

## Florfenicol Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.4	30.09.2023	7681958-00009	Date of first issue: 15.12.2020

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### SECTION 1: IDENTIFICATION

Product name : Florfenicol Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 91-105 Harpin Street  
Bendigo 3550, Victoria Australia

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

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

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H360Df May damage the unborn child. Suspected of damaging

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fertility.

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 mist or vapours.

P264 Wash skin thoroughly after handling.

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

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of water.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

**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**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
N-Methyl-2-pyrrolidone	872-50-4	>= 30 -< 60
Florfenicol	73231-34-2	>= 10 -< 30
Propylene glycol	57-55-6	>= 10 -< 30

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### SECTION 4. FIRST AID MEASURES

- |   |   |  |
|---|---|--|
| General advice  | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : | If inhaled, remove to fresh air.<br>Get medical attention.   |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.   |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation.<br>Causes serious eye irritation.<br>May cause respiratory irritation.<br>May damage the unborn child. Suspected of damaging fertility.<br>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.  |

### SECTION 5. FIREFIGHTING MEASURES

- |                                       |   |   |
|---------------------------------------|---|---|
| Suitable extinguishing media          | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media        | : | None known.   |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products         | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods        | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so. |

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Special protective equipment for firefighters : Evacuate area.  
 In the event of fire, wear self-contained breathing apparatus.  
 Use personal protective equipment.  
 Hazchem Code : •3Z

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### 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.  
 Prevent spreading over a wide area (e.g. by containment or oil barriers).  
 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 : Soak up with inert absorbent material.  
 For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
 Clean up remaining materials from spill with suitable absorbent.  
 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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
 Do not breathe mist or vapours.  
 Do not swallow.  
 Do not get in eyes.  
 Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
 Do not eat, drink or smoke when using this product.

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- Hygiene measures : Take care to prevent spills, waste and minimize release to the environment.  
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.
- Conditions for safe storage : 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.  
Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N-Methyl-2-pyrrolidone	872-50-4	TWA	25 ppm 103 mg/m <sup>3</sup>	AU OEL
	Further information: Skin absorption			
		STEL	75 ppm 309 mg/m <sup>3</sup>	AU OEL
	Further information: Skin absorption			
Florfenicol	73231-34-2	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Propylene glycol	57-55-6	TWA (particulate)	10 mg/m <sup>3</sup>	AU OEL
		TWA (Total (vapour and particles))	150 ppm 474 mg/m <sup>3</sup>	AU OEL

## Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of shift (As soon as possible after	100 mg/l	ACGIH BEI

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**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

### 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 : Combined particulates and organic vapour 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 : liquid

Colour : yellow

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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper : No data available

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flammability limit

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.050 - 1.250 g/cm<sup>3</sup>

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 : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : Not applicable

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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 : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**SECTION 11. TOXICOLOGICAL INFORMATION**Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

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**Acute toxicity**

Not classified based on available information.

**Components:****N-Methyl-2-pyrrolidone:**

Acute oral toxicity : LD50 (Rat): 4,150 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

**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

**Propylene glycol:**

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**

Causes skin irritation.

**Components:****N-Methyl-2-pyrrolidone:**

Result : Skin irritation



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**Florfenicol:**

Species	:	Rabbit
Result	:	No skin irritation

**Propylene glycol:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:****N-Methyl-2-pyrrolidone:**

Species	:	Rabbit
Result	:	Irritation to eyes, reversing within 21 days

**Florfenicol:**

Species	:	Rabbit
Result	:	Mild eye irritation

**Propylene glycol:**

Species	:	Rabbit
Result	:	No eye irritation
Method	:	OECD Test Guideline 405

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****N-Methyl-2-pyrrolidone:**

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	Skin contact
Species	:	Mouse
Method	:	OECD Test Guideline 429
Result	:	negative
Remarks	:	Based on data from similar materials

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Test Type	:	Maximisation Test
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Species : Guinea pig  
Result : negative

**Propylene glycol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

**Chronic toxicity****Germ cell mutagenicity**

Not classified based on available information.

**Components:****N-Methyl-2-pyrrolidone:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Hamster  
Application Route: Ingestion  
Method: OECD Test Guideline 475  
Result: negative

**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

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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

### Propylene glycol:

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

Test Type: Chromosome aberration test in vitro  
 Method: OECD Test Guideline 473  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
 cytogenetic assay)  
 Species: Mouse  
 Application Route: Intraperitoneal injection  
 Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### **N-Methyl-2-pyrrolidone:**

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 2 Years  
 Result : negative

Species : Rat  
 Application Route : inhalation (vapour)  
 Exposure time : 2 Years  
 Result : negative

#### **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

**Propylene glycol:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

**Reproductive toxicity**

May damage the unborn child. Suspected of damaging fertility.

**Components:****N-Methyl-2-pyrrolidone:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive

Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: inhalation (vapour)  
Result: positive

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: positive

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

**Florfenicol:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 12 mg/kg body weight  
Result: decreased pup survival, reduced lactation

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Effects on 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.

### Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Mouse  
 Application Route: Ingestion  
 Result: negative

### STOT - single exposure

May cause respiratory irritation.

#### Components:

#### **N-Methyl-2-pyrrolidone:**

Assessment : May cause respiratory irritation.

### 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.

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**Repeated dose toxicity****Components:****N-Methyl-2-pyrrolidone:**

Species : Rat, male  
NOAEL : 169 mg/kg  
LOAEL : 433 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408

Species : Rat  
NOAEL : 0.5 mg/l  
LOAEL : 1 mg/l  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 96 Days  
Method : OECD Test Guideline 413

Species : Rabbit  
NOAEL : 826 mg/kg  
LOAEL : 1,653 mg/kg  
Application Route : Skin contact  
Exposure time : 20 Days

**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

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**Propylene glycol:**

Species : Rat, male  
NOAEL :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****N-Methyl-2-pyrrolidone:**

Skin contact : Symptoms: Skin irritation

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****N-Methyl-2-pyrrolidone:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)):  $> 500$  mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)):  $> 1,000$  mg/l  
Exposure time: 24 h  
Method: DIN 38412

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l  
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l  
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 12.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50:  $> 600$  mg/l  
Exposure time: 30 min  
Method: ISO 8192

**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

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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

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



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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

### Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h

### Persistence and degradability

#### Components:

#### **N-Methyl-2-pyrrolidone:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 73 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301C

#### **Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

### Bioaccumulative potential

#### Components:

#### **N-Methyl-2-pyrrolidone:**

Partition coefficient: n-octanol/water : log Pow: -0.46  
Method: OECD Test Guideline 107

#### **Florfenicol:**

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

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### Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

### Mobility in soil

#### Components:

### Florfenicol:

Distribution among environmental compartments : Koc: 52  
Method: FDA 3.08

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Florfenicol)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

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Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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

#### ADG

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 Hazchem Code : •3Z  
 Environmentally hazardous : yes

### 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.

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## SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

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### SECTION 16: ANY OTHER RELEVANT INFORMATION

#### Further information

Revision Date : 30.09.2023

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

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average

AU OEL / STEL : Exposure standard - short term exposure limit

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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