

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

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

#### 1.1 Product identifier

Trade name : 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

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

Company : MSD  
 20 Spartan Road  
 1619 Spartan, South Africa

Telephone : +27119239300

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	H302: Harmful if swallowed.
Acute toxicity, Category 3	H331: Toxic if inhaled.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

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

Hazard pictograms : 

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
 H318 Causes serious eye damage.  
 H331 Toxic if inhaled.  
 H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P280 Wear eye protection/ face protection.

### Response:

P304 + P340 + P311 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P314 Get medical advice/ attention if you feel unwell.

Hazardous components which must be listed on the label:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate  
 Phenol

### 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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 3 - < 10
Phenol	108-95-2 203-632-7 604-001-00-2	Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Muta. 2; H341 STOT RE 2; H373 (Central nervous system, Kidney, Liver, Skin) Aquatic Chronic 2;	>= 0,25 - < 1

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

Sodium hydroxymethanesulphinate	6035-47-8	H411 Muta. 2; H341 Repr. 2; H361d	>= 0,1 - < 1
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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.  
 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.  
 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 immediately.
- 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 : Harmful if swallowed.  
 Causes serious eye damage.  
 Toxic if inhaled.  
 May cause 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.

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
Date of first issue: 21.02.2017

---

### 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.

#### 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

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

---

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.

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## 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 breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<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>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 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:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives<br>Gases  |

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

### 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
Propylene glycol	57-55-6	TWA OEL-RL (particulate)	10 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
		TWA OEL-RL (Vapour + particulates)	150 ppm 470 mg/m <sup>3</sup>	ZA OEL
Further information: Recommended Limit				
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Phenol	108-95-2	TWA OEL-RL	5 ppm 19 mg/m <sup>3</sup>	ZA OEL
Further information: Absorption through the skin, Recommended Limit				
		STEL OEL-RL	10 ppm 38 mg/m <sup>3</sup>	ZA OEL
Further information: Absorption through the skin, Recommended Limit				
		TWA	2 ppm 8 mg/m <sup>3</sup>	2009/161/EU
		STEL	4 ppm 16 mg/m <sup>3</sup>	2009/161/EU

#### Biological occupational exposure limits

Substance name	CAS-No.	Control parameters	Sampling time	Basis
Phenol	108-95-2	Total phenol: 250 mg/g Creatinine (Urine)	End of shift	ZA BEI

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

Substance name	End Use	Exposure routes	Potential health effects	Value
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>

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>
Phenol	Workers	Inhalation	Long-term systemic effects	8 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	16 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	1,23 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,32 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	0,4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,4 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57,2 mg/kg
Phenol	Soil	50 mg/kg
	Fresh water	0,0077 mg/l
	Marine water	0,00077 mg/l
	Intermittent use/release	0,031 mg/l
	Sewage treatment plant	2,1 mg/l
	Fresh water sediment	0,0915 mg/kg
	Marine sediment	0,00915 mg/kg
	Soil	0,136 mg/kg

**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 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.

**Flunixin Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

---

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 type	:	Particulates type (P)

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance	:	liquid
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	7,8 - 9,0
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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
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	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		



## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
Date of first issue: 21.02.2017

---

Viscosity, kinematic : Not applicable  
Explosive properties : Not explosive  
Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available  
Particle size : Not applicable

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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 toxicological effects

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

#### Acute toxicity

Harmful if swallowed.  
Toxic if inhaled.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 604,68 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 0,5964 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

---

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

### Components:

#### **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

#### **Phenol:**

Acute oral toxicity : LD50 (Rat): 650 mg/kg  
Method: OECD Test Guideline 401

Acute toxicity estimate (Humans): 140 - 290 mg/kg  
Method: Expert judgement

Acute inhalation toxicity : LC0 (Rat): 0,9 mg/l  
Exposure time: 8 h  
Test atmosphere: dust/mist  
Assessment: Corrosive to the respiratory tract.

Acute toxicity estimate (Humans): > 0,9 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): 660 mg/kg  
Method: OECD Test Guideline 402

Acute toxicity estimate (Humans): 300 mg/kg  
Method: Expert judgement

#### **Sodium hydroxymethanesulphinate:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
Date of first issue: 21.02.2017

---

Acute dermal toxicity      :    LD50 (Rat): > 2.000 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

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

Species                      :    Rabbit  
Result                        :    Mild skin irritation

**Phenol:**

Species                      :    Rabbit  
Result                        :    Corrosive after 3 minutes to 1 hour of exposure

**Sodium hydroxymethanesulphinate:**

Species                      :    Rat  
Result                        :    No skin irritation  
Remarks                     :    Based on data from similar materials

**Serious eye damage/eye irritation**

Causes serious eye damage.

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

Species                      :    Rabbit  
Result                        :    Irreversible effects on the eye

**Phenol:**

Species                      :    Rabbit  
Method                       :    OECD Test Guideline 405  
Result                        :    Irreversible effects on the eye

**Sodium hydroxymethanesulphinate:**

Species                      :    Rabbit  
Method                       :    OECD Test Guideline 405  
Result                        :    No eye irritation  
Remarks                     :    Based on data from similar materials

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

---

### Components:

#### **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

#### **Phenol:**

Test Type : Buehler Test  
 Exposure routes : Skin contact  
 Species : Guinea pig  
 Method : OECD Test Guideline 406  
 Result : negative

#### **Sodium hydroxymethanesulphinate:**

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

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **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

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.

