

## Florfenicol Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 04/04/2023  |
| 2.8     | 09/30/2023     | 7681962-00010 | Date of first issue: 12/15/2020 |

### SECTION 1. IDENTIFICATION

Product name : Florfenicol Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

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

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Skin irritation : Category 2  
Eye irritation : Category 2A  
Reproductive toxicity : Category 1B  
Specific target organ toxicity : Category 3  
- single exposure  
Specific target organ toxicity : Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)  
- repeated exposure

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H360Df May damage the unborn child. Suspected of damaging fertility.  
H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

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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 vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves, protective clothing, eye protection and 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 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 attention.  
P332 + P313 If skin irritation occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**  
P405 Store locked up.

**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

**Other hazards**  
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name          | Common Name/Synonym   | CAS-No.    | Concentration (% w/w)      |
|------------------------|-----------------------|------------|----------------------------|
| N-Methyl-2-pyrrolidone | 1-Methylpyrrolidinone | 872-50-4   | $\geq 33.6 - \leq 40$      |
| Florfenicol            | No data available     | 73231-34-2 | $\geq 24 - \leq 28.5714$   |
| Propylene glycol       | 1,2-Propanediol       | 57-55-6    | $\geq 22.4 - \leq 26.6667$ |

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

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|                                                             |   |                                                                                                                                                                                                                                          |
|-------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                             |   | advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                                                                                               |
| If inhaled                                                  | : | If inhaled, remove to fresh air.<br>Get medical attention.                                                                                                                                                                               |
| In case of skin contact                                     | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.                                                                       |
| If swallowed                                                | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                                    |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation.<br>Causes serious eye irritation.<br>May cause respiratory irritation.<br>May damage the unborn child. Suspected of damaging fertility.<br>Causes damage to organs through prolonged or repeated exposure.       |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).                                                              |
| Notes to physician                                          | : | Treat symptomatically and supportively.                                                                                                                                                                                                  |

### SECTION 5. FIRE-FIGHTING MEASURES

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

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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- |                                                                     |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Environmental precautions                                           | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 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.<br>Do not breathe mist or vapors.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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Materials to avoid : Do not store with the following product types:

- Strong oxidizing agents
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components             | CAS-No.    | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis     |
|------------------------|------------|----------------------------------|------------------------------------------------|-----------|
| N-Methyl-2-pyrrolidone | 872-50-4   | TWA                              | 400 mg/m <sup>3</sup>                          | CA ON OEL |
| Florfenicol            | 73231-34-2 | TWA                              | 100 µg/m <sup>3</sup> (OEB 2)                  | Internal  |
| Propylene glycol       | 57-55-6    | TWA (Vapour and aerosols)        | 50 ppm<br>155 mg/m <sup>3</sup>                | CA ON OEL |
|                        |            | TWA (aerosol)                    | 10 mg/m <sup>3</sup>                           | CA ON 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., 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 vapor 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,

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mist 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                                   |
|--------------------------------------------------|-----------------------------------|
| Appearance                                       | : liquid                          |
| Color                                            | : yellow                          |
| Odor                                             | : No data available               |
| Odor Threshold                                   | : No data available               |
| pH                                               | : No data available               |
| Melting point/freezing point                     | : No data available               |
| Initial boiling point and boiling range          | : No data available               |
| Flash point                                      | : No data available               |
| Evaporation rate                                 | : No data available               |
| Flammability (solid, gas)                        | : Not applicable                  |
| Flammability (liquids)                           | : No data available               |
| Upper explosion limit / Upper flammability limit | : No data available               |
| Lower explosion limit / Lower flammability limit | : No data available               |
| Vapor pressure                                   | : No data available               |
| Relative vapor density                           | : No data available               |
| Relative density                                 | : No data available               |
| Density                                          | : 1.050 - 1.250 g/cm <sup>3</sup> |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Solubility(ies)                        |   |                                                          |
| Water solubility                       | : | No data available                                        |
| Partition coefficient: n-octanol/water | : | Not applicable                                           |
| Autoignition temperature               | : | No data available                                        |
| Decomposition temperature              | : | No data available                                        |
| Viscosity                              |   |                                                          |
| Viscosity, kinematic                   | : | No data available                                        |
| Explosive properties                   | : | Not explosive                                            |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight                       | : | No data available                                        |
| Particle size                          | : | Not applicable                                           |

### 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

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

|                     |   |                                                                      |
|---------------------|---|----------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
|---------------------|---|----------------------------------------------------------------------|

#### Components:

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

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

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

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

### Florfenicol:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 2,000 mg/kg  
LD50 (Dog): > 1,280 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.28 mg/l  
Exposure time: 4 h

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): 1,913 - 2,253 mg/kg  
Application Route: Intraperitoneal  
LD50 (Mouse): 100 mg/kg  
Application Route: Intravenous

### Propylene glycol:

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

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

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

### Skin corrosion/irritation

Causes skin irritation.

### Components:

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

Result : Skin irritation

#### Florfenicol:

Species : Rabbit  
Result : No skin irritation

#### Propylene glycol:



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

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

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

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

##### **Florfenicol:**

|         |   |                     |
|---------|---|---------------------|
| Species | : | Rabbit              |
| Result  | : | Mild eye irritation |

##### **Propylene glycol:**

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

### Respiratory or skin sensitization

#### **Skin sensitization**

Not classified based on available information.

