

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

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

#### 1.1 Product identifier

Trade name : Florfenicol / Flunixin Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland

Telephone : +1-908-740-4000

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

#### 1.4 Emergency telephone number

+1-908-423-6000

---

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Acute toxicity, Category 4	H332: Harmful if inhaled.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

Hazard pictograms	:	
Signal word	:	Danger
Hazard statements	:	H319 Causes serious eye irritation. H332 Harmful if inhaled. H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<b>Prevention:</b> P201 Obtain special instructions before use. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  <b>Response:</b> P308 + P313 IF exposed or concerned: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P391 Collect spillage.

### Hazardous components which must be listed on the label:

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

### 2.3 Other hazards

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

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
---------------	---------	----------------	---------------

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

	EC-No. Index-No. Registration number		(% w/w)
Florfenicol	73231-34-2	Repr. 2; H361fd STOT RE 1; H372 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 20 - < 25
2-Pyrrolidone	616-45-5 210-483-1	Eye Irrit. 2; H319 Repr. 1B; H360FD  specific concentration limit Repr. 1B; H360FD > 3 %	>= 20 - < 30
Malic Acid	6915-15-7 230-022-8	Eye Irrit. 2; H319	>= 1 - < 10
1-deoxy-1-(methylamino)-D- glucitol 2-[2-methyl-3- (perfluoromethyl)anilino]nicotinate	42461-84-7 255-836-0	Acute Tox. 3; H301 Acute Tox. 2; H330 Eye Dam. 1; H318 STOT SE 3; H335 STOT RE 1; H372 (Gastrointestinal tract, Kidney, Blood) Aquatic Chronic 2; H411	>= 1 - < 2.5

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

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

When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
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.  
Never give anything by mouth to an unconscious person.

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

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

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

Treatment : Treat symptomatically and supportively.

---

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

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

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

Hazardous combustion prod- : Carbon oxides

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

ucts Fluorine compounds  
Nitrogen oxides (NOx)

### 5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

## SECTION 6: Accidental release measures

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

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

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

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

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures	: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

Requirements for storage areas and containers	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents 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)	Control parameters	Basis
------------	---------	-------------------	--------------------	-------

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

		of exposure)		
Florfenicol	73231-34-2	TWA	100 µg/m3 (OEB 2)	Internal
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m3 (OEB 3)	Internal
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
2-Pyrrolidone	Workers	Inhalation	Long-term systemic effects	57.8 mg/m3
	Workers	Skin contact	Long-term systemic effects	10 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	277 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	17.1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	167 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	5.2 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	33.3 mg/kg bw/day
Malic Acid	Workers	Inhalation	Long-term systemic effects	36.6 mg/m3
	Workers	Skin contact	Long-term systemic effects	5.2 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	9 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2.6 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	2.6 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
2-Pyrrolidone	Fresh water	0.5 mg/l
	Freshwater - intermittent	0.5 mg/l
	Marine water	0.05 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	0.4205 mg/kg dry weight (d.w.)
	Soil	0.0612 mg/kg dry

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0 Revision Date: 17.06.2025 SDS Number: 28043-00029 Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

II

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. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. 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. Filter should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : yellow

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

---

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 : 1.22

Density : No data available

Relative vapour density : No data available

Particle characteristics  
Particle size : Not applicable

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0      Revision Date: 17.06.2025      SDS Number: 28043-00029      Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

---

### SECTION 11: Toxicological information

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

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

#### Acute toxicity

||| Harmful if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 2.28 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

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

### 2-Pyrrolidone:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 401 Assessment: The substance or mixture has no acute oral toxicity
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

### Malic Acid:

Acute oral toxicity	:	LD50 (Rat): 3,500 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials

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

Acute oral toxicity	:	LD50 (Rat): 53 - 157 mg/kg  LD50 (Mouse): 176 - 249 mg/kg  LD50 (Guinea pig): 488.3 mg/kg  LD50 (Monkey): 300 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): < 0.52 mg/l Exposure time: 4 h Test atmosphere: dust/mist
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

### Skin corrosion/irritation

Not classified based on available information.
--

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0      Revision Date: 17.06.2025      SDS Number: 28043-00029      Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

### Components:

#### **Florfenicol:**

Species	:	Rabbit
Result	:	No skin irritation

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

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

#### **Malic Acid:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation
Remarks	:	Based on data from similar materials

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

Species	:	Rabbit
Result	:	Mild skin irritation

#### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### Components:

#### **Florfenicol:**

Species	:	Rabbit
Result	:	Mild eye irritation

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

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

#### **Malic Acid:**

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irritation to eyes, reversing within 21 days
Remarks	:	Based on data from similar materials

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

Species	:	Rabbit
Result	:	Irreversible effects on the eye

#### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

### Respiratory sensitisation

Not classified based on available information.

### Components:

#### **Florfenicol:**

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

#### **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

#### **Malic Acid:**

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
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:**

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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

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

### 2-Pyrrolidone:

#### Genotoxicity in vitro

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

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

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

#### Genotoxicity in vivo

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

### Malic Acid:

#### Genotoxicity in vitro

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

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

Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

### 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

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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

		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.

### 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
Target Organs	:	Testes, Blood

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

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

#### **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
---------	---	-------

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

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 fertility. May damage the unborn child.

