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

Flunixin Injection Formulation

Version 4.6  Revision Date: 27.08.2021  SDS Number: 1318076-00012  Date of last issue: 09.04.2021

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 Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet

Company: MSD
Kilsheean
Clonmel Tipperary, IE

Telephone: 353-51-601000

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

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

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

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

**3.2 Mixtures**

<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>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</td>
<td>&gt;= 3 - &lt; 10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>203-632-7</td>
<td>Acute Tox. 3; H301 Acute Tox. 3; H331</td>
<td>&gt;= 0.25 - &lt; 1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
See Engineering measures under EXPOSURE
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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.

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

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></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>
</tbody>
</table>
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1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate 42461-84-7 TWA 40 µg/m3 (OEB 3) Internal

Phenol 108-95-2 TWA 2 ppm 8 mg/m3 2009/161/EU

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

STEL 4 ppm 16 mg/m3 2009/161/EU

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

OELV - 15 min (STEL) 4 ppm 16 mg/m3 IE OEL

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

OELV - 8 hrs (TWA) 2 ppm 8 mg/m3 IE OEL

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

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

<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></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>Skin contact</td>
<td>Acute local effects</td>
<td>16 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.23 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1.32 mg/m3</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>0.4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.4 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
</tbody>
</table>
Marine water | 26 mg/l
---|---
Sewage treatment plant | 20000 mg/l
Fresh water sediment | 572 mg/kg dry weight (d.w.)
Marine sediment | 57.2 mg/kg dry weight (d.w.)
Soil | 50 mg/kg dry weight (d.w.)
Phenol
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.

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

**Filter type**

Particulates type (P)
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SECTION 9: Physical and chemical properties

9.1 Information on basic 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
Initial boiling point and boiling range : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
pH : 7.8 - 9.0
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
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
Particle size : Not applicable

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure : Inhalation
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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>

Phenol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Corrosive after 3 minutes to 1 hour of exposure</td>
</tr>
</tbody>
</table>

Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Irreversible effects on the eye</td>
</tr>
</tbody>
</table>

Phenol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>Irreversible effects on the eye</td>
</tr>
</tbody>
</table>

Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximisation Test</td>
<td>Dermal</td>
</tr>
</tbody>
</table>
**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
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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:
- Test Type: Bacterial reverse mutation assay (AMES) method
- 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
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
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:
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

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
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<tbody>
<tr>
<td>Rat</td>
<td>1</td>
<td>Oral</td>
<td>1 y</td>
<td>Gastrointestinal tract, Kidney</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td>15</td>
<td>Oral</td>
<td>90 d</td>
<td>Gastrointestinal tract, Blood</td>
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<td></td>
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<td></td>
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<tr>
<td>Rabbit</td>
<td>80</td>
<td>Dermal</td>
<td>21 d</td>
<td>Severe irritation</td>
</tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>11</td>
<td>Oral</td>
<td>9 d</td>
<td>Gastrointestinal tract</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Vomiting</td>
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</table>

**Phenol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>300</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>OECD Test Guideline 408</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>&gt;= 0.1 mg/l</td>
<td>inhalation (vapour)</td>
<td>74 Days</td>
<td>OECD Test Guideline 408</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Rabbit</td>
<td>260</td>
<td>Skin contact</td>
<td>18 Days</td>
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</table>

**Sodium hydroxymethanesulphinate:**

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<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>600</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>OECD Test Guideline 408</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.
11.2 Information on other hazards

Endocrine disrupting properties

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

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
Flunixin Injection Formulation

Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates  
EC50 (Daphnia magna (Water flea)): 15 mg/l  
Exposure time: 48 h  
Method: FDA 4.08

Toxicity to algae/aquatic plants  
NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l  
Exposure time: 13 d  
Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 96 mg/l  
Exposure time: 12 d

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
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

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.

12.6 Endocrine disrupting properties

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

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

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

SECTION 14: Transport information

14.1 UN number or ID number

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 Maritime transport in bulk according to IMO instruments

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, 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
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
REACH - List of substances subject to authorisation (Annex XIV): Not applicable

<table>
<thead>
<tr>
<th>H2</th>
<th>ACUTE TOXIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity 1</td>
<td>50 t</td>
</tr>
<tr>
<td>Quantity 2</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 : 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.
H373 (EUH071) : 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
STOT SE : 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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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:

<table>
<thead>
<tr>
<th>Classification of the mixture</th>
<th>Classification procedure</th>
</tr>
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<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H302</td>
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<tr>
<td>Acute Tox. 3</td>
<td>H331</td>
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<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
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<tr>
<td>STOT RE 2</td>
<td>H373</td>
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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.