

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Injection Formulation

|         |                |                |                                 |
|---------|----------------|----------------|---------------------------------|
| Version | Revision Date: | SDS Number:    | Date of last issue: 14.04.2025  |
| 5.1     | 17.06.2025     | 10846445-00007 | Date of first issue: 06.09.2022 |

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

#### 1.1 Product identifier

Trade name : Florfenicol / Flunixin Injection 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)

|                                                                |                                                                       |
|----------------------------------------------------------------|-----------------------------------------------------------------------|
| Acute toxicity, Category 4                                     | H302: Harmful if swallowed.                                           |
| Acute toxicity, Category 4                                     | H332: Harmful if inhaled.                                             |
| 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.           |

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### 2.2 Label elements

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

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.  
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.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
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  
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate  
Citric acid

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.

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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.<br>Index-No.<br>Registration number | Classification                                                                                                                                                                                                                            | Concentration<br>(% w/w) |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Florfenicol                                                                             | 73231-34-2                                            | Repr. 2; H361fd<br>STOT RE 1; H372<br>(Liver, Brain, Testis, Spinal cord, Blood, gallbladder)<br>Aquatic Acute 1; H400<br>Aquatic Chronic 1; H410<br><br>M-Factor (Acute aquatic toxicity): 10<br>M-Factor (Chronic aquatic toxicity): 10 | >= 30 - < 50             |
| N-Methyl-2-pyrrolidone                                                                  | 872-50-4<br>212-828-1<br>606-021-00-7                 | Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Repr. 1B; H360D<br>STOT SE 3; H335<br><br>specific concentration limit<br>STOT SE 3; H335<br>>= 10 %                                                                                         | >= 20 - < 30             |
| 1-deoxy-1-(methylamino)-D-glucitol<br>2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7<br>255-836-0                               | Acute Tox. 3; H301<br>Acute Tox. 2; H330<br>Eye Dam. 1; H318<br>STOT SE 3; H335<br>STOT RE 1; H372<br>(Gastrointestinal tract, Kidney, Blood)<br>Aquatic Chronic 2; H411                                                                  | >= 2,5 - < 3             |
| Citric acid                                                                             | 77-92-9<br>201-069-1<br>607-750-00-3                  | Eye Irrit. 2; H319<br>STOT SE 3; H335                                                                                                                                                                                                     | >= 1 - < 10              |

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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.<br>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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                                                                                  |
| In case of skin contact    | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.                                                                       |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.                                                                          |

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

- |       |   |                                                                                                                                                                                                                                                                           |
|-------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : | Harmful if swallowed or if inhaled.<br>Causes skin irritation.<br>Causes serious eye irritation.<br>May cause respiratory irritation.<br>May damage the unborn child. Suspected of damaging fertility.<br>Causes damage to organs through prolonged or repeated exposure. |
|-------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

- |           |   |                                         |
|-----------|---|-----------------------------------------|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|-----------------------------------------|

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### 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  
Fluorine compounds  
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.

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### 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.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Do not eat, drink or smoke when using this product.<br>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.<br>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 : Keep in properly labelled containers. Store locked up. Keep

