

**Florfenicol / Flunixin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
10.0	2023/09/30	28047-00024	Date of first issue: 2014/11/04

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Florfenicol / Flunixin Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

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**2. HAZARDS IDENTIFICATION****GHS classification of chemical product**

Acute toxicity (Inhalation) : Category 4

Serious eye damage/eye irritation : Category 2

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**

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- Hazard pictograms :   
- Signal word : Danger
- Hazard statements : H319 Causes serious eye irritation.  
H332 Harmful if inhaled.  
H360FD May damage fertility. May damage the unborn child.  
H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.  
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 protection/ 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/ attention.  
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.

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
2-Pyrrolidone	616-45-5	$\geq 20 - < 30$	5-112
Florfenicol	73231-34-2	$\geq 20 - < 25$	
Malic Acid	6915-15-7	$\geq 1 - < 10$	2-1442
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	$\geq 1 - < 2.5$	

### 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

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- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 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.
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### 7. HANDLING AND STORAGE

#### Handling

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

### Storage

- 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
- Packaging material : Unsuitable material: None known.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / 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-	42461-84-7	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal

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(perfluoromethyl)anilino]nicotinate				
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 vapour type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

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

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical state** : liquid

**Colour** : yellow

**Odour** : No data available

**Odour Threshold** : No data available

**Melting point/freezing point** : No data available

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Boiling point, initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Lower explosion limit and upper explosion limit / flammability limit	:	
Upper explosion limit / Upper per flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Evaporation rate	:	No data available
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density	:	
Relative density	:	1.22
Density	:	No data available
Relative vapour density	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	Not applicable

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**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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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**Acute toxicity**

Harmful if inhaled.

**Product:**

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

**Florfenicol:**

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

### 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:

#### 2-Pyrrolidone:

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

#### Florfenicol:

Species	:	Rabbit
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.

**Components:****2-Pyrrolidone:**

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

**Florfenicol:**

Species	: Rabbit
Result	: Mild eye irritation

**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.

**Components:****2-Pyrrolidone:**

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse

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Method	: OECD Test Guideline 429
Result	: negative
Remarks	: Based on data from similar materials

### Florfenicol:

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

### Malic Acid:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

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

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Assessment	: Does not cause skin sensitisation.
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 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
Genotoxicity in vivo	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 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

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### 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

### Malic Acid:

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

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

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: in vitro assay Test system: mouse lymphoma cells Result: positive
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive
		Test Type: in vitro assay Test system: Escherichia coli Result: positive

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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:****2-Pyrrolidone:**

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

**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

**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

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### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

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

- |                                    |   |  |
|------------------------------------|---|--|
| Effects on fertility               | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials       |
| Effects on foetal development      | : | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>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. |

##### **Florfenicol:**

- |                                    |   |  |
|------------------------------------|---|--|
| Effects on fertility               | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 12 mg/kg body weight<br>Result: decreased pup survival, reduced lactation  |
| Effects on foetal development      | : | Test Type: Embryo-foetal development<br>Species: Rat<br>General Toxicity Maternal: NOAEL: 4 mg/kg body weight<br>Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight<br>Result: No teratogenic effects, Fetotoxicity<br>Remarks: The effects were seen only at maternally toxic doses.<br><br>Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: oral (gavage)<br>General Toxicity Maternal: NOAEL: 120 mg/kg body weight<br>Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight<br>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.   |

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

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

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

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

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

Effects on foetal development : Test Type: Development  
 Species: Rat  
 Application Route: Oral  
 General Toxicity Maternal: LOAEL: 2 mg/kg body weight  
 Embryo-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

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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:****2-Pyrrolidone:**

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

**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

**Malic Acid:**

Species : Rat  
NOAEL : > 250 mg/kg



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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

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## II

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

##### 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

##### 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

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	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
<b>Malic Acid:</b>	
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	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

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plants : 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

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

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

#### Bioaccumulative potential

#### Components:

##### 2-Pyrrolidone:

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

##### Florfenicol:

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

##### 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

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

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## 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.

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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### 15. REGULATORY INFORMATION

#### Related Regulations

##### Fire Service Law

Not applicable to dangerous materials / designated flammables.

##### Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

##### Industrial Safety and Health Law

##### Harmful Substances Prohibited from Manufacture

Not applicable

##### Harmful Substances Required Permission for Manufacture

Not applicable

##### Substances Prevented From Impairment of Health

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

##### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

##### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
malic acid	>=1 - <10	From April 1st, 2026

##### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
malic acid	From April 1st, 2026

##### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

##### Ordinance on Prevention of Lead Poisoning

Not applicable

##### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

##### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

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**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

|| Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

**Aviation Law**

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD



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compile the Safety Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : yyyy/mm/dd

**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

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.