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

1.1 Product identifier
Trade name : Florfenicol Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Veterinary product

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Skin irritation, Category 2 : H315: Causes skin irritation.
Eye irritation, Category 2 : H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B : H360Df: May damage the unborn child. Suspected of damaging fertility.
Specific target organ toxicity - single exposure, Category 3 : H335: May cause respiratory irritation.
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)
Hazard pictograms : [Images of hazard symbols]
Signal word : Danger
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Florfenicol Liquid Formulation

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 through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
- Prevention:
  - P201 Obtain special instructions before use.
  - P264 Wash skin thoroughly after handling.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:
  - P308 + P313 IF exposed or concerned: Get medical advice/ attention.
  - P391 Collect spillage.

Hazardous components which must be listed on the label:
- Florfenicol
- N-Methyl-2-pyrrolidone

Additional Labelling:
- Restricted to professional users.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 2; H361fd</td>
<td>&gt;= 30 - &lt; 50</td>
<td></td>
</tr>
</tbody>
</table>
## 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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
- Thoroughly clean shoes before reuse.

**In case of eye contact**
- In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
- If easy to do, remove contact lens, if worn.
- Get medical attention.

---

### Section 3: Classification and labelling information

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>STOT RE 1; H372</td>
<td>(Liver, Brain, Testis, Spinal cord, Blood, gallbladder)</td>
</tr>
<tr>
<td>Aquatic Acute 1; H400</td>
<td></td>
</tr>
<tr>
<td>Aquatic Chronic 1; H410</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity): 10</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity): 10</td>
<td></td>
</tr>
</tbody>
</table>

### Section 4: First aid measures

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Numbers</th>
<th>Skin Irrit. 2; H315</th>
<th>Eye Irrit. 2; H319</th>
<th>Rep. 1B; H360D</th>
<th>STOT SE 3; H335</th>
<th>STOT SE 3; H335</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4, 212-828-1, 606-021-00-7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
4.2 Most important symptoms and effects, both acute and delayed

Risks:
- Causes skin irritation.
- Causes serious eye irritation.
- May cause respiratory irritation.
- May damage the unborn child. Suspected of damaging fertility.
- Causes damage to organs through prolonged or repeated exposure.

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 (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

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

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>872-50-4</td>
<td>TWA</td>
<td>10 ppm</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Identifies the possibility of significant uptake through the skin, Indicative

|                             |             | STEL                          | 20 ppm             | 2009/161/EU|
|                             |             |                               | 80 mg/m³           |            |

Further information: Identifies the possibility of significant uptake through the skin, Indicative

|                             |             | OELV - 8 hrs (TWA)            | 10 ppm             | IE OEL     |
|                             |             |                               | 40 mg/m³           |            |

Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body

|                             |             | OELV - 15 min (STEL)          | 20 ppm             | IE OEL     |
|                             |             |                               | 80 mg/m³           |            |

Further information: Substances which have the capacity to penetrate intact
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Propylene glycol

<table>
<thead>
<tr>
<th>Substance</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.4 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>40 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4.8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>3.6 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>2.4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.85 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m^3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m^3</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Methyl-2-pyrrolidone</td>
<td>Fresh water</td>
<td>0.25 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.025 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.09 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.07 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
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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 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
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.
Equipment should conform to I.S. 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>viscous</td>
</tr>
<tr>
<td>Colour</td>
<td>gold</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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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
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

Florfenicol:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
- LD50 (Mouse): > 2,000 mg/kg
- LD50 (Dog): > 1,280 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 0.28 mg/l
  Exposure time: 4 h
- Acute dermal toxicity: Remarks: No data available
- Acute toxicity (other routes of administration): LD50 (Rat): 1,913 - 2,253 mg/kg
  Application Route: Intraperitoneal
  LD50 (Mouse): 100 mg/kg
  Application Route: Intravenous

N-Methyl-2-pyrrolidone:
- Acute oral toxicity: LD50 (Rat): 4,150 mg/kg
- 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

Skin corrosion/irritation
Causes skin irritation.