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areas and containers      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  
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/m3 (OEB 2)  | Internal            |
| N-Methyl-2-pyrrolidone                                         | 872-50-4                                                                                                      | TWA                           | 14,4 mg/m3         | FOR-2011-12-06-1358 |
|                                                                | Further information: Substances considered to be reprotoxic, Chemicals that can be absorbed through the skin. |                               |                    |                     |
|                                                                |                                                                                                               | STEL                          | 20 ppm<br>80 mg/m3 | FOR-2011-12-06-1358 |
|                                                                | Further information: Substances considered to be reprotoxic, Chemicals that can be absorbed through the skin. |                               |                    |                     |
|                                                                |                                                                                                               | TWA                           | 10 ppm<br>40 mg/m3 | 2009/161/EU         |
|                                                                | Further information: Identifies the possibility of significant uptake through the skin, Indicative            |                               |                    |                     |
|                                                                |                                                                                                               | STEL                          | 20 ppm<br>80 mg/m3 | 2009/161/EU         |
|                                                                | Further information: Identifies the possibility of significant uptake through the skin, Indicative            |                               |                    |                     |
|                                                                |                                                                                                               | TWA                           | 10 ppm<br>40 mg/m3 | 2004/37/EC          |
|                                                                | Further information: Skin, Carcinogens or mutagens                                                            |                               |                    |                     |
|                                                                |                                                                                                               | STEL                          | 20 ppm<br>80 mg/m3 | 2004/37/EC          |
|                                                                | Further information: Skin, Carcinogens or mutagens                                                            |                               |                    |                     |
| Propylene glycol                                               | 57-55-6                                                                                                       | TWA                           | 25 ppm<br>79 mg/m3 | FOR-2011-12-06-1358 |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluorome- | 42461-84-7                                                                                                    | TWA                           | 40 µg/m3 (OEB 3)   | Internal            |

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|                             |                           |            |                            |          |
|-----------------------------|---------------------------|------------|----------------------------|----------|
| thyl)anilino]nicotina<br>te |                           |            |                            |          |
|                             | Further information: Skin |            |                            |          |
|                             |                           | Wipe limit | 400 µg/100 cm <sup>2</sup> | Internal |

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

| Substance name         | End Use   | Exposure routes | Potential health effects   | Value                  |
|------------------------|-----------|-----------------|----------------------------|------------------------|
| N-Methyl-2-pyrrolidone | Workers   | Inhalation      | Long-term systemic effects | 14,4 mg/m <sup>3</sup> |
|                        | Workers   | Inhalation      | Long-term local effects    | 40 mg/m <sup>3</sup>   |
|                        | Workers   | Skin contact    | Long-term systemic effects | 4,8 mg/kg bw/day       |
|                        | Consumers | Inhalation      | Long-term systemic effects | 3,6 mg/m <sup>3</sup>  |
|                        | Consumers | Inhalation      | Long-term local effects    | 4,5 mg/m <sup>3</sup>  |
|                        | Consumers | Skin contact    | Long-term systemic effects | 2,4 mg/kg bw/day       |
|                        | Consumers | Ingestion       | Long-term systemic effects | 0,85 mg/kg bw/day      |
| Propylene glycol       | Workers   | Inhalation      | Long-term local effects    | 10 mg/m <sup>3</sup>   |
|                        | Workers   | Inhalation      | Long-term systemic effects | 168 mg/m <sup>3</sup>  |
|                        | Consumers | Inhalation      | Long-term local effects    | 10 mg/m <sup>3</sup>   |
|                        | Consumers | Inhalation      | Long-term systemic effects | 50 mg/m <sup>3</sup>   |

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

| Substance name         | Environmental Compartment | Value                         |
|------------------------|---------------------------|-------------------------------|
| N-Methyl-2-pyrrolidone | Fresh water               | 0,25 mg/l                     |
|                        | Freshwater - intermittent | 5 mg/l                        |
|                        | Marine water              | 0,025 mg/l                    |
|                        | Sewage treatment plant    | 10 mg/l                       |
|                        | Fresh water sediment      | 1,09 mg/kg dry weight (d.w.)  |
|                        | Marine sediment           | 0,109 mg/kg dry weight (d.w.) |
|                        | Soil                      | 0,07 mg/kg dry weight (d.w.)  |
| Propylene glycol       | Fresh water               | 260 mg/l                      |
|                        | Freshwater - intermittent | 183 mg/l                      |
|                        | Marine water              | 26 mg/l                       |
|                        | Sewage treatment plant    | 20000 mg/l                    |
|                        | Fresh water sediment      | 572 mg/kg dry weight (d.w.)   |
|                        | Marine sediment           | 57,2 mg/kg dry weight (d.w.)  |



