

Flunixin Injection Formulation

Version 4.0 Revision Date: 04.04.2023 SDS Number: 1318087-00016 Date of last issue: 01.10.2022
Date of first issue: 21.02.2017

SECTION 1. IDENTIFICATION

Product name : Flunixin Injection Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 3

Serious eye damage/eye irritation : Category 1

Specific target organ toxicity - repeated exposure : Category 2 (Gastrointestinal tract, Kidney, Blood)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H318 Causes serious eye damage.
H331 Toxic if inhaled.
H373 May cause damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

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Precautionary Statements : **Prevention:**
 P260 Do not breathe mist or vapors.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P271 Use only outdoors or in a well-ventilated area.
 P280 Wear eye protection/ face protection.

Response:
 P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
 P304 + P340 + P311 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor.
 P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
 P314 Get medical advice/ attention if you feel unwell.

Storage:
 P405 Store locked up.

Disposal:
 P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | >= 5 -< 10 |
| Phenol | 108-95-2 | >= 0,25 -< 1 |
| 2,2'-Iminodiethanol | 111-42-2 | >= 0,25 -< 1 |
| Sodium hydroxymethanesulphinate | 6035-47-8 | >= 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

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- 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

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Fluorine compounds
Nitrogen oxides (NO_x)
- 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 (see section 7) and personal protective equipment recommendations (see section 8).
- 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

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- 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 mist or vapors.
 Do not swallow.
 Do not get in eyes.
 Avoid prolonged or repeated contact with skin.
 Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.
- 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
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type | Control parame- | Basis |
|------------|---------|------------|-----------------|-------|
|------------|---------|------------|-----------------|-------|

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| | | | | |
|--|------------|------------------------------------|----------------------------------|----------|
| | | (Form of exposure) | ters / Permissible concentration | |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | TWA | 40 µg/m ³ (OEB 3) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 400 µg/100 cm ² | Internal |
| Phenol | 108-95-2 | CMP | 5 ppm | AR OEL |
| Further information: A4 - Not classifiable as a human carcinogen, Skin | | | | |
| | | TWA | 5 ppm | ACGIH |
| 2,2'-Iminodiethanol | 111-42-2 | CMP | 2 mg/m ³ | AR OEL |
| Further information: Skin | | | | |
| | | TWA (Inhalable fraction and vapor) | 1 mg/m ³ | ACGIH |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|------------|----------|--------------------|---------------------|--|---------------------------|-----------|
| Phenol | 108-95-2 | total phenol | Urine | End of shift | 250 mg/g Creatinine | AR BEI |
| | | 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 : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

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| Remarks | : | Consider double gloving. |
| Eye protection | : | Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| 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. |

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 |

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

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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

2,2'-Iminodiethanol:

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| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1.600 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat, male): > 3,35 mg/l Exposure time: 4 h Test atmosphere: dust/mist |

Sodium hydroxymethanesulphinate:

| | | |
|-----------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5.000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials |

Skin corrosion/irritation

Not classified based on available information.

Components:

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

| | | |
|---------|---|----------------------|
| Species | : | Rabbit |
| Result | : | Mild skin irritation |

Phenol:

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

2,2'-Iminodiethanol:

| | | |
|---------|---|-----------------|
| Species | : | Rabbit |
| Result | : | Skin irritation |

Sodium hydroxymethanesulphinate:

| | | |
|---------|---|--------------------------------------|
| Species | : | Rat |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

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

| | | |
|---------|---|---------------------------------|
| Species | : | Rabbit |
| Result | : | Irreversible effects on the eye |

Phenol:

| | | |
|---------|---|---------------------------------|
| Species | : | Rabbit |
| Result | : | Irreversible effects on the eye |
| Method | : | OECD Test Guideline 405 |

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2,2'-Iminodiethanol:

Species : Rabbit
Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

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
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

2,2'-Iminodiethanol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Sodium hydroxymethanesulphinate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

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Components:

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

| | | |
|-------------------------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro test Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro test Test system: Escherichia coli Result: positive |
| Genotoxicity in vivo | : | Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

Phenol:

| | | |
|-------------------------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: positive |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: positive Remarks: Annex VI From 1272/2008 |
| Germ cell mutagenicity - Assessment | : | Positive result(s) from in vivo mammalian somatic cell mutagenicity tests. |

2,2'-Iminodiethanol:

| | | |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Result: negative Test Type: Chromosome aberration test in vitro Result: negative Test Type: In vitro sister chromatid exchange assay in mammalian cells |
|-----------------------|---|---|

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Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
 Species: Mouse
 Application Route: Skin contact
 Result: negative

Sodium hydroxymethanesulphinate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 Method: OECD Test Guideline 471
 Result: negative
 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

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2,2'-Iminodiethanol:

Species : Mouse
 Application Route : Skin contact
 Exposure time : 103 weeks
 Result : positive
 Remarks : The mechanism or mode of action may not be relevant in humans.

