according to the Globally Harmonized System



Florfenicol / Flunixin Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 7.0 28.09.2024 28044-00025 Date of first issue: 04.11.2014

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol / Flunixin Formulation

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number: +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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Serious eye damage/eye irri-

tation

Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure

Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallblad-

der)

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

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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 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:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe mist or vapours.

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or with adequate ventilation.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P301 + P317 + P330 IF SWALLOWED: Get medical help.

Rinse mouth.

P304 + P340 + P317 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. Get medical help.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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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

4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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, DO NOT induce vomiting. If swallowed

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).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING MEASURES

Water spray Suitable extinguishing media

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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 pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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.

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Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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 labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Florfenicol	73231-34-2	TWA	100 μg/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 inform	Further information: Skin			
		Wipe limit	400 μg/100 cm ²	Internal	

Engineering measures : Use

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 contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Combined particulates and organic vapour type

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : yellow

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

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Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac- :

tions

Can react with strong oxidizing agents.

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous de

products

: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

Acute toxicity

Harmful if swallowed or if inhaled.

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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 tox-

icity

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

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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

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Malic Acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials

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

Species : Rabbit

Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Florfenicol:

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

2-Pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Malic Acid:

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

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

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

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Result : negative

Germ cell mutagenicity

Not classified based on available information.

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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

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

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Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

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

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

Result: negative

Test Type: in vitro assay

Test system: mouse lymphoma cells

Result: positive

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

Result: positive

Test Type: in vitro assay
Test system: Escherichia coli

Result: positive

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: MouseApplication Route: IngestionExposure time: 18 month(s)Result: negative

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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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight

Result: No teratogenic effects, Fetotoxicity

Remarks: The effects were seen only at maternally toxic dos-

es.

Test Type: Embryo-foetal development

Species: Mouse

Application Route: oral (gavage)

General Toxicity Maternal: NOAEL: 120 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity

Reproductive toxicity - 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 experi-

ments.

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П

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 foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

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 foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

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

Effects on fertility: Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity - Parent: LOAEL: 1 - 1.5 mg/kg body weight

Symptoms: No foetal abnormalities

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 2 mg/kg body weight Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: LOAEL: 3 mg/kg body weight Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected only at high maternally toxic doses

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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

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Species: RatNOAEL: 1 mg/kgLOAEL: 3 mg/kgExposure time: 52 WeeksTarget 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</td>

 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

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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, hyperten-

sion, Kidney disorders

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

according to the Globally Harmonized System



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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)

10

Toxicity to fish (Chronic tox-:

icity)

NOEC: 5.5 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 1.5 mg/l

Exposure time: 21 d

Species: Daphnia magna (Water flea) 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

aquatic invertebrates

Toxicity to daphnia and other : 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

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Method: OECD Test Guideline 209

Malic Acid:

LC50 (Danio rerio (zebra fish)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : 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: Neutralised product Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

Test substance: Neutralised product Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC50: > 100 mg/l Toxicity to microorganisms

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

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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- : log Pow: 0.373

octanol/water pH: 7

2-Pyrrolidone:

Partition coefficient: n- : log Pow: -0.71

octanol/water Method: OECD Test Guideline 107

Malic Acid:

Partition coefficient: n- : log Pow: -1.26

octanol/water

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

Partition coefficient: n- : log Pow: 1.34

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- : log Koc: 1.92

mental compartments

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Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Florfenicol)

Class 9 Ш Packing group 9 Labels Environmentally hazardous yes

IATA-DGR

UN/ID No. UN 3082

Proper shipping name Environmentally hazardous substance, liquid, n.o.s.

(Florfenicol)

9 Class Ш Packing group

Miscellaneous Labels 964

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

964

Environmentally hazardous

yes

IMDG-Code

UN number UN 3082

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

> N.O.S. (Florfenicol)

Class Packing group Ш Labels 9 **EmS Code** F-A, S-F

Marine pollutant yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

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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.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 28.09,2024

Further information

Sources of key data used to

compile the Safety Data

eChem Portal search results and European Chemicals Agen-

Internal technical data, data from raw material SDSs, OECD

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

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

Date format : dd.mm.yyyy

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

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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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