

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Florfenicol (with Triacetin) Liquid Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 06.04.2024  |
| 3.12    | 28.09.2024     | 898807-00022 | Date of first issue: 16.09.2016 |

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Florfenicol (with Triacetin) Liquid Formulation

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                                |                                                                       |
|----------------------------------------------------------------|-----------------------------------------------------------------------|
| Eye irritation, Category 2                                     | H319: Causes serious eye irritation.                                  |
| Reproductive toxicity, Category 1B                             | H360FD: May damage fertility. May damage the unborn child.            |
| Specific target organ toxicity - repeated exposure, Category 1 | H372: Causes damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1                  | H400: Very toxic to aquatic life.                                     |
| Long-term (chronic) aquatic hazard, Category 1                 | H410: Very toxic to aquatic life with long lasting effects.           |

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                                                   |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                            |
| Hazard statements        | : | H319 Causes serious eye irritation.<br>H360FD May damage fertility. May damage the unborn child.<br>H372 Causes damage to organs through prolonged or repeated exposure.<br>H410 Very toxic to aquatic life with long lasting effects.                                                                                                                                                            |
| Precautionary statements | : | <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.<br><b>Response:</b><br>P308 + P313 IF exposed or concerned: Get medical advice/ attention.<br>P337 + P313 If eye irritation persists: Get medical advice/ attention.<br>P391 Collect spillage. |

Hazardous components which must be listed on the label:

2-Pyrrolidone  
Florfenicol

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No. | Classification | Concentration<br>(% w/w) |
|---------------|-------------------|----------------|--------------------------|
|---------------|-------------------|----------------|--------------------------|

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|               | Index-No.<br>Registration number |                                                                                                                                                                                                                                                               |              |
|---------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 2-Pyrrolidone | 616-45-5<br>210-483-1            | Eye Irrit. 2; H319<br>Repr. 1B; H360FD<br><br>specific concentra-<br>tion limit<br>Repr. 1B; H360FD<br>> 3 %                                                                                                                                                  | >= 30 - < 50 |
| Florfenicol   | 73231-34-2                       | Repr. 2; H361fd<br>STOT RE 1; H372<br>(Liver, Brain, Tes-<br>tis, Spinal cord,<br>Blood, gallbladder)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity): 10<br>M-Factor (Chronic<br>aquatic toxicity): 10 | >= 30 - < 50 |

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of 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.
- 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).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove 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.

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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.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.  
May damage fertility. May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

#### 6.2 Environmental precautions

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.

#### 6.3 Methods and material for containment and cleaning up

Methods for 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.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

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.

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Hygiene measures : Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.  
: 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.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

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

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use   | Exposure routes | Potential health effects   | Value                  |
|----------------|-----------|-----------------|----------------------------|------------------------|
| 2-Pyrrolidone  | Workers   | Inhalation      | Long-term systemic effects | 57,8 mg/m <sup>3</sup> |
|                | Workers   | Skin contact    | Long-term systemic effects | 10 mg/kg bw/day        |
|                | Workers   | Skin contact    | Acute systemic effects     | 277 mg/kg bw/day       |
|                | Consumers | Inhalation      | Long-term systemic effects | 17,1 mg/m <sup>3</sup> |
|                | Consumers | Skin contact    | Long-term systemic effects | 6 mg/kg bw/day         |

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|-----------|-----------|--------------|----------------------------|-------------------|
|           | Consumers | Skin contact | Acute systemic effects     | 167 mg/kg bw/day  |
|           | Consumers | Ingestion    | Long-term systemic effects | 5,2 mg/kg bw/day  |
|           | Consumers | Ingestion    | Acute systemic effects     | 33,3 mg/kg bw/day |
| triacetin | Workers   | Inhalation   | Long-term systemic effects | 35,275 mg/m3      |
|           | Workers   | Skin contact | Long-term systemic effects | 5 mg/kg bw/day    |
|           | Consumers | Inhalation   | Long-term systemic effects | 8,7 mg/m3         |
|           | Consumers | Skin contact | Long-term systemic effects | 2,5 mg/kg bw/day  |
|           | Consumers | Ingestion    | Long-term systemic effects | 2,5 mg/kg bw/day  |

