

# **Florfenicol Premix Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 6.1 30.09.2023 437410-00019 Date of first issue: 06.01.2016

#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Florfenicol Premix Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure

Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)

**GHS** label elements

Hazard pictograms



Signal Word : Danger

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

the unborn child.

H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated expo-

sure.

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 dust.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

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

attention.



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Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

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.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 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.

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.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. Suspected of damaging fertility. Suspected of damaging the

Most important symptoms

and effects, both acute and

unborn child.

delayed

Causes 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.

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**



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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

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: :

ucts

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.

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



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and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate 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

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.



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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 : Particulates type

Hand protection

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** 

Appearance : 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

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



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Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

No data available Autoignition temperature

Decomposition temperature No data available

Viscosity

Not applicable Viscosity, kinematic

Explosive properties Not explosive

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

Particle size No data available

#### **SECTION 10. STABILITY AND REACTIVITY**

Not classified as a reactivity hazard. Reactivity 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

Hazardous decomposition

Oxidizing agents

No hazardous decomposition products are known.

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 toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

#### Components:

#### Florfenicol:



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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

#### 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

#### 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.



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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

#### 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

Result : negative Target 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



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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

Causes 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.

#### 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



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Species: DogNOAEL: 3 mg/kgLOAEL: 12 mg/kgExposure time: 52 Weeks

Target Organs : Liver, gallbladder

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

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

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

## Persistence and degradability

No data available

#### **Bioaccumulative potential**

#### **Components:**

#### Florfenicol:

Partition coefficient: n-

log Pow: 0.373

octanol/water

Mobility in soil

# **Components:**

## Florfenicol:

Distribution among environ-

: Koc: 52

pH: 7

mental compartments Method: FDA 3.08

#### Other adverse effects

No data available



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#### **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)

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**

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.



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(Florfenicol)

Class : 9
Packing group : III
Labels : 9

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

: Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

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#### 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



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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

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

MX / Z8