

Florfenicol / Flunixin Injection Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 10846421-00003 Date of first issue: 06.09.2022 2.1

SECTION 1. IDENTIFICATION

Product name Florfenicol / Flunixin Injection Formulation

Manufacturer or supplier's details

MSD Company

Address Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone 908-740-4000

1-908-423-6000 Emergency telephone

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 (Liver, Brain, Testis, Spinal cord, Blood,

gallbladder)

repeated exposure

Specific target organ toxicity - : Category 2 (Gastrointestinal tract, Kidney)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1



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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 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated expo-

sure.

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 protec-

tion/ 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/ atten-

tion.

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

P391 Collect spillage.

Storage:



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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	>= 30 -< 50
N-Methyl-2-pyrrolidone	872-50-4	>= 20 -< 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-	42461-84-7	>= 2,5 -< 3
methyl-3-(perfluoromethyl)anilino]nicotinate		
Citric acid	77-92-9	>= 1 -< 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 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 contact, immediately flush eyes with plenty of water In case of eye contact

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 fertili-

Causes damage to organs through prolonged or repeated

exposure.



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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

media

None known.

Specific hazards during fire

fighting

Hazardous combustion prod- : C

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Fluorine compounds Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

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 emer-

gency 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.



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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 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.

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.

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- (perfluorome- thyl)anilino]nicotinate	42461-84-7	TWA	40 μg/m3 (OEB 3)	Internal		
	Further information: Skin					
		Wipe limit	400 μg/100 cm ²	Internal		



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Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling	Permissible concentra-	Basis
				time	tion	
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

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 vapor type

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



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use of administrative controls.

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

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



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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. Stable under normal conditions. Chemical stability Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

None known.

Conditions to avoid 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 toxicity estimate: 1.435 mg/kg Acute oral toxicity

Method: Calculation method

Acute toxicity estimate: 1,86 mg/l Acute inhalation toxicity

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

LC50 (Rat): > 0.28 mg/lAcute inhalation toxicity

Exposure time: 4 h

Acute dermal toxicity Remarks: No data available



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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

Acute inhalation toxicity : LC50 (Rat): > 5,1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

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



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N-Methyl-2-pyrrolidone:

Result : 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

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 syn-

thesis 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

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-



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thesis in mammalian cells (in vitro)

Result: negative

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

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Hamster

Application Route: Ingestion Method: OECD Test Guideline 475

Result: negative

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

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

Result: negative

Test Type: in vitro test

Test system: mouse lymphoma cells

Result: positive

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

Result: positive

Test Type: in vitro test
Test system: Escherichia coli

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

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
Result : negative

Species : Rat

Application Route : inhalation (vapor)

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

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.



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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 dos-

es.

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 - As-

sessment

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

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion
Method: OECD Test Guideline 414

Result: positive

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: inhalation (vapor)

Result: positive

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.



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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.

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.



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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

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

Species : Rat



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NOAEL : 0,5 mg/l LOAEL : 1 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 96 Days

Method : OECD Test Guideline 413

Species : Rabbit

NOAEL : 826 mg/kg

LOAEL : 1.653 mg/kg

Application Route : Skin contact

Exposure time : 20 Days

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



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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact : Symptoms: Skin irritation

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, hyperten-

sion, 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



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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 tox-

icity)

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

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

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 (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 12,5 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 600 mg/l

Exposure time: 30 min



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Method: ISO 8192

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

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



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Bioaccumulative potential

Components:

Florfenicol:

Partition coefficient: n- : log Pow: 0,373

octanol/water pH: 7

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0,46

octanol/water Method: OECD Test Guideline 107

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-

log Pow: -1,72

octanol/water

Mobility in soil

Components:

Florfenicol:

Distribution among environ: Koc: 52

mental compartments Method: FDA 3.08

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

Distribution among environ-

mental 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)



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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)

Packing instruction (passen-

ger aircraft)

964

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.

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 : Not applicable

Registry.

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



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SECTION 16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

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



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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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