

Florfenicol / Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
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SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol / Flunixin Injection Formulation

Manufacturer or supplier's details

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



Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

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 (Gastrointestinal tract, Kidney, Blood, Liver, Brain, Testis, Spinal cord, gallbladder)

GHS label elements

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 (Gastrointestinal tract, Kidney, Blood, Liver, Brain, Testis, Spinal cord, gallbladder) through

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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 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 or doctor/ physician if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 30 -< 50
N-Methyl-2-pyrrolidone	872-50-4	>= 20 -< 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 1 -< 3
Citric acid	77-92-9	>= 1 -< 5

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

SECTION 5. FIRE-FIGHTING MEASURES

- | | | |
|---------------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
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 _x) |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local cir- |

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cumstances 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

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

SECTION 7. HANDLING AND STORAGE

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

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

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapors.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.

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- Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
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 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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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

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		N-methyl-2-pyrrolidone		shift (As soon as possible after exposure ceases)		BEI
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Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.

Personal protective equipment

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

Filter type : Combined particulates and organic vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : light yellow
 Straw-colored

Odor : No data available

Odor Threshold : No data available

pH : No data available

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Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
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.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.

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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.

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: 1,435 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

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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

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
Remarks : The test was conducted equivalent or similar to guideline

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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

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

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Florfenicol:**

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

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N-Methyl-2-pyrrolidone:

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

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Florfenicol:

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

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

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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

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.

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

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Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Florfenicol:**

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

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

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

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

Test Type: Embryo-fetal development
Species: Mouse
Application Route: oral (gavage)
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity. |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments. |

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 fetal development | : Test Type: Embryo-fetal 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 (vapor)
Method: OECD Test Guideline 414
Result: positive
Remarks: The test was conducted equivalent or similar to guideline |

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Test Type: Embryo-fetal 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.

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

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

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

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Oral

General Toxicity Maternal: LOAEL: 3 mg/kg body weight

Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight

Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Citric acid:

Effects on fetal 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.

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

Components:**Florfenicol:**

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

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

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

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

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

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

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

Species : Dog
NOAEL : 3 mg/kg
LOAEL : 12 mg/kg
Exposure time : 52 Weeks
Target Organs : Liver, gallbladder

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

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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

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

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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

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

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NOEC (*Pseudokirchneriella subcapitata* (green algae)): 2.9 mg/l

Exposure time: 14 d

Method: FDA 4.01

IC50 (*Skeletonema costatum* (marine diatom)): 0.0336 mg/l

Exposure time: 72 h

Method: ISO 10253

NOEC (*Skeletonema costatum* (marine diatom)): 0.00423 mg/l

Exposure time: 72 h

Method: ISO 10253

EC50 (*Lemna gibba* (gibbous duckweed)): 0.76 mg/l

Exposure time: 7 d

Method: OECD Test Guideline 221

NOEC (*Lemna gibba* (gibbous duckweed)): 0.39 mg/l

Exposure time: 7 d

Method: OECD Test Guideline 221

EC50 (*Navicula pelliculosa* (Freshwater diatom)): 61 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (*Navicula pelliculosa* (Freshwater diatom)): 19 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (*Anabaena flos-aquae*): 0.066 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (*Anabaena flos-aquae*): 0.051 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

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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

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

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

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 environmental compartments : Koc: 52
Method: FDA 3.08

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

|| Distribution among environmental compartments : log Koc: 1.92

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

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

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

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
EmS Code	: F-A, S-F
Marine pollutant	: yes

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

Not applicable for product as supplied.

Domestic regulation

NOM-002-SCT

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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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.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for
producing capsules, tablets and pills.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental
Health - Biological exposure indices for workers occupational-
ly exposed to chemical agents

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 Develop-

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ment; 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

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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