

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Florfenicol Solid Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD  
Address : Avenida 16 de Septiembre No. 301  
Xaltocan - Xochimilco Mexico 16090  
Telephone : 52 55 57284444  
Telefax : 908-735-1496  
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

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Acute toxicity (Oral) : Category 5  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)  
- repeated exposure

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.  
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.

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:**

P312 Call a POISON CENTER or doctor/ physician if you feel

## Florfenicol Solid Formulation

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
 Date of first issue: 07.01.2016

unwell.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal 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	>= 50 -< 70

### 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.
- 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.

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

---

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)
- 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.
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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.
- 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.
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**SECTION 7. HANDLING AND STORAGE**

- Technical measures : Static electricity may accumulate and ignite suspended dust
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## Florfenicol Solid Formulation

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
 Date of first issue: 07.01.2016

- 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.
- 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  
 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 <sup>3</sup> (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

## Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
5.2	09/13/2019	412415-00010	Date of first issue: 07.01.2016

---

	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.

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### 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
Solubility(ies)	

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

---

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

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**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

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION****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

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

---

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.

**Components:****Florfenicol:**

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

## Florfenicol Solid Formulation

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
 Date of first issue: 07.01.2016

---

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

### 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



## Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
5.2	09/13/2019	412415-00010	Date of first issue: 07.01.2016

---

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

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

Species : Dog  
 NOAEL : 3 mg/kg  
 LOAEL : 12 mg/kg  
 Exposure time : 52 Weeks  
 Target Organs : Liver, gallbladder

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

---

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.

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**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  
Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

**Florfenicol Solid Formulation**

Version 5.2      Revision Date: 09/13/2019      SDS Number: 412415-00010      Date of last issue: 24.04.2019  
Date of first issue: 07.01.2016

---

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 toxicity) : 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 (Chronic 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-octanol/water : log Pow: 0.373

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 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.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations**

UNRTDG

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**Florfenicol Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
5.2	09/13/2019	412415-00010	Date of first issue: 07.01.2016

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  
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.  
(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, : Not applicable

**Florfenicol Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
5.2	09/13/2019	412415-00010	Date of first issue: 07.01.2016

---

essential chemical products and machinery for producing capsules, tablets and pills.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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**SECTION 16. OTHER INFORMATION****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 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

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/>

Revision Date : 09/13/2019

# SAFETY DATA SHEET



## Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.04.2019
5.2	09/13/2019	412415-00010	Date of first issue: 07.01.2016

---

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.

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