SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol / Flunixin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
          Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

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)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms :
Signal word : Danger
Hazard statements : H319 Causes serious eye irritation.
                   H332 Harmful if inhaled.
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 expo-
sure.
H373 May cause damage to organs (Gastrointestinal tract,
Kidney) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read
and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.

Response:
P304 + P340 + P312 IF INHALED: Remove person to fresh air
and keep comfortable for breathing. Call a POISON CENTER/
doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water
for several minutes. Remove contact lenses, if present and
easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/
attention.
P337 + P313 If eye irritation persists: Get medical advice/ at-
tention.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>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; 25</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>
</tbody>
</table>
| 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-
methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | >= 1 - < 2.5 |
4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation.
Harmful if inhaled.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

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

Specific extinguishing 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
6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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

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

7. HANDLING AND STORAGE

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

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

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

Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Materials to avoid:
Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<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
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</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>
<td>No data available</td>
</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>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>1.22</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td></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>
<td>No data available</td>
</tr>
</tbody>
</table>
Decomposition temperature: No data available

Viscosity
Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Harmful if 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
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Version 6.2  Revision Date: 2020/10/16  SDS Number: 28041-00017  Date of last issue: 2020/03/23  Date of first issue: 2014/11/04

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

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.
Respiratory sensitisation
Not classified based on available information.
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**Florfenicol / Flunixin Formulation**

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 429</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>2-Pyrroldione</td>
<td>Local lymph node assay (LLNA)</td>
<td>Skin contact</td>
<td>Mouse</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Malic Acid</td>
<td>Maximisation Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>Maximisation Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>Does not cause skin sensitisation.</td>
<td>negative</td>
<td></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:** | Test Type: Bacterial reverse mutation assay (AMES)  
| Genotoxicity in vitro | 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 |

**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 |

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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>oral (gavage)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver, Testes</td>
</tr>
</tbody>
</table>

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

2-Pyrrolidone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 month(s)</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>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 w</td>
</tr>
<tr>
<td>LOAEL</td>
<td>2 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>oral (feed)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>97 w</td>
</tr>
<tr>
<td>NOAEL</td>
<td>0.6 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>
Reproductive toxicity
May damage fertility. May damage the unborn child.

**Components:**

**Florfenicol:**
- **Effects on fertility**: Test Type: Two-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Oral
  - Fertility: LOAEL: 12 mg/kg body weight
  - Result: decreased pup survival, reduced lactation

- **Effects on foetal development**: Test Type: Embryo-foetal development
  - Species: Rat
  - General Toxicity Maternal: NOAEL: 4 mg/kg body weight
  - Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight
  - Result: No teratogenic effects, Fetotoxicity
  - Remarks: The effects were seen only at maternally toxic doses.

- **Reproductive toxicity - Assessment**: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**2-Pyrrolidone:**
- **Effects on fertility**: Test Type: One-generation reproduction toxicity study
  - Species: Rat
  - Application Route: Ingestion
  - Result: positive
  - Remarks: Based on data from similar materials

- **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
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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:
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Oral
- General Toxicity - Parent: LOAEL: 1 - 1.5 mg/kg body weight
- Symptoms: No foetal abnormalities
- Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development:
- Test Type: Development
- Species: Rat
- Application Route: Oral
- General Toxicity Maternal: LOAEL: 2 mg/kg body weight
- Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight
- Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development
- Species: Rabbit
- Application Route: Oral
- General Toxicity Maternal: LOAEL: 3 mg/kg body weight
- Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight
- Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

STOT - single exposure
Not classified based on available information.

Components:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Assessment: May cause respiratory irritation.

STOT - repeated exposure
Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.
May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

Components:

Florfenicol:
Target Organs: Liver, Brain, Testis, Spinal cord, Blood, gallbladder
Assessment: Causes damage to organs through prolonged or repeated exposure.

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Target Organs: Gastrointestinal tract, Kidney, Blood
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

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
NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organs: Gastrointestinal tract, Blood

Species: Rabbit
LOAEL: 80 mg/kg
Application Route: Dermal
Exposure time: 21 d
Symptoms: Severe irritation

Species: Dog
LOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 9 d
Target Organs: Gastrointestinal tract
Symptoms: Vomiting

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

Inhalation: Symptoms: respiratory tract irritation
Skin contact: Symptoms: Skin irritation
Eye contact: Symptoms: Severe irritation
Ingestion: Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Florfenicol:

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l  
Exposure time: 14 d  
Method: FDA 4.01

IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l  
Exposure time: 72 h  
Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l  
Exposure time: 72 h  
Method: ISO 10253

EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

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

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

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

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

M-Factor (Acute aquatic toxicity): 10

Toxicity to fish (Chronic toxicity)
NOEC (Pimephales promelas (fathead minnow)): 5.5 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

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

- **M-Factor (Chronic aquatic toxicity)**: 10

## 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

Persistence and degradability

Components:

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

Malic Acid:
Biodegradability
: Result: Readily biodegradable.
Method: OECD Test Guideline 301C
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Stability in water
: Hydrolysis: 0 % (28 d)

Bioaccumulative potential

Components:

Florfenicol:
Partition coefficient: n-octanol/water
: log Pow: 0.373

2-Pyrrolidone:
Partition coefficient: n-octanol/water
: log Pow: -0.71
Method: OECD Test Guideline 107

Malic Acid:
Partition coefficient: n-octanol/water
: log Pow: -1.26

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Partition coefficient: n-
octanol/water

Mobility in soil

Components:

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

Distribution among environmental compartments

: log Koc: 1.92

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)

Class : 9
Packing group : III
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.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

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

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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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