

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Florfenicol / Flunixin Formulation

Version 7.5      Revision Date: 09/30/2023      SDS Number: 28030-00025      Date of last issue: 04/04/2023  
Date of first issue: 11/04/2014

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### SECTION 1. IDENTIFICATION

Product name : Florfenicol / Flunixin Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

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

#### GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 + H332 Harmful if swallowed or if inhaled.  
H319 Causes serious eye irritation.  
H360FD May damage fertility. May damage the unborn child.  
H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder, Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read

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and understood.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.  
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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 attention.  
P337 + P313 If eye irritation persists: Get medical attention.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Florfenicol	No data available	73231-34-2	24.59
2-Pyrrolidone	No data available	616-45-5	24.59
Malic Acid	Butanedioic acid, 2-hydroxy-	6915-15-7	2.87
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	No data available	42461-84-7	2.24

## SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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- When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed or if inhaled.  
Causes serious eye irritation.  
May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Fluorine compounds  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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

### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
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 labeled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

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Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Florfenicol	73231-34-2	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.

#### Personal protective equipment

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type** : Combined particulates and organic vapor type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

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Hygiene measures : Use appropriate degowning techniques to remove potentially contaminated clothing.  
: 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid  
Color : yellow  
Odor : No data available  
Odor Threshold : No data available  
pH : No data available  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : No data available  
Flash point : No data available  
Evaporation rate : No data available  
Flammability (solid, gas) : Not applicable  
Flammability (liquids) : No data available  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available  
Vapor pressure : No data available  
Relative vapor density : No data available  
Relative density : 1.22  
Density : No data available  
Solubility(ies)  
Water solubility : No data available

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Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

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### 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.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Harmful if swallowed or if inhaled.

#### Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,890 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 2.28 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

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### 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



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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

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Result : Irreversible effects on the eye

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Florfenicol:

Test Type : Maximization Test  
Species : Guinea pig  
Result : negative

##### 2-Pyrrolidone:

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

##### Malic Acid:

Test Type : Maximization Test  
Routes of exposure : 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 : Maximization Test  
Routes of exposure : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Florfenicol:

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)

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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)

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Result: negative

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

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

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

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

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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Florfenicol:

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

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

#### 2-Pyrrolidone:

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

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

Species : Rat  
Application Route : oral (feed)  
Exposure time : 104 w  
LOAEL : 2 mg/kg body weight

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Result : negative  
Target Organs : Gastrointestinal tract  
Remarks : Significant toxicity observed in testing

Species : Mouse  
Application Route : oral (feed)  
Exposure time : 97 w  
NOAEL : 0.6 mg/kg body weight  
Result : negative  
Target Organs : Gastrointestinal tract  
Remarks : Significant toxicity observed in testing

### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

##### **Florfenicol:**

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

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

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: oral (gavage)  
General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
Embryo-fetal 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 fetal development : Test Type: Embryo-fetal development  
Species: Rat

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Application Route: Ingestion  
Result: positive

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

### Malic Acid:

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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

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

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

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

### STOT-single exposure

Not classified based on available information.

### Components:

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

Assessment : May cause respiratory irritation.

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### STOT-repeated exposure

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

#### Components:

##### **Florfenicol:**

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

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

Target Organs : Gastrointestinal tract, Kidney, Blood  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### **Florfenicol:**

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

Species : Mouse  
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

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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



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Eye contact : Symptoms: Severe irritation  
Ingestion : Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### **Florfenicol:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l  
Exposure time: 96 h  
Method: FDA 4.11  
  
LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 330 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9 mg/l  
Exposure time: 14 d  
Method: FDA 4.01  
  
NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l  
Exposure time: 14 d  
Method: FDA 4.01  
  
IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l  
Exposure time: 72 h  
Method: ISO 10253  
  
NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l  
Exposure time: 72 h  
Method: ISO 10253  
  
EC50 (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

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Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### 2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l  
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

### Malic Acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 240 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Neutralized product  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

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NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Test substance: Neutralized product  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

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

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 15 mg/l  
Exposure time: 48 h  
Method: FDA 4.08

Toxicity to algae/aquatic plants : NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l  
Exposure time: 13 d  
Method: FDA 4.01

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

### **Persistence and degradability**

#### **Components:**

##### **2-Pyrrolidone:**

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

##### **Malic Acid:**

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

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

Stability in water : Hydrolysis: 0 %(28 d)

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### Bioaccumulative potential

#### Components:

##### **Florfenicol:**

Partition coefficient: n-octanol/water : log Pow: 0.373  
pH: 7

##### **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:

##### **Florfenicol:**

Distribution among environmental compartments : Koc: 52  
Method: FDA 3.08

##### **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

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
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.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### **UNRTDG**

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

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(Florfenicol)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

### IATA-DGR

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Florfenicol)

Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

### IMDG-Code

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

Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

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

Class : 9  
Packing group : III  
Labels : 9  
ERG Code : 171  
Marine pollutant : yes(Florfenicol)

### 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.

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## SECTION 15. REGULATORY INFORMATION

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

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

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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