

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Chemical product name : Flunixin Injection Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

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

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

Recommended use : Veterinary product

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**2. HAZARDS IDENTIFICATION****GHS classification of chemical product**

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 3

Serious eye damage/eye irritation : Category 1

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Kidney, Blood)

**GHS label elements**

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 (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.

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## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

P280 Wear eye protection/ face protection.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

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.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name  | CAS-No.    | Concentration (% w/w) | ENCS No.     |
|--|------------|-----------------------|--------------|
| Propylene glycol   | 57-55-6    | >= 20 - < 30          | 2-234        |
| 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | >= 3 - < 10           |              |
| Phenol   | 108-95-2   | >= 0.25 - < 1         | 3-481        |
| 2,2'-Iminodiethanol  | 111-42-2   | >= 0.25 - < 1         | 2-302, 2-354 |
| Sodium hydroxymethanesulphinate  | 6035-47-8  | >= 0.1 - < 1          | 2-1633       |

### 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
 When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
 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

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

|   |   |  |
|---|---|--|
|   |   | of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse.                          |
| In case of eye contact                                      | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person.                |
| Most important symptoms and effects, both acute and delayed | : | Harmful if swallowed.<br>Causes serious eye damage.<br>Toxic if inhaled.<br>May cause damage to organs through prolonged or repeated exposure.                                 |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).    |
| Notes to physician  | : | Treat symptomatically and supportively.  |

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### 5. FIREFIGHTING MEASURES

|   |   |   |
|---|---|---|
| Suitable extinguishing media                  | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                | : | None known.   |
| Specific hazards during fire-fighting         | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                 | : | Carbon oxides<br>Fluorine compounds<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods                | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |

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### 6. ACCIDENTAL RELEASE MEASURES

|   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).         |
| Environmental precautions   | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil |

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

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

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### 7. HANDLING AND STORAGE

#### 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.  
Do not swallow.  
Do not get in eyes.  
Avoid prolonged or repeated contact with skin.  
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.

Avoidance of contact : Oxidizing agents

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.

#### Storage

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

Materials to avoid : Store in accordance with the particular national regulations.  
 : Do not store with the following product types:  
 Strong oxidizing agents

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

| Components   | CAS-No.    | Value type (Form of exposure)  | Control parameters / Permissible concentration | Basis          |
|--|------------|--|--|----------------|
| 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   | OEL-M  | 5 ppm<br>19 mg/m <sup>3</sup>                  | JP OEL<br>JSOH |
|  |            | Further information: Group 3: Substances suspected to cause reproductive toxicity in humans, Skin absorption |  |                |
| 2,2'-Iminodiethanol  | 111-42-2   | TWA  | 5 ppm  | ACGIH          |
|  |            | TWA (Inhalable fraction and vapor)   | 1 mg/m <sup>3</sup>                            | ACGIH          |

#### Biological occupational exposure limits

| Components | CAS-No.  | Target substance | Biological specimen | Sampling time  | Permissible concentration | Basis        |
|------------|----------|------------------|---------------------|--|---------------------------|--------------|
| Phenol     | 108-95-2 | Phenol           | Urine               | End of shift   | 250 mg/g Creatinine       | JSOH         |
|            |          | Phenol           | Urine               | End of shift (As soon as possible after exposure ceases) | 250 mg/g Creatinine       | ACGIH<br>BEI |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 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.

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

### Personal protective equipment

|                          |   |  |
|--------------------------|---|--|
| 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  |
| Hand protection          | : |  |
| Material                 | : | Chemical-resistant gloves  |
| Remarks                  | : | Consider double gloving.   |
| Eye protection           | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat. 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.                    |

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |                   |
|--|---|-------------------|
| Physical state   | : | liquid            |
| Colour   | : | clear             |
| Odour  | : | No data available |
| Odour Threshold  | : | No data available |
| Melting point/freezing point   | : | No data available |
| Boiling point, initial boiling point and boiling range               | : | No data available |
| Flammability (solid, gas)  | : | Not applicable    |
| Flammability (liquids)   | : | No data available |
| Lower explosion limit and upper explosion limit / flammability limit | : |                   |
| Upper explosion limit / Upper flammability limit                     | : | No data available |
| Lower explosion limit / Lower flammability limit                     | : | No data available |
| Flash point  | : | No data available |
| Decomposition temperature  | : | No data available |
| pH   | : | 7.8 - 9.0         |

