

## Florfenicol Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/29
13.0	2023/11/30	26280-00025	Date of first issue: 2014/10/29

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Florfenicol Liquid Formulation  
Other means of identification : NUFLOL LA INJECTABLE SOLUTION (52201)

#### 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

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### 2. HAZARDS IDENTIFICATION


#### GHS classification of chemical product

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)  
Short-term (acute) aquatic hazard : Category 1  
Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

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Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	<p>H315 Causes skin irritation.          H319 Causes serious eye irritation.          H335 May cause respiratory irritation.          H360Df May damage the unborn child. Suspected of damaging fertility.          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.</p>
Precautionary statements	:	<p><b>Prevention:</b>          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.          P273 Avoid release to the environment.          P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p><b>Response:</b>          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.          P362 + P364 Take off contaminated clothing and wash it before reuse.          P391 Collect spillage.</p> <p><b>Storage:</b>          P405 Store locked up.</p> <p><b>Disposal:</b>          P501 Dispose of contents/ container to an approved waste disposal plant.</p>

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### II

#### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Florfenicol	73231-34-2	>= 30 - < 40	
N-Methyl-2-pyrrolidone	872-50-4	25	5-113
Propylene glycol	57-55-6	>= 10 - < 20	2-234

### 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.  
 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.  
 If easy to do, remove contact lens, if worn.  
 Get medical attention.
- 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 : Causes skin irritation.  
 Causes serious eye irritation.  
 May cause respiratory irritation.  
 May damage the unborn child. Suspected of damaging fertility.  
 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

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- 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 : 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.
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### 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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### 7. HANDLING AND STORAGE

#### Handling

- Technical measures : See Engineering measures under EXPOSURE

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- Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
 : 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.  
 : 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.  
 : 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
- 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 <sup>3</sup> (OEB)	Internal

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N-Methyl-2-pyrrolidone	872-50-4	OEL-M	2) 1 ppm 4 mg/m <sup>3</sup>	JP OEL JSOH
Further information: Skin absorption				

### Biological occupational exposure limits

Components	CAS-No.	Target substance	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 exposure ceases)	100 mg/l	ACGIH BEI

**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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Aqueous solution

Colour : gold

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

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

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available  
Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : Not applicable

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**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.

**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

**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



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### 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:

#### Florfenicol:

Species	: Rabbit
Result	: No skin irritation

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

Result	: Skin irritation
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#### Propylene glycol:

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### Florfenicol:

Species	: Rabbit
Result	: Mild eye irritation

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

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

#### Propylene glycol:

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

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### 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

##### 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

##### Propylene glycol:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
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

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

**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

**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.

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### 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

#### **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

#### **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:

#### **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.

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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.

### 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.

### 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

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**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.

**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

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### 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

### 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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## 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

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		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
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 5.5 mg/l Exposure time: 32 d



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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

M-Factor (Chronic aquatic toxicity) : 10

### 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

### 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

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**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:****Florfenicol:**

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

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

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

**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

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

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### 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 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

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

Refer to section 15 for specific national regulation.

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### 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

Priority Assessment Chemical Substance

Chemical name	Number
N-Methyl-2-pyrrolidone	136
Propane-1,2-diol	106

#### 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

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

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
1-Methyl-2-pyrrolidone	>=20 - <30	-
propane-1,2-diol	>=10 - <20	From April 1st, 2025

#### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
1-Methyl-2-pyrrolidone	-
propane-1,2-diol	From April 1st, 2025

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### Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

|| 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

### Class I Designated Chemical Substances

Chemical name	Administration number	Concentration (%)
N-Methyl-2-pyrrolidone	746	25

### 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 : Noxious liquid substance(Category Y)

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

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### 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

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## 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

ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
JP OEL JSOH	:	Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits
JP OEL JSOH / OEL-M	:	Occupational Exposure Limit-Mean

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, Bioaccumu-

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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; 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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