SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Flunixin Injection Formulation

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 Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
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:**
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
None known.

**SECTION 3: Composition/information on ingredients**

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>255-836-0</td>
<td></td>
<td></td>
<td>Acute Tox. 3; H301 Acute Tox. 2; H330 Eye Dam. 1; H318 STOT SE 3; H335 STOT RE 1; H372 Aquatic Chronic 2; H411</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>203-632-7</td>
<td>604-001-00-2</td>
<td></td>
<td>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 Aquatic Chronic 2; H411</td>
<td>&gt;= 0.25 - &lt; 1</td>
</tr>
<tr>
<td>Sodium hydroxymethanesulphonate</td>
<td>6035-47-8</td>
<td></td>
<td></td>
<td></td>
<td>Muta. 2; H341 Repr. 2; H361d</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray Alcohol-resistant foam Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products:
- Carbon oxides
- Fluorine compounds
- Nitrogen oxides (NOx)

5.3 Advice for firefighters
Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

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

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

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not breathe vapours or spray mist. Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage : Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available
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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>OELV - 8 hrs (TWA) (particles)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-(methyl-3-(perfluoromethyl)anilino)nicotinate]</td>
<td>42461-84-7</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (total (vapour and particles))</td>
<td>150 ppm 470 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>TWA</td>
<td>2 ppm 8 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>4 ppm 16 mg/m³</td>
<td>2009/161/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>2 ppm 8 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Identifies the possibility of significant uptake through the skin, Indicative

Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body, Indicative Occupational Exposure Limit Value

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>Phenol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>16 mg/m³</td>
</tr>
</tbody>
</table>
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Workers | Skin contact | Long-term systemic effects | Value
--- | --- | --- | ---
Consumers | Inhalation | Long-term systemic effects | 1.32 mg/m³
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:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Phenol</td>
<td>Fresh water</td>
<td>0.0077 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.00077 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.031 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.0915 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.00915 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.136 mg/kg</td>
</tr>
</tbody>
</table>

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.

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.
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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. Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

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
   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

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on 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 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
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.
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.
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
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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

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

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
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Result: negative

Sodium hydroxymethanesulphinate:
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
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Application Route: Oral
Exposure time: 6 w
Target Organs: Gastrointestinal tract

Species: Rat
NOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 1 y
Target Organs: Gastrointestinal tract, Kidney

Species: Monkey
NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organs: Gastrointestinal tract, Blood

Species: Rabbit
LOAEL: 80 mg/kg
Application Route: Dermal
Exposure time: 21 d
Symptoms: Severe irritation

Species: Dog
LOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 9 d
Target Organs: Gastrointestinal tract
Symptoms: Vomiting

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.

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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC (Microcystis aeruginosa)</td>
<td></td>
<td>97 mg/l</td>
<td>13 d</td>
<td>FDA 4.01</td>
</tr>
<tr>
<td>NOEC (Selenastrum capricornutum)</td>
<td></td>
<td>96 mg/l</td>
<td>12 d</td>
<td></td>
</tr>
</tbody>
</table>

Phenol:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Pimephales promelas)</td>
<td></td>
<td>24.9 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Ceriodaphnia dubia)</td>
<td></td>
<td>3.1 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Selenastrum capricornutum)</td>
<td></td>
<td>61.1 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>IC50 (Nitrosonomas sp.)</td>
<td></td>
<td>21 mg/l</td>
<td>24 h</td>
<td></td>
</tr>
<tr>
<td>NOEC:</td>
<td></td>
<td>0.077 mg/l</td>
<td>60 d</td>
<td></td>
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<tr>
<td>NOEC:</td>
<td></td>
<td>10 mg/l</td>
<td>16 d</td>
<td></td>
</tr>
</tbody>
</table>

Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Effect</th>
<th>Concentration</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Leuciscus idus)</td>
<td></td>
<td>&gt; 10,000 mg/l</td>
<td>96 h</td>
<td></td>
</tr>
<tr>
<td>EC50 (Daphnia magna)</td>
<td></td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td></td>
</tr>
<tr>
<td>ErC50 (Desmodesmus subspicatus)</td>
<td></td>
<td>370 mg/l</td>
<td>72 h</td>
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</tr>
<tr>
<td>EC50</td>
<td></td>
<td>&gt; 1,000 mg/l</td>
<td>4 h</td>
<td></td>
</tr>
<tr>
<td>NOEC:</td>
<td></td>
<td>13.5 mg/l</td>
<td>35 d</td>
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</tr>
<tr>
<td>NOEC:</td>
<td></td>
<td>5.6 mg/l</td>
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<td></td>
</tr>
</tbody>
</table>
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

Not relevant
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Flunixin Injection Formulation

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

SECTION 14: Transport information

14.1 UN number
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.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable


### Quantity

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

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

The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

### 15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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

Full text of H-Statements

- **H301**: Toxic if swallowed.
- **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.

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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Flunixin Injection Formulation

Version: 4.3
Revision Date: 23.03.2020
SDS Number: 1318076-00009
Date of last issue: 13.09.2019
Date of first issue: 21.02.2017

STOT SE 2009/161/EU: Specific target organ toxicity - single exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2009/161/EU / TWA: Limit Value - eight hours
2009/161/EU / STEL: Short term exposure limit
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

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; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; Ec-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICBO - International Civil Aviation Organization; IECS - 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 Organization 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
Acute Tox. 4: H302

Classification procedure:
Calculation method
Flunixin Injection Formulation

Version 4.3  Revision Date: 23.03.2020  SDS Number: 1318076-00009  Date of last issue: 13.09.2019  Date of first issue: 21.02.2017

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Code</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 3</td>
<td>H331</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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

IE / EN