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : Not applicable

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

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

Particle characteristics  
Particle size : Not applicable

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### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### 11. TOXICOLOGICAL INFORMATION

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

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## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 0.5964 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

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

### **Components:**

#### **Propylene glycol:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

#### **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.



## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

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

**2,2'-Iminodiethanol:**

Acute oral toxicity : LD50 (Rat): 1,600 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3.35 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

**Sodium hydroxymethanesulphinate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials

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:****Propylene glycol:**

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

**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

**2,2'-Iminodiethanol:**

Species : Rabbit  
Result : Skin irritation

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

**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:****Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

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

Species : Rabbit  
Result : Irreversible effects on the eye

**Phenol:**

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

**2,2'-Iminodiethanol:**

Species : Rabbit  
Result : Irreversible effects on the eye

**Sodium hydroxymethanesulphinate:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
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.

**Components:****Propylene glycol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

### 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                |

### 2,2'-Iminodiethanol:

|                 |                           |
|-----------------|---------------------------|
| Test Type       | : Maximisation 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:

#### Propylene glycol:

|                       |  |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative   |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Result: negative |

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

|                       |  |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative             |
|                       | : Test Type: in vitro assay<br>Test system: mouse lymphoma cells<br>Result: positive |

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

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.

**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.

**2,2'-Iminodiethanol:**

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

Test Type: Chromosome aberration test in vitro  
 Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells  
 Result: negative

Test Type: In vitro mammalian cell gene mutation test  
 Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
 Species: Mouse  
 Application Route: Skin contact  
 Result: negative

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

### 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:

#### Propylene glycol:

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 2 Years  
 Result : negative

#### 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

#### Phenol:

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

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

### 2,2'-Iminodiethanol:

Species : Mouse  
 Application Route : Skin contact  
 Exposure time : 103 weeks  
 Result : positive  
 Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat  
 Application Route : Skin contact  
 Exposure time : 103 weeks  
 Result : negative

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Propylene glycol:

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

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Mouse  
 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

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

### 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

### 2,2'-Iminodiethanol:

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: Inhalation  
Method: OECD Test Guideline 414  
Result: negative

### Sodium hydroxymethanesulphinat:

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.

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

### STOT - repeated exposure

May cause damage to organs (Gastrointestinal tract, Kidney, Blood) 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. |

#### **2,2'-Iminodiethanol:**

|                 |   |   |
|-----------------|---|---|
| Exposure routes | : | inhalation (dust/mist/fume)   |
| Assessment      | : | No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less. |

|                 |   |  |
|-----------------|---|--|
| Exposure routes | : | Ingestion  |
| Target Organs   | : | Kidney, Blood, Liver   |
| Assessment      | : | Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw. |

|                 |   |  |
|-----------------|---|--|
| Exposure routes | : | Skin contact   |
| Target Organs   | : | Blood, Liver   |
| Assessment      | : | Shown to produce significant health effects in animals at concentrations of >20 to 200 mg/kg bw. |

### Repeated dose toxicity

#### Components:

#### **Propylene glycol:**

|                   |   |             |
|-------------------|---|-------------|
| Species           | : | Rat, male   |
| NOAEL             | : | 1,700 mg/kg |
| Application Route | : | Ingestion   |
| Exposure time     | : | 2 yr        |

#### **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     |



## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

---

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 :  $\geq 0.1$  mg/l  
 Application Route : inhalation (vapour)  
 Exposure time : 74 Days

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

### 2,2'-Iminodiethanol:

Species : Rat  
 LOAEL : 14 - 25 mg/kg  
 Application Route : Ingestion  
 Exposure time : 13 Weeks

Species : Rat  
 LOAEL : 0.015 mg/l  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 90 Days  
 Method : OECD Test Guideline 413

Species : Rat  
 LOAEL : 32 mg/kg  
 Application Route : Skin contact  
 Exposure time : 13 Weeks

**Flunixin Injection Formulation**

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

**Sodium hydroxymethanesulphonate:**

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.

