

# Florfenicol Premix Formulation

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 8.0 28.09.2024 437318-00020 Date of first issue: 06.01.2016

#### **SECTION 1. IDENTIFICATION**

Product identifier : Florfenicol Premix Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 2 (Liver, Brain, Testis, Spinal cord, Blood,

gallbladder)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :





Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damag-

ing the unborn child.

H373 May cause damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated expo-

sure

H410 Very toxic to aquatic life with long lasting effects.



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Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

### Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

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

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Florfenicol	73231-34-2	Acute Tox. (Oral), 5 Repr., 2 STOT RE, (Liver, Brain, Testis, Spinal cord, Blood, gallblad- der), 1 Aquatic Acute, 1 Aquatic Chronic, 1	>= 3 -< 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.

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 : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.



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If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Protection of first-aiders

Suspected of damaging fertility. Suspected of damaging the

unborn child.

May assess

May cause damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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

delayed

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

icts

Carbon oxides Metal oxides

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. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.



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Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres. Use only with adequate ventilation.

Local/Total ventilation Advice on safe handling

Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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

assessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up.

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



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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

**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

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

Particulates type

Material : Chemical-resistant gloves

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : powder

Color : white

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 : Not applicable



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Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

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 : Not applicable

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 : Not applicable

Explosive properties : Not explosive

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

Particle characteristics

Particle size : No data available

# **SECTION 10. STABILITY AND REACTIVITY**

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.



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products

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity Acute toxicity estimate: > 5.000 mg/kg

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

administration)

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

Application Route: Intraperitoneal

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Florfenicol:

Species Rabbit

Result No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Florfenicol:

**Species** Rabbit

Result Mild eye irritation



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#### 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

### 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

# 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



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Species: MouseApplication Route: oral (gavage)Exposure time: 2 YearsResult: negativeTarget Organs: Testes, Blood

### Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging 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 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.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

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

### **Components:**

#### Florfenicol:

Target Organs : Liver, Brain, Testis, Spinal cord, Blood, gallbladder

Assessment : Causes damage to organs through prolonged or repeated

exposure.



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### 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: RatNOAEL: 1 mg/kgLOAEL: 3 mg/kgExposure time: 52 WeeksTarget Organs: Testis

#### **Aspiration toxicity**

Not classified based on available information.

#### **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



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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 tox-

city)

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

10



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### Persistence and degradability

No data available

### **Bioaccumulative potential**

#### **Components:**

#### Florfenicol:

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

octanol/water pH: 7

### Mobility in soil

#### **Components:**

#### Florfenicol:

Distribution among environ- : Koc: 52

mental compartments

Method: FDA 3.08

### 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 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Florfenicol)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Florfenicol)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)



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Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Florfenicol)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

# **Domestic regulation**

**ANTT** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Florfenicol)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

#### 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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal : Calcium carbonate

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

### **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/

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

### 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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