SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Florfenicol / Flunixin Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
  Trade name : Florfenicol / Flunixin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
  Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
  Company : MSD
  Shotton Lane
  NE23 3JU Cramlington NU - Great Britain
  Telephone : 44 1 670 59 30 00
  Telefax : 908-735-1496
  E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
  1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
  Classification (REGULATION (EC) No 1272/2008)
  Acute toxicity, Category 4 : H332: Harmful if inhaled.
  Eye irritation, Category 2 : H319: Causes serious eye irritation.
  Reproductive toxicity, Category 1B : H360FD: May damage fertility. May damage the unborn child.
  Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.
  Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
  Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
  Labelling (REGULATION (EC) No 1272/2008)
  Hazard pictograms :
  Signal word : Danger
Florfenicol / Flunixin Formulation

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 through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
- P201 Obtain special instructions before use.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
Response:
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P337 + P313 If eye irritation persists: Get medical advice/attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:
- 2-Pyrrolidone
- Florfenicol
- 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td></td>
<td></td>
<td>Repr. 2; H361fd STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 20 - &lt; 25</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>210-483-1</td>
<td></td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Malic Acid</td>
<td>6915-15-7</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>
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SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. Harmful if inhaled. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

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

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.
6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

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

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: 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.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives
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Version 3.1
Revision Date: 23.03.2020
SDS Number: 28043-00016
Date of last issue: 12.12.2019
Date of first issue: 04.11.2014

Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>triacetin</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>35.275 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td></td>
<td>5 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>8.7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>2.5 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57.8 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>167 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5.2 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>33.3 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>
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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>triacetin</td>
<td>Fresh water</td>
<td>1.88 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.188 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1088 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>4.73 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.47 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.57 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>69.9 mg/kg food</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.05 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.4205 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0612 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves
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Remarks
Consider double gloving.

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.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387
Filter type
Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
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
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
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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.

9.2 Other information
Flammability (liquids): No data available

Particle size: Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Harmful if inhaled.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method
Acute inhalation toxicity: Acute toxicity estimate: 2.28 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

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

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

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
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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

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
Method: OECD Test Guideline 405
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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:
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Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Test system: rat hepatocytes
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Test system: mouse lymphoma cells
  Result: negative
- Test Type: Chromosome aberration test in vitro
  Test system: Chinese hamster ovary cells
  Result: positive

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Cell type: Bone marrow
  Application Route: Oral
  Result: negative

2-Pyrrolidone:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
    Method: OECD Test Guideline 476
    Result: negative
    Remarks: Based on data from similar materials
  - Test Type: Chromosome aberration test in vitro
    Method: OECD Test Guideline 473
    Result: negative

- Genotoxicity in vivo:
  - Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    Species: Mouse
    Application Route: Intraperitoneal injection
    Method: OECD Test Guideline 474
    Result: negative

Malic Acid:
- Genotoxicity in vitro:
  - Test Type: Bacterial reverse mutation assay (AMES)
    Result: negative
  - Test Type: In vitro mammalian cell gene mutation test
    Method: OECD Test Guideline 476
    Result: negative
    Remarks: Based on data from similar materials
  - Test Type: Chromosome aberration test in vitro
    Result: negative
Remarks: Based on data from similar materials

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

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

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

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

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

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

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

Carcinogenicity:
Not classified based on available information.

**Components:**

**Florfenicol:**
Species: Rat
Application Route: oral (gavage)
Exposure time: 2 Years
Result: negative
Target Organs: Liver, Testes

Species: 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 dosages.

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
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Result: positive
Remarks: Based on data from similar materials

Effects on 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:
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:
Species: Rat
Application Route: Oral
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

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 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
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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:

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Symptoms: respiratory tract irritation</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Symptoms: Skin irritation</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Symptoms: Severe irritation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders</td>
</tr>
</tbody>
</table>

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Florfenicol:**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>LC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>L. macrochirus</td>
<td>&gt; 830 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td>L. mykiss</td>
<td>&gt; 780 mg/l</td>
<td>96 h</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna</td>
<td>&gt; 330 mg/l</td>
<td>48 h</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>P. subcapitata</td>
<td>&gt; 2.9 mg/l</td>
<td>14 d</td>
</tr>
<tr>
<td>Skeletonema costatum</td>
<td>0.0336 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>Lemna gibba</td>
<td>0.76 mg/l</td>
<td>7 d</td>
</tr>
<tr>
<td>P. subcapitata</td>
<td>2.9 mg/l</td>
<td>14 d</td>
</tr>
<tr>
<td>Skeletonema costatum</td>
<td>0.00423 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>Lemna gibba</td>
<td>0.39 mg/l</td>
<td>7 d</td>
</tr>
</tbody>
</table>

