SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Florfenicol / Flunixin Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral): Category 4
Acute toxicity (Inhalation): Category 4
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder, Gastrointestinal tract, Kidney)

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, Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

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 vapors.
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.
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Malic Acid</td>
<td>6915-15-7</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2- methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
</tbody>
</table>

SECTION 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.

### SECTION 5. FIRE-FIGHTING MEASURES

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

- **Unsuitable extinguishing media**: None known.

- **Specific hazards during fire fighting**: 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 so. Evacuate area.

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

### SECTION 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
Methods and materials for containment and cleaning up:

Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 vapors or spray mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage:
Keep in properly labeled 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 Organic peroxides Explosives Gases
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients 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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</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 vapor type

**Hand protection**

Material: Chemical-resistant gloves

**Remarks**

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

liquid
Color : yellow
Odor : No data available
Odor 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
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : 1.22
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY
SECTION 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:

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

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
Result: No skin irritation

2-Pyrrolidone:
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
SAFETY DATA SHEET
Florfenicol / Flunixin Formulation

Version 7.0 Revision Date: 12.12.2019 SDS Number: 28049-00015 Date of last issue: 13.09.2019
Date of first issue: 04.11.2014

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

**Malic Acid**:
- **Species**: Rabbit
- **Result**: Irritation to eyes, reversing within 21 days
- **Method**: OECD Test Guideline 405
- **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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components**:

**Florfenicol**:
- **Test Type**: Maximization Test
- **Species**: Guinea pig
- **Result**: negative

**2-Pyrrolidone**:
- **Test Type**: Local lymph node assay (LLNA)
- **Routes of exposure**: Skin contact
- **Species**: Mouse
- **Method**: OECD Test Guideline 429
- **Result**: negative
- **Remarks**: Based on data from similar materials
### Malic Acid:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</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>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Assessment</td>
<td>Does not cause skin sensitization.</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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
Genotoxicity in vivo

Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vitro

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 test
Test system: mouse lymphoma cells
Result: positive

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

Test Type: in vitro test
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 fetal development**: Test Type: Embryo-fetal development
  Species: Rat
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Toxicity Maternal:</strong></td>
<td>NOAEL: 4 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td><strong>Embryo-fetal toxicity:</strong></td>
<td>LOAEL: 40 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>No teratogenic effects., Fetotoxicity.</td>
<td></td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td>The effects were seen only at maternally toxic doses.</td>
<td></td>
</tr>
<tr>
<td><strong>Test Type:</strong></td>
<td>Embryo-fetal development</td>
<td></td>
</tr>
<tr>
<td><strong>Species:</strong></td>
<td>Mouse</td>
<td></td>
</tr>
<tr>
<td><strong>Application Route:</strong></td>
<td>oral (gavage)</td>
<td></td>
</tr>
<tr>
<td><strong>General Toxicity Maternal:</strong></td>
<td>NOAEL: 120 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td><strong>Embryo-fetal toxicity:</strong></td>
<td>LOAEL: 40 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td><strong>Result:</strong></td>
<td>Fetotoxicity.</td>
<td></td>
</tr>
<tr>
<td><strong>Remarks:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive toxicity - Assessment:</strong></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

### 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 fetal development**
  - Test Type: Embryo-fetal 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.

### Malic Acid:

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

- **Effects on fetal development**
  - Test Type: Embryo-fetal 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 fetal abnormalities.
  - Result: No effects on fertility and early embryonic
development were detected.

Effects on fetal development

Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 2 mg/kg body weight
Embryo-fetal 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-fetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: LOAEL: 3 mg/kg body weight
Embryo-fetal 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, 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:

Florfenicol:
Species: Dog
NOAEL: 3 mg/kg
Exposure time: 13 Weeks
Target Organs: Liver, Testis, Brain, Spinal cord

Species: Mouse
## SAFETY DATA SHEET

### Florfenicol / Flunixin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

| 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 |
| 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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

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 (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

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

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

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: Neutralized 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: Neutralized 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

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

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

SECTION 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.
SECTION 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.

Domestic regulation

NOM-002-SCT
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
Class : 9
Packing group : III
Labels : 9

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

If not otherwise specified: Dispose of as unused product.
Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills:

: Not applicable

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

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>Australian Inventory of Chemical Substances</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List (Canada)</td>
</tr>
<tr>
<td>IECSC</td>
<td>Inventory of Existing Chemical Substances in China</td>
</tr>
</tbody>
</table>

**SECTION 16. OTHER INFORMATION**

**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; 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
**SAFETY DATA SHEET**

**Florfenicol / Flunixin Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

- Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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


Revision Date: 12.12.2019

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8