

Florfenicol Premix Formulation

Version 7.1 Revision Date: 30.09.2023 SDS Number: 437318-00019 Date of last issue: 04.04.2023
Date of first issue: 06.01.2016

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : 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 damaging the unborn child.
H373 May cause damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.
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 protection/ face protection.

Response:
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

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 toxicity (Oral), Category 5 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Liver, Brain, Testis, Spinal cord, Blood, gallbladder), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 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.

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		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.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Suspected of damaging fertility. Suspected of damaging the unborn child. 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.
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 (CO ₂) 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 products	:	Carbon oxides Metal oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

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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 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

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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/m ³ (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 : 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

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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
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 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 reactions	:	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

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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

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

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

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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 synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

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

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

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

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	:	Mouse
Application Route	:	oral (gavage)
Exposure time	:	2 Years
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
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Rat General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight Result: No teratogenic effects., Fetotoxicity. Remarks: The effects were seen only at maternally toxic doses. Test Type: Embryo-fetal development Species: Mouse Application Route: oral (gavage) General Toxicity Maternal: NOAEL: 120 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight Result: Fetotoxicity.
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

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 : 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

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Toxicity to algae/aquatic plants	:	<p>EC50 (Pseudokirchneriella subcapitata (green algae)): > 2,9 mg/l Exposure time: 14 d Method: FDA 4.01</p> <p>NOEC (Pseudokirchneriella subcapitata (green algae)): 2,9 mg/l Exposure time: 14 d Method: FDA 4.01</p> <p>IC50 (Skeletonema costatum (marine diatom)): 0,0336 mg/l Exposure time: 72 h Method: ISO 10253</p> <p>NOEC (Skeletonema costatum (marine diatom)): 0,00423 mg/l Exposure time: 72 h Method: ISO 10253</p> <p>EC50 (Lemna gibba (gibbous duckweed)): 0,76 mg/l Exposure time: 7 d Method: OECD Test Guideline 221</p> <p>NOEC (Lemna gibba (gibbous duckweed)): 0,39 mg/l Exposure time: 7 d Method: OECD Test Guideline 221</p> <p>EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>EC50 (Anabaena flos-aquae): 0,066 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p> <p>NOEC (Anabaena flos-aquae): 0,051 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</p>
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to fish (Chronic toxicity)	:	<p>NOEC (Pimephales promelas (fathead minnow)): 5,5 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</p>
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	<p>NOEC (Daphnia magna (Water flea)): 1,5 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</p>
M-Factor (Chronic aquatic toxicity)	:	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)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo : 956
aircraft)

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Packing instruction (passenger aircraft) : 956
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 - (LINACH) : Not applicable

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

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

Full text of other abbreviations

AIIIC - 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; TECl - 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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