#### **Respiratory sensitization**

Not classified based on available information.

#### Components:

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

|                    |   |                                      |
|--------------------|---|--------------------------------------|
| Test Type          | : | Local lymph node assay (LLNA)        |
| Routes of exposure | : | Skin contact                         |
| Species            | : | Mouse                                |
| Method             | : | OECD Test Guideline 429              |
| Result             | : | negative                             |
| Remarks            | : | Based on data from similar materials |

##### **Florfenicol:**

|           |   |                   |
|-----------|---|-------------------|
| Test Type | : | Maximization Test |
| Species   | : | Guinea pig        |
| Result    | : | negative          |

##### **Propylene glycol:**

|                    |   |                   |
|--------------------|---|-------------------|
| Test Type          | : | Maximization Test |
| Routes of exposure | : | Skin contact      |
| Species            | : | Guinea pig        |
| Result             | : | negative          |

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### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

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

|                       |   |                                                                                                                                                                                                           |
|-----------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative                                                                                                 |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative                                                                                              |
|                       |   | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Result: negative                                                                                             |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 474<br>Result: negative                   |
|                       |   | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Hamster<br>Application Route: Ingestion<br>Method: OECD Test Guideline 475<br>Result: negative |

#### **Florfenicol:**

|                       |   |                                                                                                                                               |
|-----------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                                        |
|                       |   | Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Test system: rat hepatocytes<br>Result: negative |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Test system: mouse lymphoma cells<br>Result: negative                                |
|                       |   | Test Type: Chromosome aberration test in vitro<br>Test system: Chinese hamster ovary cells<br>Result: positive                                |
| Genotoxicity in vivo  | : | Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Oral                                           |

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Result: negative

### Propylene glycol:

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

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

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

### Carcinogenicity

Not classified based on available information.

### Components:

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

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

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

#### 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

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### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

#### Components:

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

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

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

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

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

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

##### **Florfenicol:**

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

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
General Toxicity Maternal: NOAEL: 4 mg/kg body weight  
Embryo-fetal 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-fetal development  
Species: Mouse  
Application Route: oral (gavage)  
General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
Embryo-fetal toxicity.: LOAEL: 40 mg/kg body weight  
Result: Fetotoxicity.

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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 fetal development : Test Type: Embryo-fetal 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  
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

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Method : OECD Test Guideline 413

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

### Florfenicol:

Species : Dog  
NOAEL : 3 mg/kg  
Exposure time : 13 Weeks  
Target Organs : Liver, Testis, Brain, Spinal cord

Species : Mouse  
NOAEL : 200 mg/kg  
Exposure time : 13 Weeks  
Target Organs : Liver, Testis

Species : Rat  
NOAEL : 30 mg/kg  
Exposure time : 13 Weeks  
Target Organs : Liver, Testis

Species : Dog  
NOAEL : 3 mg/kg  
LOAEL : 12 mg/kg  
Exposure time : 52 Weeks  
Target Organs : Liver, gallbladder

Species : Rat  
NOAEL : 1 mg/kg  
LOAEL : 3 mg/kg  
Exposure time : 52 Weeks  
Target Organs : Testis

### Propylene glycol:

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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

### Components:

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

Skin contact : Symptoms: Skin irritation

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### SECTION 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Components:

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

|                                                                        |   |                                                                                                                                                                        |
|------------------------------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l<br>Exposure time: 96 h                                                                                          |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia magna (Water flea)): > 1,000 mg/l<br>Exposure time: 24 h<br>Method: DIN 38412                                                                            |
| Toxicity to algae/aquatic plants                                       | : | ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l<br>Exposure time: 72 h<br><br>EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l<br>Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 12.5 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211                                                                 |
| Toxicity to microorganisms                                             | : | EC50: > 600 mg/l<br>Exposure time: 30 min<br>Method: ISO 8192                                                                                                          |

##### **Florfenicol:**

|                                                     |   |                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11<br><br>LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11                                                                                                       |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 330 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                                                                                                                                                                             |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9 mg/l<br>Exposure time: 14 d<br>Method: FDA 4.01<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l<br>Exposure time: 14 d<br>Method: FDA 4.01<br><br>IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l<br>Exposure time: 72 h |

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Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l  
Exposure time: 72 h  
Method: ISO 10253

EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.066 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.051 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 5.5 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1.5 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Propylene glycol:

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

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

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

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

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



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Exposure time: 18 h

### Persistence and degradability

#### Components:

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

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

##### **Propylene glycol:**

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

### Bioaccumulative potential

#### Components:

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

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

##### **Florfenicol:**

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

##### **Propylene glycol:**

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

### Mobility in soil

#### Components:

##### **Florfenicol:**

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

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.

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Contaminated packaging : Dispose of in accordance with local regulations.  
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 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.

#### Domestic regulation

##### TDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)  
Class : 9  
Packing group : III  
Labels : 9

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ERG Code : 171  
Marine pollutant : yes(Florfenicol)

### 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

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

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

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
CA ON OEL : Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.  
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)

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 Tempera-

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ture; 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023  
Date format : mm/dd/yyyy

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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