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|             |                        |                              |
|-------------|------------------------|------------------------------|
|             | Soil                   | 50 mg/kg dry weight (d.w.)   |
| Citric acid | Fresh water            | 0,44 mg/l                    |
|             | Marine water           | 0,044 mg/l                   |
|             | Sewage treatment plant | 1000 mg/l                    |
|             | Fresh water sediment   | 34,6 mg/kg dry weight (d.w.) |
|             | Marine sediment        | 3,46 mg/kg dry weight (d.w.) |
|             | Soil                   | 33,1 mg/kg dry weight (d.w.) |

### 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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

#### Personal protective equipment

|                          |   |                                                                                                                                                                                                                                                                                                                |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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                                                                                                                                                                                                                                                                                      |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                                       |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing.                    |
| Respiratory protection   | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.<br>Filter 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

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Colour : light yellow

Straw-coloured

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

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

Particle size : Not applicable

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### 9.2 Other information

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

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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.

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## 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

Harmful if swallowed or if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1.935 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 1,86 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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Method: Calculation method

### Components:

#### **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><br>LD50 (Mouse): 100 mg/kg<br>Application Route: Intravenous |

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

|                           |   |                                                                                                                                                                         |
|---------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 4.150 mg/kg<br>Method: OECD Test Guideline 401<br>Remarks: The test was conducted equivalent or similar to guideline                                        |
| Acute inhalation toxicity | : | LC50 (Rat): > 5,1 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>Remarks: The test was conducted according to guideline |
| Acute dermal toxicity     | : | LD50 (Rat): > 5.000 mg/kg<br>Method: OECD Test Guideline 402<br>Remarks: The test was conducted equivalent or similar to guideline                                      |

#### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

|                           |   |                                                                                                                           |
|---------------------------|---|---------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 53 - 157 mg/kg<br>LD50 (Mouse): 176 - 249 mg/kg<br>LD50 (Guinea pig): 488,3 mg/kg<br>LD50 (Monkey): 300 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): < 0,52 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                                               |

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Acute toxicity (other routes of administration) : LD50 (Rat): 59,4 - 185,3 mg/kg  
Application Route: Intraperitoneal

LD50 (Mouse): 164 - 363 mg/kg  
Application Route: Intraperitoneal

### Citric acid:

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Causes skin irritation.

### Components:

#### Florfenicol:

Species : Rabbit  
Result : No skin irritation

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

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

#### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rabbit  
Result : Mild skin irritation

### Citric acid:

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Components:

#### Florfenicol:

Species : Rabbit  
Result : Mild eye irritation

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

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|         |   |                                                           |
|---------|---|-----------------------------------------------------------|
| Species | : | Rabbit                                                    |
| Method  | : | OECD Test Guideline 405                                   |
| Result  | : | Irritation to eyes, reversing within 21 days              |
| Remarks | : | The test was conducted equivalent or similar to guideline |

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

|         |   |                                 |
|---------|---|---------------------------------|
| Species | : | Rabbit                          |
| Result  | : | Irreversible effects on the eye |

### Citric acid:

|         |   |                                              |
|---------|---|----------------------------------------------|
| Species | : | Rabbit                                       |
| Method  | : | OECD Test Guideline 405                      |
| 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 |

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

|                 |   |                                    |
|-----------------|---|------------------------------------|
| Test Type       | : | Maximisation Test                  |
| Exposure routes | : | Dermal                             |
| Species         | : | Guinea pig                         |
| Assessment      | : | Does not cause skin sensitisation. |
| Result          | : | negative                           |

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Florfenicol:

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

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

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

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

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

### N-Methyl-2-pyrrolidone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Method: OECD Test Guideline 482  
Result: negative  
Remarks: The test was conducted equivalent or similar to guideline

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: The test was conducted according to guideline

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

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

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Test Type: in vitro assay  
Test system: mouse lymphoma cells  
Result: positive

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: positive

Test Type: in vitro assay  
Test system: Escherichia coli  
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Citric acid:

