SAFETY DATA SHEET

Flunixin Injection Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Flunixin Injection Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Coronel Bento Soares, 530
          Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Acute toxicity (Oral) : Category 4
Acute toxicity (Inhalation) : Category 3
Serious eye damage : Category 1
Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Kidney, Blood)

GHS label elements in accordance with ABNT NBR 14725 Standard
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:
                           P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection/ face protection.

Response:
P304 + P340 + P311 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P314 Get medical advice/ attention if you feel unwell.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>
| 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7   | Acute toxicity (Oral), Category 3  
Acute toxicity (Inhalation), Category 2  
Serious eye damage, Category 1  
Specific target organ toxicity - single exposure, Category 3  
Specific target organ toxicity - repeated exposure (Gastrointestinal tract, Kidney, Blood), Category 1  
Short-term (acute) aquatic hazard, Category 2  
Long-term (chronic) aquatic hazard, Category 2 | >= 5 < 10   |
| Phenol                                             | 108-95-2     | Acute toxicity (Oral), Category 3  
Acute toxicity (Inhalation), Category 3  
Acute toxicity (Dermal), Category 3  
Skin corrosion, Category 1B  
Serious eye damage, Category 1  
Germ cell mutagenicity, Category 2 | >= 0.25 < 1 |
SAFETY DATA SHEET

Flunixin Injection Formulation

Specific target organ toxicity - repeated exposure (Central nervous system, Kidney, Liver, Skin), Category 2
Short-term (acute) aquatic hazard, Category 2
Long-term (chronic) aquatic hazard, Category 2

| Sodium hydroxymethanesulphinate | 6035-47-8 | Germ cell mutagenicity, Category 2
Reproductive toxicity, Category 2 | >= 0,1 -< 1 |

SECTION 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.
SECTION 5. FIRE-FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
</tbody>
</table>

Specific hazards during fire fighting: 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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

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

Conditions for safe storage : Keep in properly labeled 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
                        : Organic peroxides
                        : Explosives
                        : Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<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></td>
<td>Wipe limit 400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Phenol</td>
<td>108-95-2</td>
<td>LT</td>
<td>4 ppm 15 mg/m³</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA 5 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Absorption through the skin, Degree of harmfulness: maximum
### Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</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 last day of the working day (recommended to avoid the first day of the week). You can differentiate between pre- and post-shift</td>
<td>250 mg/g Creatinine</td>
<td>BR BEI</td>
</tr>
</tbody>
</table>

| Phenol     | Urine               | End of shift (As soon as possible after exposure ceases) | 250 mg/g Creatinine | ACGIH BEI |

### 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

**Respiratory protection**

- **Filter type**
  - Particulates type

- **Material**
  - Chemical-resistant gloves

- **Remarks**
  - If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Hand protection**

- **Material**
  - Chemical-resistant gloves

- **Remarks**
  - Consider double gloving.

**Eye protection**

- **Material**
  - Safety glasses with side shields or goggles.

- **Remarks**
  - If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Skin and body protection: Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: liquid

Color: clear

Odor: No data available

Odor Threshold: No data available

pH: 7.8 - 9.0

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)

Water solubility: No data available

Partition coefficient: n-octanol/water: No data available

Autoignition temperature: No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

SECTION 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.

SECTION 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: > 5.000 mg/kg
  Method: Calculation method

Components:
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
  Acute oral toxicity : LD50 (Rat): 53 - 157 mg/kg
  LD50 (Mouse): 176 - 249 mg/kg
LD50 (Guinea pig): 488.3 mg/kg
LD50 (Monkey): 300 mg/kg

Acute inhalation toxicity
- LC50 (Rat): < 0.52 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

Acute toxicity (other routes of administration)
- LD50 (Rat): 59.4 - 185.3 mg/kg
  - Application Route: Intraperitoneal
- LD50 (Mouse): 164 - 363 mg/kg
  - Application Route: Intraperitoneal

Phenol:

Acute oral toxicity
- LD50 (Rat): 650 mg/kg
  - Method: OECD Test Guideline 401
- Acute toxicity estimate (Humans): 140 - 290 mg/kg
  - Method: Expert judgment

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 judgment

Acute dermal toxicity
- LD50 (Rabbit): 660 mg/kg
  - Method: OECD Test Guideline 402
- Acute toxicity estimate (Humans): 300 mg/kg
  - Method: Expert judgment

Sodium hydroxymethanesulphinate:

Acute oral toxicity
- LD50 (Rat): > 5.000 mg/kg
  - Method: OECD Test Guideline 423
  - Remarks: Based on data from similar materials

Acute dermal toxicity
- LD50 (Rat): > 2.000 mg/kg
  - Method: OECD Test Guideline 402
  - Remarks: Based on data from similar materials

Skin corrosion/irritation
- Not classified based on available information.