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name | Environmental Compartment  | Value                          |
|----------------|----------------------------|--------------------------------|
| 2-Pyrrolidone  | Fresh water                | 0,5 mg/l                       |
|                | Freshwater - intermittent  | 0,5 mg/l                       |
|                | Marine water               | 0,05 mg/l                      |
|                | Sewage treatment plant     | 10 mg/l                        |
|                | Fresh water sediment       | 0,4205 mg/kg dry weight (d.w.) |
|                | Soil                       | 0,0612 mg/kg dry weight (d.w.) |
| triacetin      | Fresh water                | 1,88 mg/l                      |
|                | Marine water               | 0,188 mg/l                     |
|                | Intermittent use/release   | 1 mg/l                         |
|                | Sewage treatment plant     | 1088 mg/l                      |
|                | Fresh water sediment       | 4,73 mg/kg                     |
|                | Marine sediment            | 0,47 mg/kg                     |
|                | Soil                       | 0,57 mg/kg                     |
|                | Oral (Secondary Poisoning) | 69,9 mg/kg food                |

## 8.2 Exposure controls

### 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

Eye/face 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.

Hand protection

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|                          |   |                                                                                                                                                                                                                 |
|--------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                       |
| Skin and body protection | : | Work uniform or laboratory coat.                                                                                                                                                                                |
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Equipment should conform to NS EN 14387 |
| Filter type              | : | Combined particulates and organic vapour type (A-P)                                                                                                                                                             |

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|                                                  |   |                   |
|--------------------------------------------------|---|-------------------|
| Physical state                                   | : | liquid            |
| Colour                                           | : | yellow            |
| Odour                                            | : | No data available |
| Odour Threshold                                  | : | No data available |
| Melting point/freezing point                     | : | No data available |
| Initial boiling point and boiling range          | : | 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 |
| Flash point                                      | : | No data available |
| Auto-ignition temperature                        | : | No data available |
| Decomposition temperature                        | : | No data available |
| pH                                               | : | No data available |
| Viscosity                                        | : |                   |
| Viscosity, kinematic                             | : | No data available |
| Solubility(ies)                                  | : |                   |
| Water solubility                                 | : | No data available |

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|                                           |   |                   |
|-------------------------------------------|---|-------------------|
| Partition coefficient: n-octanol/water    | : | Not applicable    |
| Vapour pressure                           | : | No data available |
| Relative density                          | : | No data available |
| Density                                   | : | No data available |
| Relative vapour density                   | : | No data available |
| Particle characteristics<br>Particle size | : | Not applicable    |

### 9.2 Other information

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Explosives           | : | Not explosive                                            |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate     | : | No data available                                        |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

|                     |   |                                         |
|---------------------|---|-----------------------------------------|
| Hazardous reactions | : | Can react with strong oxidizing agents. |
|---------------------|---|-----------------------------------------|

### 10.4 Conditions to avoid

|                     |   |             |
|---------------------|---|-------------|
| Conditions to avoid | : | None known. |
|---------------------|---|-------------|

### 10.5 Incompatible materials

|                    |   |                  |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

|                                          |   |                                                        |
|------------------------------------------|---|--------------------------------------------------------|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|------------------------------------------|---|--------------------------------------------------------|

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### Acute toxicity

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

|                       |   |                                                                                                                                      |
|-----------------------|---|--------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 401<br>Assessment: The substance or mixture has no acute oral toxicity      |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>Assessment: The substance or mixture has no acute dermal toxicity |

#### Florfenicol:

|                                                 |   |                                                                                                                                    |
|-------------------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity                             | : | LD50 (Rat): > 2.000 mg/kg<br>LD50 (Mouse): > 2.000 mg/kg<br>LD50 (Dog): > 1.280 mg/kg                                              |
| Acute inhalation toxicity                       | : | LC50 (Rat): > 0,28 mg/l<br>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<br>Application Route: Intraperitoneal<br>LD50 (Mouse): 100 mg/kg<br>Application Route: Intravenous |

