

Florfenicol Solid Formulation

Version 4.2 Revision Date: 09/13/2019 SDS Number: 444134-00010 Date of last issue: 24.04.2019
Date of first issue: 07.01.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol Solid Formulation

Manufacturer or supplier's details

Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

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

GHS label elements

Hazard pictograms :  

Signal word : Danger

Hazard statements : H303 May be harmful if swallowed.

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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 exposure.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 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

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 50 - < 70

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.

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- 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.
- 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 : May be harmful if swallowed.
 Suspected of damaging fertility. Suspected of damaging the unborn child.
 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.

5. FIREFIGHTING MEASURES

- 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 products : Carbon oxides
 Nitrogen oxides (NO_x)
- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
 Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
 Follow safe handling advice and personal protective equipment recommendations.

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- Environmental precautions : Discharge into the environment must be avoided. 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.

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. 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. Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

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Florfenicol	73231-34-2	TWA	100 µg/m ³ (OEB 2)	Internal
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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.

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 : powder

Colour : white

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 : Not applicable

Evaporation rate : Not applicable

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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
Vapour pressure	:	No data available
Relative vapour 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
Auto-ignition 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

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
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

May be harmful if swallowed.

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

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

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Respiratory sensitisation

Not classified based on available information.

Components:**Florfenicol:**

Test Type : Maximisation 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

Species : Mouse
Application Route : oral (gavage)
Exposure time : 2 Years
Result : negative
Target Organs : Testes, Blood

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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 foetal development : 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 doses.
- 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 - 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

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

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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.

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

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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 toxicity) : 10

Toxicity to fish (Chronic toxicity) : 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 (Chronic 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

Persistence and degradability

No data available

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Bioaccumulative potential**Components:****Florfenicol:**

Partition coefficient: n-octanol/water : log Pow: 0.373

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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.

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

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 aircraft) : 956
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

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Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

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

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**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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

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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; 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.

IN / EN