#### 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
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.

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

Effects on fertility	:	Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: positive Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: positive
Reproductive toxicity - As-	:	Clear evidence of adverse effects on sexual function and ferti-

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0      Revision Date: 17.06.2025      SDS Number: 28043-00029      Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

Assessment        
ity, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

### Malic Acid:

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

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

### 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  
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

### STOT - single exposure

Not classified based on available information.

### Components:

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

Assessment      : May cause respiratory irritation.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

### Components:

#### **Florfenicol:**

Target Organs  
Assessment

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

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

Target Organs  
Assessment

: Gastrointestinal tract, Kidney, Blood  
: Causes damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

### Components:

#### **Florfenicol:**

Species  
NOAEL  
Exposure time  
Target Organs

: Dog  
: 3 mg/kg  
: 13 Weeks  
: Liver, Testis, Brain, Spinal cord

Species  
NOAEL  
Exposure time  
Target Organs

: Mouse  
: 200 mg/kg  
: 13 Weeks  
: Liver, Testis

Species  
NOAEL  
Exposure time  
Target Organs

: Rat  
: 30 mg/kg  
: 13 Weeks  
: Liver, Testis

Species  
NOAEL  
LOAEL  
Exposure time  
Target Organs

: Dog  
: 3 mg/kg  
: 12 mg/kg  
: 52 Weeks  
: Liver, gallbladder

Species  
NOAEL  
LOAEL  
Exposure time  
Target Organs

: Rat  
: 1 mg/kg  
: 3 mg/kg  
: 52 Weeks  
: Testis

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

Species  
NOAEL  
Application Route  
Exposure time  
Method

: Rat  
: 207 mg/kg  
: Ingestion  
: 3 Months  
: OECD Test Guideline 408

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0      Revision Date: 17.06.2025      SDS Number: 28043-00029      Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

### Malic Acid:

Species	:	Rat
NOAEL	:	> 250 mg/kg
Application Route	:	Ingestion
Exposure time	:	104 Weeks

### 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

### 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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

levels of 0.1% or higher.

### Experience with human exposure

#### Components:

#### **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
	NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l Exposure time: 14 d Method: FDA 4.01
	IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l Exposure time: 72 h Method: ISO 10253
	NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l Exposure time: 72 h Method: ISO 10253
	EC50 (Lemma gibba (gibbous duckweed)): 0.76 mg/l Exposure time: 7 d Method: OECD Test Guideline 221

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

		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
<b>2-Pyrrolidone:</b>		
Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h  EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50 : > 1,000 mg/l Exposure time: 30 min

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version  
4.0

Revision Date:  
17.06.2025

SDS Number:  
28043-00029

Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

Method: OECD Test Guideline 209

### Malic Acid:

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 240 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
	NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC50 : > 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials

### 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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0      Revision Date: 17.06.2025      SDS Number: 28043-00029      Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

### 12.2 Persistence and degradability

#### Components:

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

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

##### **Malic Acid:**

Biodegradability : Result: Readily biodegradable.  
Method: OECD Test Guideline 301C  
Remarks: Based on data from similar materials

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

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

### 12.3 Bioaccumulative potential

#### Components:

##### **Florfenicol:**

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

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

Partition coefficient: n-octanol/water : log Pow: -0.71  
Method: OECD Test Guideline 107

##### **Malic Acid:**

Partition coefficient: n-octanol/water : log Pow: -1.26

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

Partition coefficient: n-octanol/water : log Pow: 1.34

### 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:

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

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  
**ADR** : UN 3082  
**RID** : UN 3082  
**IMDG** : UN 3082  
**IATA** : UN 3082

### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)  
**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Florfenicol)

# SAFETY DATA SHEET

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



## **Florfenicol / Flunixin Formulation**

Version Revision Date: SDS Number: Date of last issue: 14.04.2025  
4.0 17.06.2025 28043-00029 Date of first issue: 04.11.2014

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

**ADN**  
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	:	(-)

**RID**  
Packing group : III  
Classification Code : M6  
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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

---

### 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

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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

Remarks : Not applicable for product as supplied.

---

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

: Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

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

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0 Revision Date: 17.06.2025 SDS Number: 28043-00029 Date of last issue: 14.04.2025  
Date of first issue: 04.11.2014

---

II

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : not.  
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  
REACH - List of substances subject to authorisation (Annex XIV) : 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.

	Quantity 1	Quantity 2
E1	100 t	200 t

ENVIRONMENTAL HAZARDS

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

---

## SECTION 16: Other information

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

### Full text of H-Statements

H301	: Toxic if swallowed.
H318	: Causes serious eye damage.
H319	: Causes serious eye irritation.
H330	: Fatal if inhaled.
H335	: May cause respiratory irritation.
H360FD	: May damage fertility. May damage the unborn child.
H361fd	: Suspected of damaging fertility. Suspected of damaging the unborn child.
H372	: Causes damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

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
STOT RE	: Specific target organ toxicity - repeated exposure
STOT SE	: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; 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; KECL - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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/>

# SAFETY DATA SHEET

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



## Florfenicol / Flunixin Formulation

Version 4.0	Revision Date: 17.06.2025	SDS Number: 28043-00029	Date of last issue: 14.04.2025 Date of first issue: 04.11.2014
----------------	------------------------------	----------------------------	---

---

### Classification of the mixture:

Acute Tox. 4	H332	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 1B	H360FD	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

### Classification procedure:

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

IE / EN