SAFETY DATA SHEET

Flunixin Injection Formulation

Version 4.0 Revision Date: 2020/03/23 SDS Number: 1308611-00009 Date of last issue: 2019/09/13 Date of first issue: 2017/02/21

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. Menuma 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

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.
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P271 Use only outdoors or in a well-ventilated area.
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

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

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 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.

Most important symptoms and effects, both acute and delayed: Harmful if swallowed. Causes serious eye damage. Toxic if inhaled. 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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Fluorine compounds
Nitrogen oxides (NOx)

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.

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

6. ACCIDENTAL RELEASE MEASURES

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

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.

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.

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 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.

Avoidance of contact
- Hygiene measures: Oxidizing agents
- 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. Store in accordance with the particular national regulations.
Materials to avoid: 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</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>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>OEL-M</td>
<td>5 ppm 19 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Further information: Group 3: Substances suspected to cause reproductive toxicity in humans, Skin absorption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>5 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2,2’-Iminodiethanol</td>
<td>111-42-2</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>1 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Biological occupational exposure limits

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

Engineering measures: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

Respiratory protection: If adequate local exhaust ventilation is not available or expo-
Filter type
Hand protection: Particulates type

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.

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: 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

Decomposition temperature: No data available

pH: 7.8 - 9.0

Evaporation rate: No data available
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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

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.

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
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.
  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

Sodium hydroxymethanesulphinate:
Species: Rat
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

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)  
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
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)  
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
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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 vivo
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'-Iminodioethanol:
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

Sodium hydroxymethanesulphinate:
Genotoxicity in vitro
Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: 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

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

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

Phenol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>2020/03/23</td>
<td>1308611-00009</td>
<td>2019/09/13</td>
<td>2017/02/21</td>
</tr>
</tbody>
</table>

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 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 (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
- **Target Organs:** Gastrointestinal tract, Kidney

- **Species:** Monkey
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<table>
<thead>
<tr>
<th>NOAEL</th>
<th>15 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Gastrointestinal tract, Blood</td>
</tr>
</tbody>
</table>

| 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 |

## 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 |
SAFETY DATA SHEET

Flunixin Injection Formulation

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

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:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants:

- ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d

Toxicity to microorganisms:

- NOEC (Pseudomonas putida): > 20,000 mg/l
  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
  Exposure time: 96 h
  Method: FDA 4.11

- LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l
  Exposure time: 96 h
  Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): 15 mg/l
  Exposure time: 48 h
  Method: FDA 4.08

Toxicity to algae/aquatic plants:

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

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

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 fish (Chronic toxicity):

- NOEC: 0.077 mg/l
  Exposure time: 60 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 10 mg/l
  Exposure time: 16 d

Toxicity to microorganisms:

- IC50 (Nitrosomonas sp.): 21 mg/l
  Exposure time: 24 h

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

### 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

#### 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

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

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:  
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 han-
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>Phenol</td>
<td>62</td>
</tr>
<tr>
<td>Diethanolamine</td>
<td>91</td>
</tr>
</tbody>
</table>

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)
SAFETY DATA SHEET

Flunixin Injection Formulation

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phenol</td>
<td>474</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
<tr>
<td>Diethanolamine</td>
<td>219</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>phenol</td>
<td>474</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Bulk transportation</th>
<th>Pack transportation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noxious liquid substance(Category Z)</td>
<td>Not classified as marine pollutant</td>
</tr>
</tbody>
</table>

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

16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet:

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

Date format: yyyy/mm/dd

Full text of other abbreviations

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- 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

Abbreviations:
- AICS - Australian Inventory of Chemical Substances; 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 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 Civil Aviation Organization; 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 substances; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
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.