

Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/04/04
2.1	2023/09/30	10843912-00003	Date of first issue: 2022/08/31

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Florfenicol (45%) Injection Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

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

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

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 : 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.
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.
- 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.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.
- Storage:**
P405 Store locked up.
- Disposal:**
P501 Dispose of contents/ container to an approved waste disposal plant.

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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	>= 40 - < 50	
N-Methyl-2-pyrrolidone	872-50-4	35	5-113
Diethylene glycol monoethyl ether	111-90-0	>= 20 - < 30	2-422, 7-97

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 (CO₂)
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_x)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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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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- 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.
- 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 ³ (OEB)	Internal

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N-Methyl-2-pyrrolidone	872-50-4	OEL-M	2) 1 ppm 4 mg/m ³	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 : clear

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	:	No data available
Upper explosion limit / Upper per 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	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Density and / or relative density	:	No data available
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.
Molecular weight	:	No data available
Particle characteristics	:	No data available
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
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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

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

Diethylene glycol monoethyl ether:

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

Acute inhalation toxicity : LC50 (Rat): > 5.24 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): 9,143 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:**Florfenicol:**

Species : Rabbit
Result : No skin irritation

N-Methyl-2-pyrrolidone:

Result : Skin irritation

Diethylene glycol monoethyl ether:

Species : Rabbit
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

Diethylene glycol monoethyl ether:

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

Germ cell mutagenicity

Not classified based on available information.

Components:**Florfenicol:**

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

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

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

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

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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

Diethylene glycol monoethyl ether:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
- Genotoxicity in vivo : Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Florfenicol:**

- Species : Rat
Application Route : oral (gavage)
Exposure time : 2 Years
Result : negative
Target Organs : Liver, Testes
- Species : Mouse

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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

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.

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

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	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.

Diethylene glycol monoethyl ether:

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: Rat
	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

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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

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

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

Diethylene glycol monoethyl ether:

Species : Dog
NOAEL : 1,000 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Species : Rat
NOAEL : ≥ 1.06 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days

Species : Rabbit
NOAEL : $\geq 1,000$ mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Aspiration toxicity

Not classified based on available information.

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

Skin contact : Symptoms: Skin irritation

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Florfenicol:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l
Exposure time: 96 h
Method: FDA 4.11

LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l
Exposure time: 96 h
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 330 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9

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plants	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
	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

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toxicity)

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

Diethylene glycol monoethyl ether:

- Toxicity to fish : LC50 (Ictalurus catus (catfish)): 6,010 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,982 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- NOEC (Selenastrum capricornutum (green algae)): >= 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- Toxicity to microorganisms : IC50: > 5,000 mg/l
Exposure time: 16 h

Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 73 %

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Exposure time: 28 d
Method: OECD Test Guideline 301C

Diethylene glycol monoethyl ether:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 16 d
Method: OECD Test Guideline 301B

Bioaccumulative potential**Components:****Florfenicol:**

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

N-Methyl-2-pyrrolidone:

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

Diethylene glycol monoethyl ether:

Partition coefficient: n- : log Pow: -0.54
octanol/water

Mobility in soil**Components:****Florfenicol:**

Distribution among environ- : Koc: 52
mental compartments Method: FDA 3.08

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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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.

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

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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
2-(2-Ethoxyethoxy)ethanol	110

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	>=30 - <40	-
2-(2-ethoxyethoxy)ethanol	>=20 - <30	From April 1st, 2025

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
1-Methyl-2-pyrrolidone	-
2-(2-ethoxyethoxy)ethanol	From April 1st, 2025

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

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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	35

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

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/>

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, 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 mate-

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rial is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

JP / EN