Components:

Florfenicol:
- Species: Rabbit
- Result: No skin irritation
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according to Regulation (EC) No. 1907/2006

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Version 2.6  Revision Date: 27.08.2021  SDS Number: 26276-00019  Date of last issue: 09.04.2021
Date of first issue: 29.10.2014

N-Methyl-2-pyrrolidone:
Result : Skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Florfenicol:
Species : Rabbit
Result : Mild eye irritation

N-Methyl-2-pyrrolidone:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Florfenicol:
Test Type : Maximisation Test
Species : Guinea pig
Result : negative

N-Methyl-2-pyrrolidone:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

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

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

N-Methyl-2-pyrrolidone:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

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

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

Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Hamster
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

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

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

N-Methyl-2-pyrrolidone:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Species: Rat
Application Route: Inhalation (vapour)
Exposure time: 2 Years
Result: negative

Reproductive toxicity
May damage the unborn child. Suspected of damaging fertility.

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

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

Reproductive toxicity - Assessment: 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

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

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

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

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

STOT - single exposure  
May cause respiratory irritation.  

Components:  

N-Methyl-2-pyrrolidone:  
Assessment: May cause respiratory irritation.  

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:  

Florfenicol:  
Species: Dog  
NOAEL: 3 mg/kg  
Exposure time: 13 Weeks  
Target Organs: Liver, Testis, Brain, Spinal cord  
Species: Mouse
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NOAEL : 200 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis

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

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

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

N-Methyl-2-pyrrolidone:

Species : Rat, male
NOAEL : 169 mg/kg
LOAEL : 433 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408

Species : Rat
NOAEL : 0.5 mg/l
LOAEL : 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 96 Days
Method : OECD Test Guideline 413

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

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
Experience with human exposure

**Components:**

**N-Methyl-2-pyrrolidone:**
Skin contact: Symptoms: Skin irritation

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

**Florfenicol:**

- **Toxicity to fish**
  - LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l
  - Exposure time: 96 h
  - Method: FDA 4.11
  - LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l
  - Exposure time: 96 h
  - Method: FDA 4.11

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

- **Toxicity to algae/aquatic plants**
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9 mg/l
  - Exposure time: 14 d
  - Method: FDA 4.01
  - NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l
  - Exposure time: 14 d
  - Method: FDA 4.01
  - IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l
  - Exposure time: 72 h
  - Method: ISO 10253
  - NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l
  - Exposure time: 72 h
  - Method: ISO 10253
  - EC50 (Lemma gibba (gibbous duckweed)): 0.76 mg/l
  - Exposure time: 7 d
  - Method: OECD Test Guideline 221
  - NOEC (Lemma gibba (gibbous duckweed)): 0.39 mg/l
  - Exposure time: 7 d
  - Method: OECD Test Guideline 221
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<table>
<thead>
<tr>
<th>M-Factor (Acute aquatic toxicity)</th>
<th>:</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicty to fish (Chronic toxicity)</td>
<td>:</td>
<td>NOEC: 5.5 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td>Toxicty to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>:</td>
<td>NOEC: 1.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>:</td>
<td>10</td>
</tr>
<tr>
<td>N-Methyl-2-pyrrolidone:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>:</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 500 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>:</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 1,000 mg/l Exposure time: 24 h Method: DIN 38412</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>:</td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l Exposure time: 72 h</td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>:</td>
<td>EC50 : &gt; 600 mg/l Exposure time: 30 min Method: ISO 8192</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>:</td>
<td>NOEC: 12.5 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>
12.2 Persistence and degradability

**Components:**

**N-Methyl-2-pyrrolidone:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 73%
  - Exposure time: 28 d
- Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

**Components:**

**Florfenicol:**
- Partition coefficient: n-octanol/water: log Pow: 0.373

**N-Methyl-2-pyrrolidone:**
- Partition coefficient: n-octanol/water: log Pow: -0.46
  - Method: OECD Test Guideline 107

12.4 Mobility in soil

No data available

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.

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.
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According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

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

14.3 Transport hazard class(es)

ADN: 9
ADR: 9
RID: 9
IMDG: 9
IATA: 9

14.4 Packing group

ADN
Packing group: III
Classification Code: M6
Hazard Identification Number: 90
Labels: 9
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14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

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
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according to Regulation (EC) No. 1907/2006

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Date of first issue: 29.10.2014

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, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3 N-Methyl-2-pyrrolidone (Number on list 72, 71, 30)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59), Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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Full text of H-Statements

H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H335 : May cause respiratory irritation.
H360D : 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
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2009/161/EU / TWA : Limit Value - eight hours
2009/161/EU / STEL : Short term exposure limit
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 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; 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
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Date of last issue: 09.04.2021 Date of first issue: 29.10.2014

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360Df</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H335</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN