

SAFETY DATA SHEET



Florfenicol (45%) Injection Formulation

Version 3.0 Revision Date: 2025/04/14 SDS Number: 10843914-00004 Date of last issue: 2023/09/30
Date of first issue: 2022/08/31

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol (45%) Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

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

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>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.</p> <p>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.</p> <p>Storage: P405 Store locked up.</p> <p>Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.</p> |

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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) |
|------------------------|------------|-----------------------|
| Florfenicol | 73231-34-2 | >= 30 -< 60 |
| N-Methyl-2-pyrrolidone | 872-50-4 | >= 30 -< 60 |

4. FIRST AID MEASURES

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

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

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

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

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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 (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.

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.

7. HANDLING AND STORAGE

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Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|------------|-------------------------------|--|----------|
| Florfenicol | 73231-34-2 | TWA | 100 µg/m ³ (OEB 2) | Internal |

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

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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 : Chemical-resistant gloves

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : clear

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

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| | |
|--|--|
| 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 | : No data available |
| 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 |

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 | : No hazardous decomposition products are known. |

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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 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 |

Skin corrosion/irritation

Causes skin irritation.

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Components:

Florfenicol:

| | | |
|---------|---|--------------------|
| Species | : | Rabbit |
| Result | : | No skin irritation |

N-Methyl-2-pyrrolidone:

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

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

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 |

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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 |

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 |
| | 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 |

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Remarks: The test was conducted according to guideline

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 |
| 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 |
| 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 |

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 |

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| | | |
|------------------------------------|---|---|
| | | <p>Result: No teratogenic effects, Fetotoxicity Remarks: The effects were seen only at maternally toxic doses.</p> <p>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</p> |
| 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 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 |
| | | <p>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</p> |
| | | <p>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</p> |
| Reproductive toxicity - Assessment | : | Clear evidence of adverse effects on development, based on animal experiments. |

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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 |
| 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 |

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 |

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| | | 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 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic) | : | NOEC (Daphnia magna (Water flea)): 1.5 mg/l Exposure time: 21 d |

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| ic toxicity) | 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 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 |

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

Bioaccumulative potential

Components:

Florfenicol:

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

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0.46

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octanol/water

Method: OECD Test Guideline 107

Remarks: The test was conducted according to guideline

Mobility in soil

Components:

Florfenicol:

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

Other adverse effects

No data available

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.

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

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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.

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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

Revision Date : 2025/04/14

Further informationSources 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)

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

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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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