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

Test Type: in vitro micronucleus test  
Result: positive

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Components:

#### Florfenicol:

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

Species : Mouse  
Application Route : oral (gavage)  
Exposure time : 2 Years  
Result : negative



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Target Organs : Testes, Blood

### N-Methyl-2-pyrrolidone:

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Method : OECD Test Guideline 451  
Result : negative  
Remarks : The test was conducted according to guideline

Species : Rat  
Application Route : Inhalation  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : negative  
Remarks : The test was conducted equivalent or similar to guideline

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species : Rat  
Application Route : oral (feed)  
Exposure time : 104 w  
LOAEL : 2 mg/kg body weight  
Result : negative  
Target Organs : Gastrointestinal tract  
Remarks : Significant toxicity observed in testing

Species : Mouse  
Application Route : oral (feed)  
Exposure time : 97 w  
NOAEL : 0,6 mg/kg body weight  
Result : negative  
Target Organs : Gastrointestinal tract  
Remarks : Significant toxicity observed in testing

### 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

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Remarks: The effects were seen only at maternally toxic doses.

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

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

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: The test was conducted according to guideline

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: The test was conducted according to guideline

Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: inhalation (vapour)  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: The test was conducted equivalent or similar to guideline

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: The test was conducted equivalent or similar to guideline

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

### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat

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Application Route: Oral  
General Toxicity - Parent: LOAEL: 1 - 1,5 mg/kg body weight  
Symptoms: No foetal abnormalities  
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 2 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 2 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: LOAEL: 3 mg/kg body weight  
Embryo-foetal toxicity: NOAEL: 3 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

### Citric acid:

Effects on foetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

### STOT - single exposure

May cause respiratory irritation.

### Components:

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

Assessment : May cause respiratory irritation.

#### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Assessment : May cause respiratory irritation.

### Citric acid:

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

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exposure.

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

|               |                                                                   |
|---------------|-------------------------------------------------------------------|
| Target Organs | : Gastrointestinal tract, Kidney, Blood                           |
| Assessment    | : Causes damage to organs through prolonged or repeated exposure. |

### Repeated dose toxicity

#### Components:

##### **Florfenicol:**

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

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

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

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

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

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

|                   |                                                 |
|-------------------|-------------------------------------------------|
| Species           | : Rat, male                                     |
| NOAEL             | : 169 mg/kg                                     |
| LOAEL             | : 433 mg/kg                                     |
| Application Route | : Ingestion                                     |
| Exposure time     | : 90 Days                                       |
| Method            | : OECD Test Guideline 408                       |
| Remarks           | : The test was conducted according to guideline |

|         |            |
|---------|------------|
| Species | : Rat      |
| NOAEL   | : 0,5 mg/l |
| LOAEL   | : 1 mg/l   |

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|                   |                                                             |
|-------------------|-------------------------------------------------------------|
| Application Route | : inhalation (dust/mist/fume)                               |
| Exposure time     | : 96 Days                                                   |
| Method            | : OECD Test Guideline 413                                   |
| Remarks           | : The test was conducted according to guideline             |
| Species           | : Rabbit, male                                              |
| NOAEL             | : 826 mg/kg                                                 |
| LOAEL             | : 1.653 mg/kg                                               |
| Application Route | : Skin contact                                              |
| Exposure time     | : 20 Days                                                   |
| Method            | : OECD Test Guideline 410                                   |
| Remarks           | : The test was conducted equivalent or similar to guideline |

