SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol / Flunixin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 91-105 Harpin Street
          Bendigo 3550, Victoria Australia
Telephone : 908-740-4000
Emergency telephone number : 1 800 033 461
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 1 800 817 414

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
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)

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

Florfenicol / Flunixin Formulation

Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear eye protection/ face protection.
- P281 Use personal protective equipment as required.

**Response:**
- 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 which do not result in classification

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;= 10 - &lt; 30</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>&gt;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Malic Acid</td>
<td>6915-15-7</td>
<td>&lt; 10</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 attention.
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.

### SECTION 5. FIREFIGHTING MEASURES

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

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

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

**Hazardous combustion products:**
- Carbon oxides
- Fluorine compounds
- Nitrogen oxides (NOx)

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

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

**Hazchem Code:**
- 3Z
## 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 dyeing or other appropriate containment to keep material from spreading. If dyed material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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

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

**Conditions for safe storage**: Keep in properly labelled containers. Store locked up. Keep tightly closed.
SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Version 7.0  Revision Date: 12.12.2019  SDS Number: 28024-00015  Date of last issue: 13.09.2019
Date of first issue: 04.11.2014

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

SECTION 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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</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
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

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

Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: Not applicable

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION
Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Harmful if inhaled.

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

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

Components:
Florfenicol:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
LD50 (Mouse): > 2,000 mg/kg
LD50 (Dog): > 1,280 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.28 mg/l
Exposure time: 4 h

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  
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-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 sensitisation
Skin sensitisation
Not classified based on available information.

Components:

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
# 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>
</tr>
</thead>
</table>

### Method

- **OECD Test Guideline 429**
- **negative**
- **Based on data from similar materials**

### Malic Acid:

- **Maximisation Test**
- **Skin contact**
- **Guinea pig**
- **OECD Test Guideline 406**
- **negative**
- **Based on data from similar materials**

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

- **Maximisation Test**
- **Dermal**
- **Guinea pig**
- **Does not cause skin sensitisation.**
- **negative**

### Chronic toxicity

**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
## Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>OECD Test Guideline 473</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

## Malic Acid:

### Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

Remarks: Based on data from similar materials

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

### Genotoxicity in vitro

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>in vitro assay</td>
<td>mouse lymphoma cells</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Chinese hamster ovary cells</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>in vitro assay</td>
<td>Escherichia coli</td>
<td>positive</td>
<td></td>
</tr>
</tbody>
</table>

### Genotoxicity in vivo

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>Oral</td>
<td>negative</td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
</tr>
</tbody>
</table>

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:

- 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.

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.

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-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) 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:

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

Species: Mouse
NOAEL: 200 mg/kg
Exposure time: 13 Weeks
Target Organs: Liver, Testis

Species: Rat
NOAEL: 30 mg/kg
Exposure time: 13 Weeks
Target Organs: Liver, Testis

Species: Dog
NOAEL: 3 mg/kg
LOAEL: 12 mg/kg
Exposure time: 52 Weeks
Target Organs: Liver, gallbladder

Species: Rat
NOAEL: 1 mg/kg
LOAEL: 3 mg/kg
Exposure time: 52 Weeks
Target Organs: Testis

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

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

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Species: Rat
NOAEL: 2 mg/kg
LOAEL: < 4 mg/kg
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
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NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organ: 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 Organ: 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
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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

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: 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
Persistence and degradability

**Components:**

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

**Malic Acid:**

**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
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. If not otherwise specified: Dispose of as unused product.

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.

National Regulations

ADG
- UN number: UN 3082
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
- Class: 9
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Packing group : III
Labels : 9
Hazchem Code : •3Z

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.

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

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

SECTION 16. OTHER INFORMATION

Further information
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.

Date format : dd.mm.yyyy

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
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Version  7.0  Revision Date: 12.12.2019  SDS Number: 28024-00015  Date of last issue: 13.09.2019

- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

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