Components:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:
- Species: Rabbit
Result: Mild skin irritation

**Phenol:**
- **Species:** Rabbit
- **Result:** Corrosive after 3 minutes to 1 hour of exposure

**Sodium hydroxymethanesulphinate:**
- **Species:** Rat
- **Result:** No skin irritation
- **Remarks:** Based on data from similar materials

**Serious eye damage/eye irritation**
- **Result:** Causes serious eye damage.
- **Components:**
  - **1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**
    - **Species:** Rabbit
    - **Result:** Irreversible effects on the eye
  - **Phenol:**
    - **Species:** Rabbit
    - **Result:** Irreversible effects on the eye
    - **Method:** OECD Test Guideline 405
  - **Sodium hydroxymethanesulphinate:**
    - **Species:** Rabbit
    - **Result:** No eye irritation
    - **Method:** OECD Test Guideline 405
    - **Remarks:** Based on data from similar materials

**Respiratory or skin sensitization**

**Skin sensitization**
- **Result:** Not classified based on available information.

**Respiratory sensitization**
- **Result:** Not classified based on available information.

**Components:**
- **1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:**
  - **Test Type:** Maximization Test
  - **Routes of exposure:** Dermal
  - **Species:** Guinea pig
  - **Assessment:** Does not cause skin sensitization.
  - **Result:** negative

**Phenol:**
- **Test Type:** Buehler Test
- **Routes of exposure:** Skin contact
<table>
<thead>
<tr>
<th>Species</th>
<th>Guinea pig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Sodium hydroxymethanesulphinate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

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

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: in vitro test</td>
</tr>
<tr>
<td></td>
<td>Test system: mouse lymphoma cells</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration</td>
</tr>
<tr>
<td></td>
<td>Test system: Chinese hamster ovary cells</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: in vitro test</td>
</tr>
<tr>
<td></td>
<td>Test system: Escherichia coli</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Micronucleus test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity - Assessment**

Weight of evidence does not support classification as a germ cell mutagen.

**Phenol:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Chromosome aberration test in vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 473</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Intraperitoneal injection</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 474</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Annex VI From 1272/2008</td>
</tr>
</tbody>
</table>
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Flunixin Injection Formulation

Germ cell mutagenicity - Assessment: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive
Remarks: Based on data from similar materials

Germ cell mutagenicity - Assessment: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

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

Species: Rat
Application Route: oral (feed)
Exposure time: 104 w
LOAEL: 2 mg/kg body weight
Result: negative
Target Organs: Gastrointestinal tract
Remarks: Significant toxicity observed in testing

Species: Mouse
Application Route: oral (feed)
Exposure time: 97 w
NOAEL: 0,6 mg/kg body weight
Result: negative
Target Organs: Gastrointestinal tract
Remarks: Significant toxicity observed in testing

Phenol:

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

Reproductive toxicity

Not classified based on available information.
**Components:**

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

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>General Toxicity Parent: LOAEL: 1 - 1.5 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Symptoms: No fetal abnormalities.</td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility and early embryonic development were detected.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td>General Toxicity Maternal: LOAEL: 2 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Embryo-fetal toxicity.: NOAEL: 2 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses</td>
</tr>
</tbody>
</table>

**Phenol:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 416</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 414</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Sodium hydroxymethanesulphinate:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 422</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 414</td>
</tr>
<tr>
<td></td>
<td>Result: positive</td>
</tr>
</tbody>
</table>
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.

Repeated dose toxicity

Components:

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

Species: Rat
NOAEL: 2 mg/kg
LOAEL: < 4 mg/kg
Application Route: Oral
Exposure time: 6 w
Target Organs: Gastrointestinal tract

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

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 (vapor)  
Exposure time: 74 Days

Species: Rabbit  
LOAEL: 260 mg/kg  
Application Route: Skin contact  
Exposure time: 18 Days

Species: Rat  
NOAEL: 600 mg/kg  
Application Route: Ingestion  
Exposure time: 90 Days  
Method: OECD Test Guideline 408  
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

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

Inhalation: Symptoms: respiratory tract irritation  
Skin contact: Symptoms: Skin irritation  
Eye contact: Symptoms: Severe irritation  
Ingestion: Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders
**SECTION 12. ECOLOGICAL INFORMATION**

**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:**

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:**
  - EC50 (Selenastrum capricornutum (green algae)): 61,1 mg/l
### Toxicity to plants

Exposure time: 96 h

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>0.077 mg/l</td>
<td>60 d</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>10 mg/l</td>
<td>16 d</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Component</th>
<th>IC50 (Nitrosomonas sp.)</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>21 mg/l</td>
<td>24 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Sodium hydroxymethanesulphinate:

<table>
<thead>
<tr>
<th>Component</th>
<th>LC50 (Leuciscus idus (Golden orfe))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>&gt; 10.000 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>ErC50 (Desmodesmus subspicatus (green algae))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>370 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Danio rerio (zebra fish))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>13,5 mg/l</td>
<td>35 d</td>
<td>OECD Test Guideline 210</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>5,6 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate</td>
<td>&gt; 1.000 mg/l</td>
<td>4 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Persistence and degradability

**Components:**

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

- **Stability in water**: Hydrolysis: 0 % (28 d)

**Phenol**:

- **Biodegradability**: Result: Readily biodegradable.  
  Biodegradation: 62 %  
  Exposure time: 10 d  
  Method: OECD Test Guideline 301C
Sodium hydroxymethanesulphinate:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 77%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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

Partition coefficient: n-octanol/water: log Pow: 1.34

Phenol:

Bioaccumulation:
Species: Fish
Bioconcentration factor (BCF): 17.5
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 1.47

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

Other adverse effects
No data available

SECTION 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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 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.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH)
Group 2B: Possibly carcinogenic to humans
2,2’-Iminodiethanol 111-42-2

Brazil. List of chemicals controlled by the Federal Police: Not applicable

International Regulations

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

SECTION 16. OTHER INFORMATION

Further 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 other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
BR BEI : Brazil. NR7. Parameters for Biological Control of Occupational Exposure to Some Chemical Agents
BR OEL : Brazil. NR 15 - Unhealthy activities and operations
ACGIH / TWA : 8-hour, time-weighted average
BR OEL / LT : Up to 48 hours /week

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 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; 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 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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