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

|                   |                                  |
|-------------------|----------------------------------|
| Species           | : Rat                            |
| NOAEL             | : 2 mg/kg                        |
| LOAEL             | : < 4 mg/kg                      |
| Application Route | : Oral                           |
| Exposure time     | : 6 w                            |
| Target Organs     | : Gastrointestinal tract         |
| Species           | : Rat                            |
| NOAEL             | : 1 mg/kg                        |
| Application Route | : Oral                           |
| Exposure time     | : 1 y                            |
| Target Organs     | : Gastrointestinal tract, Kidney |
| Species           | : Monkey                         |
| NOAEL             | : 15 mg/kg                       |
| Application Route | : Oral                           |
| Exposure time     | : 90 d                           |
| Target Organs     | : Gastrointestinal tract, Blood  |
| Species           | : Rabbit                         |
| LOAEL             | : 80 mg/kg                       |
| Application Route | : Dermal                         |
| Exposure time     | : 21 d                           |
| Symptoms          | : Severe irritation              |
| Species           | : Dog                            |
| LOAEL             | : 11 mg/kg                       |
| Application Route | : Oral                           |
| Exposure time     | : 9 d                            |
| Target Organs     | : Gastrointestinal tract         |
| Symptoms          | : Vomiting                       |

### Citric acid:

|                   |               |
|-------------------|---------------|
| Species           | : Rat         |
| NOAEL             | : 4.000 mg/kg |
| LOAEL             | : 8.000 mg/kg |
| Application Route | : Ingestion   |
| Exposure time     | : 10 Days     |

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### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

Not classified based on available information.

#### 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.

### Experience with human exposure

#### Components:

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

Skin contact : Symptoms: Skin irritation

##### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

Inhalation : Symptoms: respiratory tract irritation

Skin contact : Symptoms: Skin irritation

Eye contact : Symptoms: Severe irritation

Ingestion : Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

---

## 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

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NOEC (*Pseudokirchneriella subcapitata* (green algae)): 2,9 mg/l  
Exposure time: 14 d  
Method: FDA 4.01

IC50 (*Skeletonema costatum* (marine diatom)): 0,0336 mg/l  
Exposure time: 72 h  
Method: ISO 10253

NOEC (*Skeletonema costatum* (marine diatom)): 0,00423 mg/l  
Exposure time: 72 h  
Method: ISO 10253

EC50 (*Lemna gibba* (gibbous duckweed)): 0,76 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

NOEC (*Lemna gibba* (gibbous duckweed)): 0,39 mg/l  
Exposure time: 7 d  
Method: OECD Test Guideline 221

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

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

EC50 (*Anabaena flos-aquae*): 0,066 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (*Anabaena flos-aquae*): 0,051 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10

Toxicity to fish (Chronic toxicity) : NOEC: 5,5 mg/l  
Exposure time: 32 d  
Species: *Pimephales promelas* (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1,5 mg/l  
Exposure time: 21 d  
Species: *Daphnia magna* (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

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### N-Methyl-2-pyrrolidone:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1.000 mg/l  
Exposure time: 24 h  
Method: DIN 38412  
Remarks: The test was conducted according to guideline
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 600,5 mg/l  
Exposure time: 72 h  
  
EC10 (Desmodesmus subspicatus (green algae)): 92,6 mg/l  
Exposure time: 72 h
- Toxicity to microorganisms : EC50 (activated sludge): > 600 mg/l  
Exposure time: 30 min  
Method: ISO 8192  
Remarks: The test was conducted according to guideline
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 12,5 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: The test was conducted according to guideline

### 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l  
Exposure time: 96 h  
Method: FDA 4.11  
  
LC50 (Oncorhynchus mykiss (rainbow trout)): 5,5 mg/l  
Exposure time: 96 h  
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 15 mg/l  
Exposure time: 48 h  
Method: FDA 4.08
- Toxicity to algae/aquatic plants : NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l  
Exposure time: 13 d  
Method: FDA 4.01  
  
NOEC (Selenastrum capricornutum (green algae)): 96 mg/l  
Exposure time: 12 d

### Citric acid:

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1.535 mg/l



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aquatic invertebrates

Exposure time: 24 h

### 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  
Remarks: The test was conducted according to guideline

Biodegradation Simulation Tests :

Environmental Compartment: Soil  
Value type: DT50  
Value: 11,5 d  
Temperature: 20 °C  
Remarks: No test guideline followed

##### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

Stability in water : Hydrolysis: 0 %(28 d)

