1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Florfenicol / Flunixin Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Briahnager - Off Pune Nagar Road, Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Oral) : Category 4
Acute toxicity (Inhalation) : Category 4
Serious eye damage/eye irritation : Category 2A
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: Danger

Signal word: Danger

Hazard statements:
- H302 + H332 Harmful if swallowed or if inhaled.
- H319 Causes serious eye irritation.
- H360FD May damage fertility. May damage the unborn child.
- H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.
- H373 May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- 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:
- P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
- 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; 5</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 : Harmful if swallowed or if inhaled. Causes serious eye irritation. 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 : None known.
Specific hazards during firefighting:

- Exposure to combustion products may be a hazard to health.
- 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 so.
- Evacuate area.

Special protective equipment for firefighters:

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:

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

Methods and materials for containment and cleaning up:

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

7. HANDLING AND STORAGE

Technical measures:

- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:

- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:

- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety
practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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.
- Store in accordance with the particular national regulations.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<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

Material:
- Consider double gloving.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: liquid
- Colour: yellow
- Odour: No data available
- Odour Threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point: No data available
- Evaporation rate: No data available
- Flammability (solid, gas): Not applicable
- Flammability (liquids): No data available
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapour pressure: No data available
- Relative vapour density: No data available
- Relative density: 1.22
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

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.
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 swallowed or if inhaled.

Product:
  Acute oral toxicity: Acute toxicity estimate: 1,890 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:
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity (Rat)</td>
<td>LD50: &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Dog): &gt; 1,280 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity (Rat)</td>
<td>LC50: &gt; 0.28 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Remarks: No data available</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 1,913 - 2,253 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 100 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>2-Pyrrolidone:</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 401</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute oral toxicity</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 402</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td>Malic Acid:</td>
<td>LD50 (Rat): 3,500 mg/kg</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:</td>
<td>LD50 (Rat): 53 - 157 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 176 - 249 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Guinea pig): 488.3 mg/kg</td>
</tr>
<tr>
<td></td>
<td>LD50 (Monkey): 300 mg/kg</td>
</tr>
<tr>
<td>Acute inhalation toxicity (Rat)</td>
<td>LC50: &lt; 0.52 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 59.4 - 185.3 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Application Route: Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): 164 - 363 mg/kg</td>
</tr>
</tbody>
</table>
Skin corrosion/irritation
Not classified based on available information.

Components:

Florfenicol:
Species: Rabbit
Result: No skin irritation

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

Malic Acid:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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:

Florfenicol:
Species: Rabbit
Result: Mild eye irritation

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

Malic Acid:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

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:

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
Genotoxicity in vitro:
- Test system: mouse lymphoma cells
  - Result: negative

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

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

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:

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. Some evidence of adverse effects on development, based on animal experiments.

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 fertil-
sessment

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.
# SAFETY DATA SHEET

## Florfenicol / Flunixin Formulation

**Version**: 6.1  
**Revision Date**: 23.03.2020  
**SDS Number**: 28044-00016  
**Date of last issue**: 12.12.2019  
**Date of first issue**: 04.11.2014

### 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:

**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**:

---

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SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

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
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:

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Lepomis macrochirus (Bluegill sunfish)): &gt; 830 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
<td>Method: FDA 4.11</td>
</tr>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 780 mg/l</td>
<td></td>
</tr>
<tr>
<td>Exposure time: 96 h</td>
<td>Method: FDA 4.11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 330 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 48 h</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 2.9 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 14 d</td>
<td>Method: FDA 4.01</td>
</tr>
</tbody>
</table>

| 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                                       |

<p>| NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l |                                      |
| Exposure time: 72 h                                      | Method: OECD Test Guideline 201                                       |</p>
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity</th>
<th>Control Parameter</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EC50 (Anabaena flos-aquae)</td>
<td>0.066 mg/l</td>
<td></td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC (Anabaena flos-aquae)</td>
<td>0.051 mg/l</td>
<td></td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Pimephales promelas)</td>
<td>5.5 mg/l</td>
<td></td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
<tr>
<td>Species</td>
<td>P. promelas</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOEC (Daphnia magna)</td>
<td>1.5 mg/l</td>
<td></td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
<tr>
<td>Species</td>
<td>D. magna</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Danio rerio)</td>
<td>&gt; 4,600 - 10,000 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia</td>
<td>EC50 (Daphnia magna)</td>
<td>&gt; 500 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Desmodesmus subspicatus)</td>
<td>&gt; 500 mg/l</td>
<td>72 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50</td>
<td>&gt; 1,000 mg/l</td>
<td>30 min</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Malic Acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Danio rerio)</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna)</td>
<td>240 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata)</td>
<td>&gt; 100 mg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**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

**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

**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

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

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
SAFETY DATA SHEET
Florfenicol / Flunixin Formulation

Version: 6.1
Revision Date: 23.03.2020
SDS Number: 28044-00016
Date of last issue: 12.12.2019
Date of first issue: 04.11.2014

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 IMO instruments
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

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
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.