

Florfenicol Solid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 412413-00017 Date of last issue: 2022/10/01
Date of first issue: 2016/01/07

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Florfenicol Solid Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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 : 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.

Florfenicol Solid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 412413-00017 Date of last issue: 2022/10/01
 Date of first issue: 2016/01/07

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:
 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

Important symptoms and out- : Dust contact with the eyes can lead to mechanical irritation.
 lines of the emergency as- : Contact with dust can cause mechanical irritation or drying of
 sumed : 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)	ENCS No.
Florfenicol	73231-34-2	>= 50 - < 60	

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.

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

In case of eye contact	:	Thoroughly clean shoes before reuse. 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	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure.
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 (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 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 (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.

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

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

Handling

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.

Avoidance of contact : Oxidizing agents

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.

Storage

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:

Florfenicol Solid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 412413-00017 Date of last issue: 2022/10/01
 Date of first issue: 2016/01/07

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

dling or other means.

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available
per flammability limit

Lower explosion limit / : No data available
Lower flammability limit

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n- : Not applicable
octanol/water

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Particle characteristics

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 reac- : May form explosive dust-air mixture during processing, han-
tions dling or other means.
Can react with strong oxidizing agents.

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

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

Information on likely routes of exposure :

- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

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 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.

Florfenicol Solid Formulation

Version 7.0 Revision Date: 2023/04/04 SDS Number: 412413-00017 Date of last issue: 2022/10/01
 Date of first issue: 2016/01/07

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.

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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Florfenicol:

Partition coefficient: n-octanol/water	:	log Pow: 0.373 pH: 7
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Mobility in soil

Components:

Florfenicol:

Distribution among environmental compartments	:	Koc: 52 Method: FDA 3.08
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Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

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.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**Until March 31st, 2023**

Not applicable

From April 1st, 2023

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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/>

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

Date format : yyyy/mm/dd

Full text of other abbreviations

AIC - 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; NZIcC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

Florfenicol Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2022/10/01
7.0	2023/04/04	412413-00017	Date of first issue: 2016/01/07

lative 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.

JP / EN