**NOEC**

<table>
<thead>
<tr>
<th>NOEC</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>P. subcapitata</td>
<td>2.9 mg/l</td>
<td>14 d</td>
</tr>
<tr>
<td>Skeletonema costatum</td>
<td>0.00423 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>Lemna gibba</td>
<td>0.39 mg/l</td>
<td>7 d</td>
</tr>
</tbody>
</table>
### Method: OECD Test Guideline 221

**EC50 (Navicula pelliculosa (Freshwater diatom)):** 61 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201

**NOEC (Navicula pelliculosa (Freshwater diatom)):** 19 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201

**EC50 (Anabaena flos-aquae):** 0.066 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201

**NOEC (Anabaena flos-aquae):** 0.051 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201

#### M-Factor (Acute aquatic toxicity)

: 10

#### Toxicty to fish (Chronic toxicity)

: NOEC: 5.5 mg/l  
**Exposure time:** 32 d  
**Species:** Pimephales promelas (fathead minnow)  
**Method:** OECD Test Guideline 210

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

: NOEC: 1.5 mg/l  
**Exposure time:** 21 d  
**Species:** Daphnia magna (Water flea)  
**Method:** OECD Test Guideline 211

#### M-Factor (Chronic aquatic toxicity)

: 10

### 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

NOEC (Selenastrum capricornutum (green algae)): 96 mg/l  
Exposure time: 12 d

12.2 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)

12.3 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

12.4 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

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations.
  According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
  Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste han-
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Date of first issue: 04.11.2014

disposal site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN: UN 3082
ADR: UN 3082
RID: UN 3082
IMDG: UN 3082
IATA: UN 3082

14.2 UN proper shipping name

ADN: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
RID: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
IMDG: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
IATA: Environmentally hazardous substance, liquid, n.o.s. (Florfenicol)

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
IATA: 9

14.4 Packing group

ADN
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9

ADR
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
14.5 Environmental hazards

**ADN**
Environmentally hazardous : yes

**ADR**
Environmentally hazardous : yes

**RID**
Environmentally hazardous : yes

**IMDG**
Marine pollutant : yes

**IATA (Passenger)**
Environmentally hazardous : yes

**IATA (Cargo)**
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.
SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th></th>
<th>ENVIROMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H301 : Toxic if swallowed.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H335 : May cause respiratory irritation.
## SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

### Florfenicol / Flunixin Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of first issue:</th>
<th>Date of last issue:</th>
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<td>3.1</td>
<td>23.03.2020</td>
<td>28043-00016</td>
<td>04.11.2014</td>
<td>12.12.2019</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H360FD</td>
<td>May damage fertility. May damage the unborn child.</td>
</tr>
<tr>
<td>H361fd</td>
<td>Suspected of damaging fertility. Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H411</td>
<td>Toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

**Full text of other abbreviations**

- **Acute Tox.**: Acute toxicity
- **Aquatic Acute**: Short-term (acute) aquatic hazard
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Dam.**: Serious eye damage
- **Eye Irrit.**: Eye irritation
- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **STOT SE**: Specific target organ toxicity - single exposure

**ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways**; **ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road**; **AICS - Australian Inventory of Chemical Substances**; **ASTM - American Society for the Testing of Materials**; **bw - Body weight**; **CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008**; **CMR - Carcinogen, Mutagen or Reproductive Toxicant**; **DIN - Standard of the German Institute for Standardisation**; **DSL - Domestic Substances List (Canada)**; **ECHA - European Chemicals Agency**; **EC-Number - European Community number**; **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**; **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**; **NO(A)EC - No Observed (Adverse) Effect Concentration**; **NO(A)EL - No Observed (Adverse) Effect Level**; **NOELR - No Observable Effect Loading Rate**; **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**; **RID - Regulations concerning the International Carriage of Dangerous Goods by Rail**; **SADT - Self-Accelerating Decomposition Temperature**; **SDS - Safety Data Sheet**; **SVHC - Substance of Very High Concern**; **TCI - Taiwan Chemical Substance Inventory**; **TRGS - Technical Rule for Hazardous Substances**; **TSCA - Toxic Substances Control Act (United States)**; **UN - United Nations**; **vPvB - Very Persistent and Very Bioaccumulative**

**Further information**

**Sources of key data used to:** Internal technical data, data from raw material SDSs, OECD
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Compilation of the Safety Data Sheet

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
</tr>
<tr>
<td>Repr. 1B</td>
</tr>
<tr>
<td>STOT RE 1</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
</tr>
</tbody>
</table>

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.

IE / EN