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

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

#### Florfenicol:

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

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### Components:

#### **2-Pyrrolidone:**

|         |   |                                             |
|---------|---|---------------------------------------------|
| Species | : | Rabbit                                      |
| Result  | : | Irritation to eyes, reversing within 7 days |

#### **Florfenicol:**

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

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **2-Pyrrolidone:**

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

#### **Florfenicol:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **2-Pyrrolidone:**

|                       |   |                                                                        |
|-----------------------|---|------------------------------------------------------------------------|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|---|------------------------------------------------------------------------|

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

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

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Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative

### 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

### Carcinogenicity

Not classified based on available information.

### Components:

#### 2-Pyrrolidone:

Species : Mouse  
Application Route : Ingestion  
Exposure time : 18 month(s)  
Result : negative  
Remarks : Based on data from similar materials

### Florfenicol:

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

Species : Mouse  
Application Route : oral (gavage)

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Exposure time : 2 Years  
Result : negative  
Target Organs : Testes, Blood

### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

##### **2-Pyrrolidone:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: positive  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: positive

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

##### **Florfenicol:**

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

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
General Toxicity Maternal: NOAEL: 4 mg/kg body weight  
Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight  
Result: No teratogenic effects, Fetotoxicity  
Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-foetal development  
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.

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Commission Regulation (EU) 2020/878



## Florfenicol (with Triacetin) Liquid Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 06.04.2024  |
| 3.12    | 28.09.2024     | 898807-00022 | Date of first issue: 16.09.2016 |

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### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs 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:

#### 2-Pyrrolidone:

|                   |                           |
|-------------------|---------------------------|
| Species           | : Rat                     |
| NOAEL             | : 207 mg/kg               |
| Application Route | : Ingestion               |
| Exposure time     | : 3 Months                |
| Method            | : OECD Test Guideline 408 |

#### 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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|-----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **2-Pyrrolidone:**

|                                                     |                                                                                                                                                                          |
|-----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Danio rerio (zebra fish)): > 4.600 - 10.000 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                                                       |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 500 mg/l<br>Exposure time: 48 h                                                                                                   |
| Toxicity to algae/aquatic plants                    | : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l<br>Exposure time: 72 h<br><br>EC10 (Desmodesmus subspicatus (green algae)): 22,2 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms                          | : EC50 : > 1.000 mg/l<br>Exposure time: 30 min<br>Method: OECD Test Guideline 209                                                                                        |

##### **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                                                                                                       |

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|                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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<br>Method: ISO 10253<br><br>NOEC (Skeletonema costatum (marine diatom)): 0,00423 mg/l<br>Exposure time: 72 h<br>Method: ISO 10253<br><br>EC50 (Lemna gibba (gibbous duckweed)): 0,76 mg/l<br>Exposure time: 7 d<br>Method: OECD Test Guideline 221<br><br>NOEC (Lemna gibba (gibbous duckweed)): 0,39 mg/l<br>Exposure time: 7 d<br>Method: OECD Test Guideline 221<br><br>EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 (Anabaena flos-aquae): 0,066 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Anabaena flos-aquae): 0,051 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity)                                      | : 10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 5,5 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 1,5 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

### 12.2 Persistence and degradability

#### Components:

##### **2-Pyrrolidone:**

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

#### Components:

##### **2-Pyrrolidone:**

Partition coefficient: n-octanol/water : log Pow: -0,71  
Method: OECD Test Guideline 107

##### **Florfenicol:**

Partition coefficient: n-octanol/water : log Pow: 0,373  
pH: 7

### 12.4 Mobility in soil

#### Components:

##### **Florfenicol:**

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

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

## SECTION 14: Transport information

### 14.1 UN number or ID number

|      |           |
|------|-----------|
| ADN  | : UN 3082 |
| ADR  | : UN 3082 |
| RID  | : UN 3082 |
| IMDG | : UN 3082 |
| IATA | : UN 3082 |

