SAFETY DATA SHEET

Florfenicol / Flunixin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
8.1	30.09.2023	28021-00024	Date of first issue: 04.11.2014

SECTION 1. IDENTIFICATION

Product name : Florfenicol / Flunixin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma Buenos Aires, Argentina C1013AAP

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

Serious eye damage/eye irritation : Category 2A

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

Hazard pictograms :

Signal Word : Danger

Hazard Statements :
H302 + H332 Harmful if swallowed or if inhaled.
H319 Causes serious eye irritation.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) 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 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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 20 -< 25
2-Pyrrolidone	616-45-5	>= 20 -< 30
Malic Acid	6915-15-7	>= 1 -< 5
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 1 -< 2,5

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 soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed or if inhaled.
Causes serious eye irritation.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing : None known.

media

Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Fluorine compounds Nitrogen oxides (NOx)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe mist or vapors. Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
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/m3 (OEB 2)	Internal
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	400 µg/100 cm²	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	1,22
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

Harmful if swallowed or if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: 1.890 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 2,28 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Florfenicol:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

LD50 (Mouse): > 2.000 mg/kg

LD50 (Dog): > 1.280 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,28 mg/l
Exposure time: 4 h

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1.913 - 2.253 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 100 mg/kg
Application Route: Intravenous

2-Pyrrolidone:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Malic Acid:

Acute oral toxicity : LD50 (Rat): 3.500 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg
Remarks: Based on data from similar materials

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

Acute oral toxicity : LD50 (Rat): 53 - 157 mg/kg

LD50 (Mouse): 176 - 249 mg/kg

LD50 (Guinea pig): 488,3 mg/kg

LD50 (Monkey): 300 mg/kg

Acute inhalation toxicity : LC50 (Rat): < 0,52 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 59,4 - 185,3 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 164 - 363 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Components:

Florfenicol:

Species : Rabbit
Result : No skin irritation

2-Pyrrolidone:

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

Malic Acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

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

Species : Rabbit
Result : Mild skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Florfenicol:

Species : Rabbit
Result : Mild eye irritation

2-Pyrrolidone:

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

Malic Acid:

Species : Rabbit

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

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

Species	:	Rabbit
Result	:	Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Florfenicol:

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

2-Pyrrolidone:

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

Malic Acid:

Test Type	:	Maximization Test
Routes of exposure	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative
Remarks	:	Based on data from similar materials

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Florfenicol:

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

2-Pyrrolidone:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative

Malic Acid:

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro test Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro test Test system: Escherichia coli Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

Florfenicol:

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

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

2-Pyrrolidone:

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

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

Species	:	Rat

Application Route	:	oral (feed)
Exposure time	:	104 w
LOAEL	:	2 mg/kg body weight
Result	:	negative
Target Organs	:	Gastrointestinal tract
Remarks	:	Significant toxicity observed in testing

Species	:	Mouse
Application Route	:	oral (feed)
Exposure time	:	97 w
NOAEL	:	0,6 mg/kg body weight
Result	:	negative
Target Organs	:	Gastrointestinal tract
Remarks	:	Significant toxicity observed in testing

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

Florfenicol:

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

2-Pyrrolidone:

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: positive Remarks: Based on data from similar materials

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

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

Malic Acid:

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

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

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Oral
General Toxicity Parent: LOAEL: 1 - 1,5 mg/kg body weight
Symptoms: No fetal abnormalities.
Result: No effects on fertility and early embryonic development were detected.

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

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

STOT-single exposure

Not classified based on available information.

Components:

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

Assessment : May cause respiratory irritation.

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
NOAEL	:	200 mg/kg
Exposure time	:	13 Weeks
Target Organs	:	Liver, Testis
Species	:	Rat
NOAEL	:	30 mg/kg
Exposure time	:	13 Weeks
Target Organs	:	Liver, Testis
Species	:	Dog
NOAEL	:	3 mg/kg
LOAEL	:	12 mg/kg
Exposure time	:	52 Weeks
Target Organs	:	Liver, gallbladder
Species	:	Rat
NOAEL	:	1 mg/kg
LOAEL	:	3 mg/kg
Exposure time	:	52 Weeks
Target Organs	:	Testis

2-Pyrrolidone:

Species	:	Rat

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

Malic Acid:

Species	:	Rat
NOAEL	:	> 250 mg/kg
Application Route	:	Ingestion
Exposure time	:	104 Weeks

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

Species	:	Rat
NOAEL	:	2 mg/kg
LOAEL	:	< 4 mg/kg
Application Route	:	Oral
Exposure time	:	6 w
Target Organs	:	Gastrointestinal tract

Species	:	Rat
NOAEL	:	1 mg/kg
Application Route	:	Oral
Exposure time	:	1 y
Target Organs	:	Gastrointestinal tract, Kidney

Species	:	Monkey
NOAEL	:	15 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Target Organs	:	Gastrointestinal tract, Blood

Species	:	Rabbit
LOAEL	:	80 mg/kg
Application Route	:	Dermal
Exposure time	:	21 d
Symptoms	:	Severe irritation

Species	:	Dog
LOAEL	:	11 mg/kg
Application Route	:	Oral
Exposure time	:	9 d
Target Organs	:	Gastrointestinal tract
Symptoms	:	Vomiting

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

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

Inhalation	:	Symptoms: respiratory tract irritation

Skin contact	:	Symptoms: Skin irritation
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

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

M-Factor (Acute aquatic toxicity) : 10

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 5,5 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,5 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

2-Pyrrolidone:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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

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

EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Malic Acid:

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

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

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Test substance: Neutralized product

Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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

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

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

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

LC50 (Oncorhynchus mykiss (rainbow trout)): 5,5 mg/l
Exposure time: 96 h
Method: FDA 4.11

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

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

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

Persistence and degradability

Components:

2-Pyrrolidone:

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

Malic Acid:

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

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

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

Bioaccumulative potential

Components:

Florfenicol:

Partition coefficient: n-octanol/water : log Pow: 0,373
pH: 7

2-Pyrrolidone:

Partition coefficient: n-octanol/water : log Pow: -0,71
Method: OECD Test Guideline 107

Malic Acid:

Partition coefficient: n-octanol/water : log Pow: -1,26

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

Partition coefficient: n-octanol/water : log Pow: 1,34

Mobility in soil

Components:

Florfenicol:

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

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

Distribution among environmental compartments : log Koc: 1,92

Other adverse effects

No data available

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.

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	:	yes

IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Florfenicol)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

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

Not applicable for product as supplied.

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
Control of precursors and essential chemicals for the preparation of drugs.	:	Not applicable

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 : 30.09.2023
Date format : dd.mm.yyyy

Further information

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/

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; 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 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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