### 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 Kilsheelan 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.
- **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**: ![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

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-Menthol</td>
<td>2216-51-5</td>
<td>Skin Irrit. 2; H315</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>218-690-9</td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Flunixin Liquid Formulation

<table>
<thead>
<tr>
<th>Specific Concentration Limit</th>
<th>Skin Irrit. 2; H315 &gt; 25 %</th>
<th>Eye Irrit. 2; H319 &gt; 25 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Pyrrolidone</td>
<td>616-45-5</td>
<td>Eye Irrit. 2; H319</td>
</tr>
<tr>
<td></td>
<td>210-483-1</td>
<td>Repr. 1B; H360FD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific Concentration Limit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repr. 1B; H360FD</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 3 %</td>
</tr>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>42461-84-7</td>
<td>Acute Tox. 3; H301</td>
</tr>
<tr>
<td></td>
<td>255-836-0</td>
<td>Acute Tox. 2; H330</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT SE 3; H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Gastrointestinal tract, Kidney, Blood)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 2; H411</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

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

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

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
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 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 mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-
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

### Occupational Exposure Limits

<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>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
</tr>
</tbody>
</table>

**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</td>
</tr>
</tbody>
</table>
Flunixin Liquid Formulation

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**

<table>
<thead>
<tr>
<th>Eye protection</th>
<th>Wear safety glasses with side shields or goggles.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td></td>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hand protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
<tr>
<td>Skin and body protection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Respiratory protection</th>
<th>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter type</td>
<td>Combined particulates and organic vapour type (A-P)</td>
</tr>
</tbody>
</table>

**SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Physical state</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<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>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>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Flunixin Liquid Formulation

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
- 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:
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

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
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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
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  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: 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  
- **Remarks:** Significant toxicity observed in testing

## 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
Flunixin Liquid Formulation

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 offspring 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

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.

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

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

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

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
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
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<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

H2 ACUTE TOXIC

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for
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Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazard Class</th>
<th>Code</th>
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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>Repr. 1B</td>
<td>H360FD</td>
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<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td></td>
</tr>
<tr>
<td>Aquatic Chronic 3</td>
<td>H412</td>
<td></td>
</tr>
</tbody>
</table>

Classification procedure:

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.

NO / EN