### 14.2 UN proper shipping name

|      |                                                                        |
|------|------------------------------------------------------------------------|
| ADN  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Florfenicol) |
| IATA | : Environmentally hazardous substance, liquid, n.o.s.<br>(Florfenicol) |

### 14.3 Transport hazard class(es)

|     | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | : 9   |                  |

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|             |   |   |
|-------------|---|---|
| <b>ADR</b>  | : | 9 |
| <b>RID</b>  | : | 9 |
| <b>IMDG</b> | : | 9 |
| <b>IATA</b> | : | 9 |

### 14.4 Packing group

|                              |       |
|------------------------------|-------|
| <b>ADN</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

|                              |       |
|------------------------------|-------|
| <b>ADR</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |
| Tunnel restriction code      | : (-) |

|                              |       |
|------------------------------|-------|
| <b>RID</b>                   |       |
| Packing group                | : III |
| Classification Code          | : M6  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

|               |            |
|---------------|------------|
| <b>IMDG</b>   |            |
| Packing group | : III      |
| Labels        | : 9        |
| EmS Code      | : F-A, S-F |

|                                      |                 |
|--------------------------------------|-----------------|
| <b>IATA (Cargo)</b>                  |                 |
| Packing instruction (cargo aircraft) | : 964           |
| Packing instruction (LQ)             | : Y964          |
| Packing group                        | : III           |
| Labels                               | : Miscellaneous |

|                                          |                 |
|------------------------------------------|-----------------|
| <b>IATA (Passenger)</b>                  |                 |
| Packing instruction (passenger aircraft) | : 964           |
| Packing instruction (LQ)                 | : Y964          |
| Packing group                            | : III           |
| Labels                                   | : Miscellaneous |

### 14.5 Environmental hazards

|                           |       |
|---------------------------|-------|
| <b>ADN</b>                |       |
| Environmentally hazardous | : yes |

|                           |       |
|---------------------------|-------|
| <b>ADR</b>                |       |
| Environmentally hazardous | : yes |

|                           |       |
|---------------------------|-------|
| <b>RID</b>                |       |
| Environmentally hazardous | : yes |

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|-----------------|------------------------------|-----------------------------|-------------------------------------------------------------------|

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

|    |                          |                     |                     |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL<br>HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|--------------------------|---------------------|---------------------|

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### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

|                   |   |                                                                                                                                |
|-------------------|---|--------------------------------------------------------------------------------------------------------------------------------|
| Other information | : | Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines. |
|-------------------|---|--------------------------------------------------------------------------------------------------------------------------------|

### Full text of H-Statements

|        |   |                                                                          |
|--------|---|--------------------------------------------------------------------------|
| H319   | : | Causes serious eye irritation.                                           |
| H360FD | : | May damage fertility. May damage the unborn child.                       |
| H361fd | : | Suspected of damaging fertility. Suspected of damaging the unborn child. |
| H372   | : | Causes damage to organs through prolonged or repeated exposure.          |
| H400   | : | Very toxic to aquatic life.                                              |
| H410   | : | Very toxic to aquatic life with long lasting effects.                    |

### Full text of other abbreviations

|                 |   |                                                    |
|-----------------|---|----------------------------------------------------|
| Aquatic Acute   | : | Short-term (acute) aquatic hazard                  |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard                 |
| Eye Irrit.      | : | Eye irritation                                     |
| Repr.           | : | Reproductive toxicity                              |
| STOT RE         | : | Specific target organ toxicity - repeated exposure |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 car-

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rying 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### 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/>

### Classification of the mixture:

|                   |        |
|-------------------|--------|
| Eye Irrit. 2      | H319   |
| Repr. 1B          | H360FD |
| STOT RE 1         | H372   |
| Aquatic Acute 1   | H400   |
| Aquatic Chronic 1 | H410   |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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.

NO / EN