##### **Citric acid:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 97 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 12.3 Bioaccumulative potential

#### Components:

##### **Florfenicol:**

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

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

Partition coefficient: n-octanol/water : log Pow: -0,46  
Method: OECD Test Guideline 107  
Remarks: The test was conducted according to guideline

##### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

Partition coefficient: n-octanol/water : log Pow: 1,34

##### **Citric acid:**

Partition coefficient: n-octanol/water : log Pow: -1,72

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### 12.4 Mobility in soil

#### Components:

##### **Florfenicol:**

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

##### **1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

Distribution among environmental compartments : log Koc: 1,92

### 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.  
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.  
Do not dispose of waste into sewer.

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

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : UN 3082

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|             |   |         |
|-------------|---|---------|
| <b>ADR</b>  | : | UN 3082 |
| <b>RID</b>  | : | UN 3082 |
| <b>IMDG</b> | : | UN 3082 |
| <b>IATA</b> | : | UN 3082 |

### 14.2 UN proper shipping name

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

### 14.3 Transport hazard class(es)

|             | Class | Subsidiary risks |
|-------------|-------|------------------|
| <b>ADN</b>  | :     | 9                |
| <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  |

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Hazard Identification Number : 90  
Labels : 9

### IMDG

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : 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:<br>Number on list 3<br><br>Number on list 30: N-Methyl-2-pyrrolidone |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|

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Number on list 71: N-Methyl-2-pyrrolidone

Number on list 72: N-Methyl-2-pyrrolidone

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

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) : N-Methyl-2-pyrrolidone

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

Regulation (EU) No 2024/590 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 HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|-----------------------|---------------------|---------------------|

### 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

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### 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

|        |                                                                            |
|--------|----------------------------------------------------------------------------|
| H301   | : Toxic if swallowed.                                                      |
| H315   | : Causes skin irritation.                                                  |
| H318   | : Causes serious eye damage.                                               |
| H319   | : Causes serious eye irritation.                                           |
| H330   | : Fatal if inhaled.                                                        |
| 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.                    |
| H411   | : Toxic to aquatic life with long lasting effects.                         |

#### Full text of other abbreviations

|                            |                                                                                                                                                                                                                    |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute Tox.                 | : Acute toxicity                                                                                                                                                                                                   |
| Aquatic Acute              | : Short-term (acute) aquatic hazard                                                                                                                                                                                |
| Aquatic Chronic            | : Long-term (chronic) aquatic hazard                                                                                                                                                                               |
| Eye Dam.                   | : Serious eye damage                                                                                                                                                                                               |
| 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                                                                                                                                                                 |
| 2004/37/EC                 | : Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III                                               |
| 2009/161/EU                | : Europe. COMMISSION DIRECTIVE 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC |
| FOR-2011-12-06-1358        | : Norway. Occupational Exposure limits                                                                                                                                                                             |
| 2004/37/EC / STEL          | : Short term exposure limit                                                                                                                                                                                        |
| 2004/37/EC / TWA           | : Long term exposure limit                                                                                                                                                                                         |
| 2009/161/EU / TWA          | : Limit Value - eight hours                                                                                                                                                                                        |
| 2009/161/EU / STEL         | : Short term exposure limit                                                                                                                                                                                        |
| FOR-2011-12-06-1358 / TWA  | : Long term exposure limit                                                                                                                                                                                         |
| FOR-2011-12-06-1358 / STEL | : Short term exposure limit                                                                                                                                                                                        |

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 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:

|                   |        |
|-------------------|--------|
| Acute Tox. 4      | H302   |
| Acute Tox. 4      | H332   |
| Skin Irrit. 2     | H315   |
| Eye Irrit. 2      | H319   |
| Repr. 1B          | H360Df |
| STOT SE 3         | H335   |
| STOT RE 1         | H372   |
| Aquatic Acute 1   | H400   |
| Aquatic Chronic 1 | H410   |

### Classification procedure:

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

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NO / EN