**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

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**12. ECOLOGICAL INFORMATION****Ecotoxicity****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:****Propylene glycol:**

## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

|  |   |   |
|--|---|---|
| Toxicity to fish   | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l<br>Exposure time: 96 h                                      |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l<br>Exposure time: 48 h  |
| Toxicity to algae/aquatic plants                                       | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d   |
| Toxicity to microorganisms   | : | NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h   |

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

|   |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11    |
|   |   | LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11      |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 15 mg/l<br>Exposure time: 48 h<br>Method: FDA 4.08                |
| Toxicity to algae/aquatic plants                    | : | NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l<br>Exposure time: 13 d<br>Method: FDA 4.01 |
|   |   | NOEC (Selenastrum capricornutum (green algae)): 96 mg/l<br>Exposure time: 12 d                       |

**Phenol:**

|  |   |  |
|--|---|--|
| Toxicity to fish   | : | LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l<br>Exposure time: 96 h    |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Ceriodaphnia dubia (water flea)): 3.1 mg/l<br>Exposure time: 48 h          |
| Toxicity to algae/aquatic plants                                       | : | EC50 (Selenastrum capricornutum (green algae)): 61.1 mg/l<br>Exposure time: 96 h |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: 0.077 mg/l<br>Exposure time: 60 d  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 10 mg/l<br>Exposure time: 16 d                |
| Toxicity to microorganisms   | : | IC50 (Nitrosomonas sp.): 21 mg/l<br>Exposure time: 24 h                          |

**Flunixin Injection Formulation**

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

**2,2'-Iminodiethanol:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l  
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l  
Exposure time: 72 h
- EC10 (Pseudokirchneriella subcapitata (green algae)): 1.4 mg/l  
Exposure time: 72 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 1.05 mg/l  
Exposure time: 21 d
- Toxicity to microorganisms : EC10: > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

**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 fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 13.5 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5.6 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
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

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

**Persistence and degradability****Components:****Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**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

**2,2'-Iminodiethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 93 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Sodium hydroxymethanesulphinate:**

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

**Bioaccumulative potential****Components:****Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07

**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

**2,2'-Iminodiethanol:**

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

Partition coefficient: n-octanol/water : log Pow: -2.46

### 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

#### Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

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

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

Not regulated as a dangerous good

##### IATA-DGR

Not regulated as a dangerous good

##### IMDG-Code

Not regulated as a dangerous good

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### National Regulations

Refer to section 15 for specific national regulation.

### 15. REGULATORY INFORMATION

#### Related Regulations

##### Fire Service Law

Not applicable to dangerous materials / designated flammables.

##### Chemical Substance Control Law

Priority Assessment Chemical Substance

| Chemical name    | Number |
|------------------|--------|
| Propane-1,2-diol | 106    |
| Phenol           | 62     |

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
 Date of first issue: 2017/02/21

|                |    |
|----------------|----|
| Diethanolamine | 91 |
|----------------|----|

### Industrial Safety and Health Law

#### Harmful Substances Prohibited from Manufacture

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### Substances Prevented From Impairment of Health

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

#### Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

| Chemical name  | Number | Concentration (%) |
|----------------|--------|-------------------|
| Phenol         | 474    | $\geq 0.1 - < 1$  |
| Diethanolamine | 219    | $\geq 0.1 - < 1$  |

#### Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

| Chemical name | Number |
|---------------|--------|
| phenol        | 474    |

#### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

#### Ordinance on Prevention of Lead Poisoning

Not applicable

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

#### Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### Poisonous and Deleterious Substances Control Law

Not applicable

#### Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

#### High Pressure Gas Safety Act

Not applicable

## Flunixin Injection Formulation

Version 4.1      Revision Date: 2020/10/10      SDS Number: 1308611-00010      Date of last issue: 2020/03/23  
Date of first issue: 2017/02/21

---

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****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/>

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

JP OEL JSOH : Japan. The Japan Society for Occupational Health. Recommendation of Occupational Exposure Limits

JSOH : Occupational exposure limits based on biological monitoring (JSOH).

ACGIH / TWA : 8-hour, time-weighted average

JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with



## Flunixin Injection Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 2020/03/23  |
| 4.1     | 2020/10/10     | 1308611-00010 | Date of first issue: 2017/02/21 |

---

x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

JP / EN