

# SAFETY DATA SHEET



## Florfenicol / Flunixin Injection Formulation

Version 2.0      Revision Date: 14.04.2025      SDS Number: 10846422-00005      Date of last issue: 06.04.2024  
Date of first issue: 06.09.2022

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### SECTION 1: IDENTIFICATION

Product name : Florfenicol / Flunixin Injection Formulation

#### Manufacturer or supplier's details

Company : Intervet Australia Pty Limited (trading as MSD Animal Health)

Address : 91-105 Harpin Street  
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.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

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

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)

#### GHS label elements

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Hazard pictograms



Signal word

: Danger

Hazard statements

: H302 + H332 Harmful if swallowed or if inhaled.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H360Df May damage the unborn child. Suspected of damaging fertility.  
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.

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.  
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.  
P302 + P352 IF ON SKIN: Wash with plenty of water.  
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.  
P332 + P313 If skin irritation occurs: 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.

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**Other hazards which do not result in classification**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 30 -< 60
N-Methyl-2-pyrrolidone	872-50-4	>= 20 -< 30
Propylene glycol	57-55-6	>= 10 -< 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 1 -< 3
Citric acid	77-92-9	< 10

**SECTION 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

In case of eye contact : Thoroughly clean shoes before reuse.  
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 skin irritation.  
Causes serious eye irritation.  
May cause respiratory irritation.  
May damage the unborn child. Suspected of damaging fertility.  
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

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Notes to physician : when the potential for exposure exists (see section 8).  
Treat symptomatically and supportively.

### SECTION 5. FIREFIGHTING 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Hazchem Code : •3Z

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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 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 absor-

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bent.

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	: 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. Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components 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
N-Methyl-2-pyrrolidone	872-50-4	TWA	25 ppm 103 mg/m <sup>3</sup>	AU OEL
Further information: Skin absorption				
		STEL	75 ppm 309 mg/m <sup>3</sup>	AU OEL
Further information: Skin absorption				
Propylene glycol	57-55-6	TWA (particulate)	10 mg/m <sup>3</sup>	AU OEL
		TWA (Total (vapour and particles))	150 ppm 474 mg/m <sup>3</sup>	AU OEL
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

#### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of shift (As soon as possible after exposure ceases)	100 mg/l	ACGIH BEI

#### 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

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Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type Hand protection	: Combined particulates and organic vapour type
Material	: Chemical-resistant gloves
Remarks Eye protection	: Consider double gloving. : 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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Colour	: light yellow Straw-coloured
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available

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flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition 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 characteristics  
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

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

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Harmful if swallowed or if inhaled.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1,935 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 1.86 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

**Components:****Florfenicol:**

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

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

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1,913 - 2,253 mg/kg  
Application Route: Intraperitoneal  
LD50 (Mouse): 100 mg/kg  
Application Route: Intravenous

**N-Methyl-2-pyrrolidone:**

Acute oral toxicity : LD50 (Rat): 4,150 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: The test was conducted equivalent or similar to guideline

**Propylene glycol:**

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Acute oral toxicity	: LD50 (Rat): 22,000 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

### **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

### **Citric acid:**

Acute oral toxicity	: LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

### **Skin corrosion/irritation**

Causes skin irritation.

### **Components:**

#### **Florfenicol:**

Species	: Rabbit
Result	: No skin irritation

#### **N-Methyl-2-pyrrolidone:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: Skin irritation

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||| Remarks : The test was conducted equivalent or similar to guideline

**Propylene glycol:**

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

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

||| Species : Rabbit  
||| Result : Mild skin irritation

**Citric acid:**

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

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****Florfenicol:**

||| Species : Rabbit  
||| Result : Mild eye irritation

**N-Methyl-2-pyrrolidone:**

||| Species : Rabbit  
||| Result : Irritation to eyes, reversing within 21 days  
||| Method : OECD Test Guideline 405  
||| Remarks : The test was conducted equivalent or similar to guideline

**Propylene glycol:**

||| Species : Rabbit  
||| Result : No eye irritation  
||| Method : OECD Test Guideline 405

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

||| Species : Rabbit  
||| Result : Irreversible effects on the eye

**Citric acid:**

||| Species : Rabbit  
||| Result : Irritation to eyes, reversing within 21 days  
||| Method : OECD Test Guideline 405

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**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Florfenicol:**

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

**N-Methyl-2-pyrrolidone:**

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

**Propylene glycol:**

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

**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

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****Florfenicol:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Test system: rat hepatocytes Result: negative

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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

**N-Methyl-2-pyrrolidone:**

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Method: OECD Test Guideline 482  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Genotoxicity in vivo

