

SAFETY DATA SHEET



Florfenicol Formulation

Version 7.0 Revision Date: 14.04.2025 SDS Number: 7681971-00011 Date of last issue: 06.04.2024
Date of first issue: 15.12.2020

Section 1: Identification

Product name : Florfenicol Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800
CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 1

Specific target organ toxicity - single exposure : Category 3

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

Hazardous to the aquatic environment - acute hazard : Category 1

Hazardous to the aquatic environment - chronic hazard : Category 1

GHS label elements

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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 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.

Precautionary statements

: **Prevention:**

P201 Obtain special instructions before use.
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.

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.
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

None known.

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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 -< 50
Florfenicol	73231-34-2	>= 25 -< 30
Propylene glycol	57-55-6	>= 20 -< 30

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with 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.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing : None known.

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Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)

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.

Hazchem Code : 3Z

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.

Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE

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	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. Take care to prevent spills, waste and minimize release to the environment. Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. Conditions for safe storage : Keep in properly 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
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Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
N-Methyl-2-pyrrolidone	872-50-4	WES-TWA	10 ppm 40 mg/m ³	NZ OEL
	Further information: Skin absorption			
		WES-STEL	20 ppm 80 mg/m ³	NZ OEL
	Further information: Skin absorption			
Florfenicol	73231-34-2	TWA	100 µg/m ³ (OEB)	Internal

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Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m3 2)	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m3	NZ 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 exposure ceases)	100 mg/l	ACGIH BEI

Engineering measures

- : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.

Section 9: Physical and chemical properties

Appearance	: liquid
Colour	: yellow
Odour	: No data available
Odour Threshold	: No data available

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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 flammability limit	:	No data available
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 ³
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 characteristics		
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.

Section 11: Toxicological information

Exposure routes	:	Inhalation
	:	Skin contact
	:	Ingestion
	:	Eye contact

Acute toxicity

Not classified based on available information.

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

Acute oral toxicity	:	LD50 (Rat): 4,150 mg/kg Method: OECD Test Guideline 401 Remarks: The test was conducted equivalent or similar to guideline
Acute inhalation toxicity	:	LC50 (Rat): > 5.1 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Remarks: The test was conducted according to guideline
Acute dermal toxicity	:	LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 402 Remarks: The test was conducted equivalent or similar to guideline

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

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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:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation
Remarks : The test was conducted equivalent or similar to guideline

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
Method : OECD Test Guideline 405
Remarks : The test was conducted equivalent or similar to guideline

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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

Florfenicol:

Test Type	:	Maximisation Test
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 Remarks: The test was conducted according to guideline
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Genotoxicity in vivo	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: The test was conducted according to guideline
	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Method: OECD Test Guideline 482 Result: negative Remarks: The test was conducted equivalent or similar to guideline
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 Remarks: The test was conducted according to guideline
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
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

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

Not classified based on available information.

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

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Method	:	OECD Test Guideline 451
Result	:	negative
Remarks	:	The test was conducted according to guideline
Species	:	Rat
Application Route	:	Inhalation
Exposure time	:	2 Years
Method	:	OECD Test Guideline 453
Result	:	negative
Remarks	:	The test was conducted equivalent or similar to guideline

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

Propylene glycol:

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

Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

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Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 416 Result: negative Remarks: The test was conducted according to guideline
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted according to guideline
	Test Type: Fertility/early embryonic development Species: Rat Application Route: inhalation (vapour) Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted equivalent or similar to guideline
	Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: The test was conducted equivalent or similar to guideline
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

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

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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.

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

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Method	:	OECD Test Guideline 408
Remarks	:	The test was conducted according to guideline
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
Remarks	:	The test was conducted according to guideline
Species	:	Rabbit, male
NOAEL	:	826 mg/kg
LOAEL	:	1,653 mg/kg
Application Route	:	Skin contact
Exposure time	:	20 Days
Method	:	OECD Test Guideline 410
Remarks	:	The test was conducted equivalent or similar to guideline
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
LOAEL	:	13 Weeks
Exposure time	:	Liver, Testis
Target Organs	:	
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

Propylene glycol:

Species	:	Rat, male
NOAEL	:	>= 1,700 mg/kg
Application Route	:	Ingestion

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||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

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
Remarks: The test was conducted according to guideline

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
Remarks: The test was conducted according to guideline

Toxicity to microorganisms : EC50 (activated sludge): > 600 mg/l
Exposure time: 30 min
Method: ISO 8192
Remarks: The test was conducted according to guideline

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

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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 (Lemma gibba (gibbous duckweed)): 0.76 mg/l Exposure time: 7 d Method: OECD Test Guideline 221
	NOEC (Lemma 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 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

M-Factor (Chronic aquatic toxicity) : 10

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
Remarks: The test was conducted according to guideline

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
Remarks: The test was conducted according to guideline

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Florfenicol:

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

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

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.

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) : 964

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aircraft)

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

NZS 5433

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

Marine pollutant : no

Special precautions for user

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

Section 15: Regulatory information

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

HSNO Approval Number

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Chemical name	Environmental compartment	Reference concentration
2-Pyrrolidinone, 1-methyl-	Air	0.4 mg/m ³
2-Pyrrolidinone, 1-methyl-	Drinking Water	0.375 mg/l
2-Pyrrolidinone, 1-methyl-	Skin/Surface Deposition	0.83 mg/m ²

Environmental Exposure Limits (EEL)

Not applicable

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HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

Revision Date : 14.04.2025

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 : dd.mm.yyyy

Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL : Workplace 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

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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

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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