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

---

### Phenol:

- Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: positive
- 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: positive  
Remarks: Annex VI From 1272/2008
- Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### Sodium hydroxymethanesulphinate:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials
- 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: positive  
Remarks: Based on data from similar materials
- Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

### Carcinogenicity

Not classified based on available information.

### Components:

#### 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

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
 Date of first issue: 21.02.2017

---

### Phenol:

Species : Mouse  
 Application Route : Ingestion  
 Exposure time : 103 weeks  
 Method : OECD Test Guideline 451  
 Result : negative

### Reproductive toxicity

Not classified based on available information.

### Components:

#### 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

### Phenol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Method: OECD Test Guideline 416  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Mouse  
 Application Route: Ingestion  
 Method: OECD Test Guideline 414  
 Result: negative

### Sodium hydroxymethanesulphinate:

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

---

Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive  
Remarks: Based on data from similar materials

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

### 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

May cause damage to organs through prolonged or repeated exposure.

#### Components:

#### **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.

#### **Phenol:**

Target Organs : Central nervous system, Kidney, Liver, Skin  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

#### **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

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

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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

### Phenol:

Species : Rat  
 LOAEL : 300 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days  
 Method : OECD Test Guideline 408

Species : Rat  
 NOAEL : >= 0,1 mg/l  
 Application Route : inhalation (vapour)  
 Exposure time : 74 Days

Species : Rabbit  
 LOAEL : 260 mg/kg  
 Application Route : Skin contact  
 Exposure time : 18 Days

### Sodium hydroxymethanesulphinate:

Species : Rat  
 NOAEL : 600 mg/kg  
 Application Route : Ingestion  
 Exposure time : 90 Days  
 Method : OECD Test Guideline 408  
 Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.



## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

### 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

#### Product:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
		NOEC (Pseudokirchneriella subcapitata (green algae)): 32 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

#### Components:

#### **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

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

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Exposure time: 12 d

**Phenol:**

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 24,9 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 3,1 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): 61,1 mg/l  
Exposure time: 96 h
- Toxicity to microorganisms : IC50 (Nitrosomonas sp.): 21 mg/l  
Exposure time: 24 h
- Toxicity to fish (Chronic toxicity) : NOEC: 0,077 mg/l  
Exposure time: 60 d
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 16 d  
Species: Daphnia magna (Water flea)

**Sodium hydroxymethanesulphinate:**

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC50 : > 1.000 mg/l  
Exposure time: 4 h  
Remarks: Based on data from similar materials
- Toxicity to fish (Chronic toxicity) : NOEC: 13,5 mg/l  
Exposure time: 35 d  
Species: Danio rerio (zebra fish)  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 5,6 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  
Remarks: Based on data from similar materials

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
Date of first issue: 21.02.2017

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**12.2 Persistence and degradability****Components:****1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

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

**Phenol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 62 %  
Exposure time: 10 d  
Method: OECD Test Guideline 301C

**Sodium hydroxymethanesulphinate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 77 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

**12.3 Bioaccumulative potential****Components:****1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**

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

**Phenol:**

Bioaccumulation : Species: Fish  
Bioconcentration factor (BCF): 17,5  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 1,47

**12.4 Mobility in soil****Components:****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.

## Flunixin Injection Formulation

Version 4.5      Revision Date: 09.04.2021      SDS Number: 1308644-00011      Date of last issue: 10.10.2020  
Date of first issue: 21.02.2017

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### 12.6 Other adverse effects

**Product:**

Endocrine disrupting potential : 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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## 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.

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.

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## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 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

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## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

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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.  
 H311 : Toxic in contact with skin.  
 H314 : Causes severe skin burns and eye damage.  
 H318 : Causes serious eye damage.  
 H330 : Fatal if inhaled.  
 H331 : Toxic if inhaled.  
 H335 : May cause respiratory irritation.  
 H341 : Suspected of causing genetic defects.  
 H361d : Suspected of damaging the unborn child.  
 H372 : Causes damage to organs through prolonged or repeated exposure.  
 H373 : May cause damage to organs through prolonged or repeated exposure.  
 H411 : Toxic to aquatic life with long lasting effects.  
 EUH071 : Corrosive to the respiratory tract.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity  
 Aquatic Chronic : Long-term (chronic) aquatic hazard  
 Eye Dam. : Serious eye damage  
 Muta. : Germ cell mutagenicity  
 Repr. : Reproductive toxicity  
 Skin Corr. : Skin corrosion  
 STOT RE : Specific target organ toxicity - repeated exposure  
 STOT SE : Specific target organ toxicity - single exposure  
 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  
 ZA BEI : South Africa. Hazardous Chemical Substances Regulations, Biological Exposure Indices.  
 ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits  
 2009/161/EU / TWA : Limit Value - eight hours  
 2009/161/EU / STEL : Short term exposure limit  
 ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit  
 ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for

## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

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; 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. 3	H331
Eye Dam. 1	H318
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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

# SAFETY DATA SHEET



## Flunixin Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
4.5	09.04.2021	1308644-00011	Date of first issue: 21.02.2017

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