

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol (45%) Injection Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road  
Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Veterinary product

Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Acute toxicity (Oral) : Category 5

Skin corrosion/irritation : Category 2

Serious eye damage/eye irritation : Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity - single exposure : Category 3

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




Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

### GHS label elements

Hazard pictograms	:	  
Signal word	:	Danger
Hazard statements	:	H303 May be harmful if swallowed. H315 + H319 Causes skin irritation and serious eye irritation. H335 May cause respiratory irritation. H360Df May damage the unborn child. Suspected of damaging fertility. H372 Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe mist or vapours. P264+P265 Wash hands thoroughly after handling. Do not touch eyes. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or with adequate ventilation. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  <b>Response:</b> P301 + P332 + P317 IF SWALLOWED or if skin irritation occurs: Get medical help. P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help. P362 + P364 Take off contaminated clothing and wash it before reuse. P391 Collect spillage.  <b>Storage:</b> P405 Store locked up.  <b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 10843913-00005      Date of last issue: 28.09.2024  
Date of first issue: 31.08.2022

### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Florfenicol	73231-34-2	>= 30 - < 50
N-Methyl-2-pyrrolidone	872-50-4	>= 30 - < 50

### 4. FIRST AID MEASURES

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

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing : None known.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

media

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

- 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 10843913-00005      Date of last issue: 28.09.2024  
Date of first issue: 31.08.2022

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

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.

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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

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

#### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
N-Methyl-2-pyrrolidone	872-50-4	5-Hydroxy-N-methyl-2-pyrrolidone	Urine	End of shift (As soon as possible after exposure ceases)	100 mg/l	ACGIH BEI

**Engineering measures** : Use appropriate engineering controls and manufacturing 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapour type
Hand protection	:	
Material	:	Chemical-resistant gloves
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower	:	No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-  
octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

May be harmful if swallowed.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

### **Product:**

Acute oral toxicity : Acute toxicity estimate: 3,784 mg/kg  
Method: Calculation method

### **Components:**

#### **Florfenicol:**

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

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

Acute dermal toxicity : Remarks: No data available

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

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

Acute oral toxicity : LD50 (Rat): 4,150 mg/kg  
Method: OECD Test Guideline 401  
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: The test was conducted equivalent or similar to guideline

### **Skin corrosion/irritation**

Causes skin irritation.

### **Components:**

#### **Florfenicol:**

Species : Rabbit  
Result : No skin irritation

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

Species : Rabbit



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

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

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

##### Florfenicol:

Species	: Rabbit
Result	: Mild eye irritation

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

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

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Florfenicol:

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

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

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

### 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 syn-

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

Genotoxicity in vivo	:	thesis 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
	:	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

### Carcinogenicity

Not classified based on available information.

### Components:

#### Florfenicol:

Species	:	Rat
Application Route	:	oral (gavage)
Exposure time	:	2 Years

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

Result	: negative
Target Organs	: Liver, Testes

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

### N-Methyl-2-pyrrolidone:

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

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

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### Florfenicol:

Effects on fertility	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: LOAEL: 12 mg/kg body weight Result: decreased pup survival, reduced lactation
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight Result: No teratogenic effects, Fetotoxicity Remarks: The effects were seen only at maternally toxic doses.  Test Type: Embryo-foetal development Species: Mouse Application Route: oral (gavage) General Toxicity Maternal: NOAEL: 120 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

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.

### STOT - single exposure

May cause respiratory irritation.

### Components:

### N-Methyl-2-pyrrolidone:

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 10843913-00005      Date of last issue: 28.09.2024  
Date of first issue: 31.08.2022

### Components:

#### Florfenicol:

Target Organs : Liver, Brain, Testis, Spinal cord, Blood, gallbladder  
Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

#### Florfenicol:

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

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

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

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

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

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

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

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

Method	: OECD Test Guideline 413
Remarks	: The test was conducted according to guideline
Species	: Rabbit, male
NOAEL	: 826 mg/kg
LOAEL	: 1,653 mg/kg
Application Route	: Skin contact
Exposure time	: 20 Days
Method	: OECD Test Guideline 410
Remarks	: The test was conducted equivalent or similar to guideline

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

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

Skin contact	: Symptoms: Skin irritation
--------------	-----------------------------

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Florfenicol:**

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l Exposure time: 96 h Method: FDA 4.11  LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 330 mg/l Exposure time: 48 h 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

	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

### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version 3.0      Revision Date: 14.04.2025      SDS Number: 10843913-00005      Date of last issue: 28.09.2024  
Date of first issue: 31.08.2022

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

### Persistence and degradability

#### Components:

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

Biodegradability	: Result: Readily biodegradable. Biodegradation: 73 % Exposure time: 28 d Method: OECD Test Guideline 301C Remarks: The test was conducted according to guideline
------------------	---

### Bioaccumulative potential

#### Components:

##### **Florfenicol:**

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

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

Partition coefficient: n-octanol/water	: log Pow: -0.46 Method: OECD Test Guideline 107 Remarks: The test was conducted according to guideline
--	---

### Mobility in soil

#### Components:

##### **Florfenicol:**

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

### Other adverse effects

No data available



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

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

##### IATA-DGR

UN/ID No.	:	UN 3082
Proper shipping name	:	Environmentally hazardous substance, liquid, n.o.s. (Florfenicol)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	964
Packing instruction (passenger aircraft)	:	964
Environmentally hazardous	:	yes

##### IMDG-Code

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 16. OTHER INFORMATION

Revision Date : 14.04.2025

#### 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/>

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

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Florfenicol (45%) Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	10843913-00005	Date of first issue: 31.08.2022

---

lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only 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.

IN / EN