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

Flunixin Liquid Formulation

Version 6.1 Revision Date: 23.03.2020 SDS Number: 493850-00014 Date of last issue: 12.12.2019 Date of first issue: 28.01.2016

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

1.1 Product identifier
   Trade name : Flunixin Liquid 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 NE21 Great Britain
   Telephone : 44 1670 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.
   Reproductive toxicity, Category 1B   H360FD: May damage fertility. May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.
   Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

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.  
H360FD May damage fertility. May damage the unborn child.  
H373 May cause damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects. 

Precautionary statements:  
Prevention:  
P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ 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.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  

Hazardous components which must be listed on the label:  
2-Pyrrolidone  
1-Deoxy-1-(methylamino)-D-glucitol 2-{2-methyl-3-(perfluoromethyl)anilino}nicotinate  

2.3 Other hazards  
None known.  

SECTION 3: Composition/information on ingredients  

3.2 Mixtures  

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-menthol</td>
<td>2216-51-5 218-690-9</td>
<td>Skin Irrit. 2; H315 Eye Irrit. 2; H319</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5 210-483-1</td>
<td>Eye Irrit. 2; H319 Repr. 1B; H360FD</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-{2-methyl-3-(perfluoromethyl)anilino}nicotinate</td>
<td>42461-84-7 255-836-0</td>
<td>Acute Tox. 3; H301 Acute Tox. 2; H330 Eye Dam. 1; H318 STOT SE 3; H335 STOT RE 1; H372 Aquatic Chronic 2; H411</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
</tbody>
</table>
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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders:
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled:
If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact:
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks:
Harmful if swallowed.
Causes serious eye damage.
Toxic if inhaled.
May damage fertility. May damage the unborn child.
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.
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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 contain-
ment 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 CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Do not get in eyes.
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

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>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>
</tbody>
</table>

Wipe limit 400 µg/100 cm² Internal

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>2-Pyrrolidone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>57.8 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>10 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>277 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>6 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>167 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5.2 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>33.3 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>L-menthol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>132 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>19 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>33 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>1.7 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>9.4 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic</td>
<td>9.4 mg/kg</td>
<td></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>Decanoic acid, mixed diesters with octanoic acid and propylene glycol</td>
<td>Soil</td>
<td>0.2638 mg/kg</td>
</tr>
<tr>
<td>2-Pyrrolidone</td>
<td>Fresh water</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>0.5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.05 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>0.4205 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.0612 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>L-menthol</td>
<td>Fresh water</td>
<td>15.6 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>1.56 µg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>156 µg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2.37 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>289 µg/l</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>28.9 µg/l</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>48.4 µg/l</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. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**: If adequate local exhaust ventilation is not available or expo-
Flunixin Liquid Formulation

Sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>red</td>
</tr>
<tr>
<td>Odour</td>
<td>amine-like</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic: No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
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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: 638.55 mg/kg
  Method: Calculation method
- Acute inhalation toxicity: Acute toxicity estimate: 0.6145 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
Components:

L-menthol:
Acute inhalation toxicity: LC50 (Rat): 5.289 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: OECD Test Guideline 403

Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg
   Method: OECD Test Guideline 402

2-Pyrrolidone:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 401
   Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   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

Skin corrosion/irritation
Not classified based on available information.

Components:

L-menthol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Skin irritation

2-Pyrrolidone:
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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>
</table>

**Species**

- **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

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:**

**L-menthol:**

- **Species**
  - Rabbit
- **Method**
  - OECD Test Guideline 405
- **Result**
  - Irritation to eyes, reversing within 7 days

**2-Pyrrolidone:**

- **Species**
  - Rabbit
- **Result**
  - Irritation to eyes, reversing within 7 days

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

- **Species**
  - Rabbit
- **Result**
  - Irreversible effects on the eye

**Respiratory or skin sensitisation**

**Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:**

**L-menthol:**

- **Test Type**
  - Local lymph node assay (LLNA)
- **Exposure routes**
  - Skin contact
- **Species**
  - Mouse
- **Method**
  - OECD Test Guideline 429
- **Result**
  - negative

2-Pyrrolidone:

- **Test Type**
  - Local lymph node assay (LLNA)
- **Exposure routes**
  - Skin contact
- **Species**
  - Mouse
- **Method**
  - OECD Test Guideline 429
- **Result**
  - negative
- **Remarks**
  - Based on data from similar materials
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

Germ cell mutagenicity
Not classified based on available information.

Components:

L-menthol:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
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: negative
Remarks: Based on data from similar materials

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vitro: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
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

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.

Carcinogenicity
Not classified based on available information.

Components:

L-menthol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

2-Pyrrolidone:
Species: Mouse
Application Route: Ingestion
Exposure time: 18 month(s)
Result: negative
Remarks: Based on data from similar materials

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
### Reproductive toxicity

May damage fertility. May damage the unborn child.

#### Components:

##### L-menthol:

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

##### 2-Pyrrolidone:

**Effects on fertility**
- Test Type: One-generation reproduction toxicity study
- Species: Rat
- Application Route: Ingestion
- Result: positive
- Remarks: Based on data from similar materials

**Effects on foetal development**
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: positive

**Reproductive toxicity - Assessment**
- Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.
- Clear evidence of adverse effects on development, based on animal experiments.

##### 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 off-
spring were detected only at high maternally toxic doses

**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.

**Repeated dose toxicity**

**Components:**

**L-menthol:**

- **Species:** Mouse
- **NOAEL:** 1,250 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 91 Days
- **Method:** OECD Test Guideline 408
- **Remarks:** Based on data from similar materials

**2-Pyrrolidone:**

- **Species:** Rat
- **NOAEL:** 207 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 3 Months
- **Method:** OECD Test Guideline 408

**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
Flunixin Liquid Formulation

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

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

Components:

L-menthol:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): 15.6 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 26.6 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Desmodesmus subspicatus (green algae)): 21.4 mg/l
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 9.65 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50 : 237 mg/l
Exposure time: 96 h
Test Type: Respiration inhibition of activated sludge
Method: OECD Test Guideline 209

2-Pyrrolidone:
Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 4,600 - 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 500 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l
Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 22.2 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

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

12.2 Persistence and degradability

Components:

L-menthol:
Biodegradability : Result: Readily biodegradable.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Flunixin Liquid Formulation

Biodegradation: 64 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

2-Pyrrolidone:
Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Stability in water : Hydrolysis: 0 % (28 d)

12.3 Bioaccumulative potential

Components:
L-menthol:
Bioaccumulation : Species: Cyprinus carpio (Carp)
Exposure time: 6 Weeks
Bioconcentration factor (BCF): 0.5 - 15
Method: OECD Test Guideline 305
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 3.15

2-Pyrrolidone:
Partition coefficient: n-octanol/water : log Pow: -0.71
Method: OECD Test Guideline 107

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
Partition coefficient: n-octanol/water : log Pow: 1.34

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

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

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


<table>
<thead>
<tr>
<th>Substance</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H2</td>
<td>50 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>
Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
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.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H330 : Fatal if inhaled.
H335 : May cause respiratory irritation.
H360FD : May damage fertility. May damage the unborn child.
H372 : Causes 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
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure

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; 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:  Classification procedure:

Acute Tox. 4 H302 Calculation method
Acute Tox. 3 H331 Calculation method
Eye Dam. 1 H318 Calculation method
Repr. 1B H360FD Calculation method
STOT RE 2 H373 Calculation method
Aquatic Chronic 3 H412 Calculation method

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

IE / EN