

**Florfenicol / Flunixin Formulation**

Version 6.0      Revision Date: 10/18/2017      SDS Number: 28058-00009      Date of last issue: 05/02/2017  
Date of first issue: 11/04/2014

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**SECTION 1. IDENTIFICATION**

Product name : Florfenicol / Flunixin Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - USA 1685  
Telephone : 908-740-4000  
Telefax : 908-735-1496  
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

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Acute toxicity (Oral) : Category 4  
Acute toxicity (Inhalation) : Category 4  
Eye irritation : Category 2A  
Reproductive toxicity : Category 2  
Specific target organ systemic toxicity - repeated exposure : Category 1 (Liver, Brain, Testes, 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.  
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.  
H372 Causes damage to organs (Liver, Brain, Testes, Spinal cord, Blood, gallbladder, Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

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Precautionary Statements :

**Prevention:**

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

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.  
 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/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous ingredients**

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

### 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. Suspected of damaging fertility. Suspected of damaging 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.
Notes to physician	:	Treat symptomatically and supportively.

### 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> )

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- II**
- 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 and personal protective equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide 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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use with local exhaust ventilation.
- II** Advice on safe handling : Do not breathe vapors or spray mist.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

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- Keep container tightly closed.  
 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  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Ingredients	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)	Merck
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)	Merck
		Wipe limit	400 µg/100 cm <sup>2</sup>	Merck

#### Hazardous components without workplace control parameters

Ingredients	CAS-No.
2-Pyrrolidone	616-45-5
Malic Acid	6915-15-7

- 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

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Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

### Eye protection

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

### Skin and body protection

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

### Hygiene measures

: Ensure that eye flushing systems and safety showers are located 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 information available.
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available

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Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1.22
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	Not applicable

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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.

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Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

### 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: 1,320 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

#### Ingredients:

##### **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

Acute inhalation toxicity : LC0 (Rat): 0.061 mg/l  
 Exposure time: 8 h  
 Test atmosphere: vapor

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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 inhalation toxicity : LC50 (Rat): > 1.306 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): 20,000 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.

**Ingredients:****Florfenicol:**

Species: Rabbit  
Result: No skin irritation

**2-Pyrrolidone:**

Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation

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**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.

**Ingredients:****Florfenicol:**

Species: Rabbit  
Result: Mild eye irritation

**2-Pyrrolidone:**

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

**Malic Acid:**

Species: Rabbit  
Result: Irritation to eyes, reversing within 21 days  
Method: OECD Test Guideline 405  
Remarks: Based on data from similar materials

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

Species: Rabbit  
Result: Irreversible effects on the eye

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Ingredients:****Florfenicol:**

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

**2-Pyrrolidone:**

Test Type: Local lymph node assay (LLNA)  
Routes of exposure: Skin contact

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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.

### Ingredients:

#### Florfenicol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative  Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative  Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Oral Result: negative

#### 2-Pyrrolidone:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative
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Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
 Method: OECD Test Guideline 471  
 Result: negative

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: Chromosome aberration test in vitro  
 Result: negative

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

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

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

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

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

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

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

### Carcinogenicity

Not classified based on available information.

### Ingredients:

#### Florfenicol:

Species: Rat  
 Application Route: oral (gavage)  
 Exposure time: 2 Years

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Result: negative  
 Target Organs: Liver, Testes

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

### 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

#### IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

#### NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

#### Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

#### Ingredients:

##### 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.

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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 : Species: Rat  
 Application Route: Ingestion  
 Result: negative

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

### 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

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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.

**Ingredients:****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, Testes, Spinal cord, Blood, gallbladder, Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

**Ingredients:****Florfenicol:**

Target Organs: Liver, Brain, Testes, 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****Ingredients:****Florfenicol:**

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

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

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

Species: Dog  
NOAEL: 3 mg/kg  
LOAEL: 12 mg/kg

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Exposure time: 52 Weeks  
Target Organs: Liver, gallbladder

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

**2-Pyrrolidone:**

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

**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.

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### Experience with human exposure

#### Ingredients:

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

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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Ingredients:

#### **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	:	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

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		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	: EC50 (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:

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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	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC50: > 300 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	: 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

#### Ingredients:

#### 2-Pyrrolidone:

Biodegradability	: Result: Readily biodegradable. Biodegradation: 98 % Exposure time: 9 d
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**Malic Acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 73 %  
Exposure time: 14 d  
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****Ingredients:****Florfenicol:**

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

**2-Pyrrolidone:**

Partition coefficient: n-octanol/water : log Pow: -0.71

**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****Ingredients:****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 : 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 15. REGULATORY INFORMATION

#### EPCRA - Emergency Planning and Community Right-to-Know

##### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

##### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

##### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Acute toxicity (any route of exposure)  
 Serious eye damage or eye irritation  
 Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### US State Regulations

##### Pennsylvania Right To Know

Triacetin	102-76-1
2-Pyrrolidone	616-45-5
Florfenicol	73231-34-2

##### California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

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

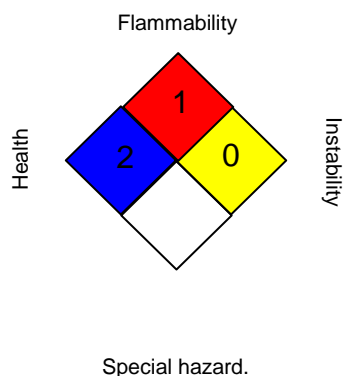
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA:



##### HMIS® IV:

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>1</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG -

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United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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/>

Revision Date : 10/18/2017

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

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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