No data available
- Explosive properties: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Particle characteristics:
  - 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:

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

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
### SAFETY DATA SHEET

#### Florfenicol / Flunixin Formulation

<table>
<thead>
<tr>
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<tr>
<td>7.0</td>
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</tbody>
</table>

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

### Skin corrosion/irritation
Not classified based on available information.

#### Components:

<table>
<thead>
<tr>
<th><strong>2-Pyrrolidone:</strong></th>
<th>Species: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 404</td>
<td></td>
</tr>
<tr>
<td>Result: No skin irritation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Florfenicol:</strong></th>
<th>Species: Rabbit</th>
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</thead>
<tbody>
<tr>
<td>Result: No skin irritation</td>
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</tr>
</tbody>
</table>

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

| **1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:** | Species: Rabbit |
|--------------------------------------------------------------------------------------------|
| Result: Mild skin irritation |

### Serious eye damage/eye irritation
Causes serious eye irritation.

#### Components:

<table>
<thead>
<tr>
<th><strong>2-Pyrrolidone:</strong></th>
<th>Species: Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result: Irritation to eyes, reversing within 7 days</td>
<td></td>
</tr>
</tbody>
</table>

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

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

| **1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:** | Species: Rabbit |
|--------------------------------------------------------------------------------------------|
| Result: Irreversible effects on the eye |
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

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:

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
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

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:

2-Pyrolidine:
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

1-Deoxy-1-(methylamino)-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: Mouse
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:

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., Clear evidence of adverse effects on development, 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.
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**: Liver, Brain, Testis, Spinal cord, Blood, gallbladder
- **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:

#### 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

### Malic Acid:
### SAFETY DATA SHEET

**Florfenicol / Flunixin Formulation**

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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt; 250 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 Weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>2 mg/kg</td>
</tr>
<tr>
<td>LOAEL</td>
<td>&lt; 4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 w</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Species</th>
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</tr>
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<tbody>
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<td>NOAEL</td>
<td>1 mg/kg</td>
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</tr>
<tr>
<td>Exposure time</td>
<td>1 y</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Kidney</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
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<td>Target Organs</td>
<td>Gastrointestinal tract, Blood</td>
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<td>Symptoms</td>
<td>Severe irritation</td>
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<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Vomiting</td>
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**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:

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
  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 (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 (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

**Malic Acid:**

Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 240 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Neutralised product
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
### NOEC (Pseudokirchneriella subcapitata (green algae)):
- 100 mg/l
- Exposure time: 72 h
- Test substance: Neutralised product
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

### Toxicity to microorganisms:
- EC50: > 100 mg/l
- Exposure time: 3 h
- Method: OECD Test Guideline 209
- 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 301C
  - Remarks: Based on data from similar materials

### Stability in water:
- Hydrolysis: 0 % (28 d)
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

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

Mobility in soil

Components:

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

Hazardous to the ozone layer
Not applicable

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
SAFETY DATA SHEET

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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.

National Regulations
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity  
Not applicable  
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity  
Not applicable  
Substances Subject to be Notified Names  
Not applicable  
Substances Subject to be Indicated Names  
Not applicable  
Ordinance on Prevention of Hazards Due to Specified Chemical Substances  
Not applicable  
Ordinance on Prevention of Lead Poisoning  
Not applicable  
Ordinance on Prevention of Tetraalkyl Lead Poisoning  
Not applicable  
Ordinance on Prevention of Organic Solvent Poisoning  
Not applicable  
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)  
Not applicable  
Poisonous and Deleterious Substances Control Law  
Not applicable  
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof  
Not applicable  
High Pressure Gas Safety Act  
Not applicable  
Explosive Control Law  
Not applicable  
Vessel Safety Law  
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)  
Aviation Law  
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)  
Marine Pollution and Sea Disaster Prevention etc Law  
Bulk transportation : Noxious liquid substance (Category Z)  
Pack transportation : Classified as marine pollutant  
Narcotics and Psychotropics Control Act  
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

**Waste Disposal and Public Cleansing Law**

**Industrial waste**

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**

Sources of key data used to compile the Safety Data Sheet:


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

Date format: yyyy/mm/dd

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen 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; IECS - 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, Evalua-
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

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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.

JP / EN