: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: The test was conducted according to guideline

**Propylene glycol:**

Genotoxicity in vitro

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

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)

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Species: Mouse  
Application Route: Intraperitoneal injection  
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 assay  
Test system: mouse lymphoma cells  
Result: positive

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

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

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

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

**Citric acid:**

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

Test Type: in vitro micronucleus test  
Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Florfenicol:**

Species : Rat

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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

**N-Methyl-2-pyrrolidone:**

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 451
Result	:	negative
Remarks	:	The test was conducted according to guideline

Species	:	Rat
Application Route	:	Inhalation
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	The test was conducted equivalent or similar to guideline

**Propylene glycol:**

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

**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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May damage the unborn child. Suspected of damaging fertility.

**Components:****Florfenicol:**

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

**N-Methyl-2-pyrrolidone:**

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: The test was conducted according to guideline
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted according to guideline
	Test Type: Fertility/early embryonic development Species: Rat Application Route: inhalation (vapour) Method: OECD Test Guideline 414 Result: positive

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Remarks: The test was conducted equivalent or similar to guideline

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: positive

Remarks: The test was conducted equivalent or similar to guideline

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

### Propylene glycol:

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

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Mouse  
 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

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**Citric acid:**

Effects on foetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

**STOT - single exposure**

May cause respiratory irritation.

**Components:****N-Methyl-2-pyrrolidone:**

Assessment : May cause respiratory irritation.

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

Assessment : May cause respiratory irritation.

**Citric acid:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

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

May cause damage to organs (Gastrointestinal tract, Kidney) through prolonged or repeated exposure.

**Components:****Florfenicol:**

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

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

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

**Repeated dose toxicity****Components:****Florfenicol:**

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

Species : Mouse

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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

**N-Methyl-2-pyrrolidone:**

Species	:	Rat, male
NOAEL	:	169 mg/kg
LOAEL	:	433 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days
Method	:	OECD Test Guideline 408
Remarks	:	The test was conducted according to guideline
Species	:	Rat
NOAEL	:	0.5 mg/l
LOAEL	:	1 mg/l
Application Route	:	inhalation (dust/mist/fume)
Exposure time	:	96 Days
Method	:	OECD Test Guideline 413
Remarks	:	The test was conducted according to guideline
Species	:	Rabbit, male
NOAEL	:	826 mg/kg
LOAEL	:	1,653 mg/kg
Application Route	:	Skin contact
Exposure time	:	20 Days
Method	:	OECD Test Guideline 410
Remarks	:	The test was conducted equivalent or similar to guideline

**Propylene glycol:**

Species	:	Rat, male
NOAEL	:	>= 1,700 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 yr

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### 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

### Citric acid:

Species	:	Rat
NOAEL	:	4,000 mg/kg
LOAEL	:	8,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	10 Days

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### N-Methyl-2-pyrrolidone:

Skin contact	:	Symptoms: Skin irritation
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**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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**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

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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

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

**N-Methyl-2-pyrrolidone:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 24 h  
Method: DIN 38412  
Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l  
Exposure time: 72 h  
EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l  
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 12.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: The test was conducted according to guideline

Toxicity to microorganisms : EC50 (activated sludge): > 600 mg/l  
Exposure time: 30 min  
Method: ISO 8192  
Remarks: The test was conducted according to guideline

**Propylene glycol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

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Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

**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

**Citric acid:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l  
Exposure time: 24 h

**Persistence and degradability****Components:****N-Methyl-2-pyrrolidone:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 73 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

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Remarks: The test was conducted according to guideline

**Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

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

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

**Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****Florfenicol:**

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

**N-Methyl-2-pyrrolidone:**

Partition coefficient: n-octanol/water : log Pow: -0.46  
Method: OECD Test Guideline 107  
Remarks: The test was conducted according to guideline

**Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

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

Partition coefficient: n-octanol/water : log Pow: 1.34

**Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1.72

**Mobility in soil****Components:****Florfenicol:**

Distribution among environ- : Koc: 52

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||| mental compartments 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.  
(Florfenicol)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : no

#### 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

#### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)  
Class : 9  
Packing group : III  
Labels : 9

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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.

### National Regulations

#### ADG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : •3Z  
Environmentally hazardous : no

### 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

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

Therapeutic Goods (Poisons Standard) Instrument : Schedule 5 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)  
Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

## SECTION 16: ANY OTHER RELEVANT INFORMATION

### Further information

Revision Date : 14.04.2025  
Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average  
AU OEL / STEL : Exposure standard - short term exposure limit

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; KECL - 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; TECI - 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

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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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