Species : Rat
 Application Route : Skin contact
 Exposure time : 103 weeks
 Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity

Not classified based on available information.

Components:

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral
 General Toxicity Parent: LOAEL: 1 - 1,5 mg/kg body weight
 Symptoms: No fetal abnormalities.
 Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Development
 Species: Rat
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 2 mg/kg body weight
 Embryo-fetal 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-fetal development
 Species: Rabbit
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 3 mg/kg body weight
 Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight
 Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Phenol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 Result: negative

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Effects on fetal development : Test Type: Embryo-fetal development
 Species: Mouse
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: negative

2,2'-Iminodiethanol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 443
 Result: positive

Effects on fetal development : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 443
 Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

Sodium hydroxymethanesulphinate:

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

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: positive
 Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

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

Assessment : May cause respiratory irritation.

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STOT-repeated exposure

May cause damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Components:

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

Target Organs : Gastrointestinal tract, Kidney, Blood
 Assessment : Causes damage to organs through prolonged or repeated exposure.

Phenol:

Target Organs : Central nervous system, Kidney, Liver, Skin
 Assessment : May cause damage to organs through prolonged or repeated exposure.

2,2'-Iminodiethanol:

Routes of exposure : Ingestion
 Target Organs : Kidney, Blood, Liver, Nervous system
 Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Routes of exposure : inhalation (dust/mist/fume)
 Target Organs : Kidney, Blood
 Assessment : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

Routes of exposure : Skin contact
 Target Organs : Blood, Liver, Kidney
 Assessment : Shown to produce significant health effects in animals at concentrations of >20 to 200 mg/kg bw.

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

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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

Phenol:

Species : Rat
 LOAEL : 300 mg/kg
 Application Route : Ingestion
 Exposure time : 90 Days
 Method : OECD Test Guideline 408

Species : Rat
 NOAEL : $\geq 0,1$ mg/l
 Application Route : inhalation (vapor)
 Exposure time : 74 Days

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

2,2'-Iminodiethanol:

Species : Rat, female
 LOAEL : 14 mg/kg
 Application Route : Ingestion
 Exposure time : 13 Weeks

Species : Rat
 NOAEL : 0,015 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 90 Days
 Method : OECD Test Guideline 413

Species : Rat
 LOAEL : 32 mg/kg
 Application Route : Skin contact
 Exposure time : 13 Weeks

Sodium hydroxymethanesulphinate:

Species : Rat
 NOAEL : 600 mg/kg

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| | | |
|-------------------|---|--------------------------------------|
| 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 | : | EC50 (Daphnia magna (Water flea)): 15 mg/l |

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| | |
|----------------------------------|--|
| aquatic invertebrates | Exposure time: 48 h Method: FDA 4.08 |
| Toxicity to algae/aquatic plants | : NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l Exposure time: 13 d Method: FDA 4.01 |
| | NOEC (Selenastrum capricornutum (green algae)): 96 mg/l Exposure time: 12 d |

Phenol:

| | |
|--|--|
| Toxicity to fish | : LC50 (Pimephales promelas (fathead minnow)): 24,9 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Ceriodaphnia dubia (water flea)): 3,1 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : EC50 (Selenastrum capricornutum (green algae)): 61,1 mg/l Exposure time: 96 h |
| Toxicity to fish (Chronic toxicity) | : NOEC: 0,077 mg/l Exposure time: 60 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 16 d |
| Toxicity to microorganisms | : IC50 (Nitrosomonas sp.): 21 mg/l Exposure time: 24 h |

2,2'-Iminodiethanol:

| | |
|--|---|
| Toxicity to fish | : LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Ceriodaphnia dubia (water flea)): 30,1 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : ErC50 (Pseudokirchneriella subcapitata (green algae)): 9,5 mg/l Exposure time: 72 h |
| | EC10 (Pseudokirchneriella subcapitata (green algae)): 1,1 mg/l Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : EC10 (Daphnia magna (Water flea)): 1,05 mg/l Exposure time: 21 d |
| Toxicity to microorganisms | : EC10 (activated sludge): > 1.000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209 |

Sodium hydroxymethanesulphinate:

| | |
|------------------|--|
| Toxicity to fish | : LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l |
|------------------|--|

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| | |
|--|--|
| | Exposure time: 96 h Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| Toxicity to fish (Chronic toxicity) | : NOEC (Danio rerio (zebra fish)): 13,5 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 5,6 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : EC50: > 1.000 mg/l Exposure time: 4 h Remarks: Based on data from similar materials |

Persistence and degradability

Components:

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

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

Phenol:

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

2,2'-Iminodiethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 93 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Sodium hydroxymethanesulphinate:

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

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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 |
|--|-----------------|

2,2'-Iminodiethanol:

| | |
|--|---|
| Partition coefficient: n-octanol/water | : log Pow: -2,46 Method: OECD Test Guideline 107 |
|--|---|

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 | : Do not dispose of waste into sewer. 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

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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATIONRevision Date : 04.04.2023
Date format : dd.mm.yyyy**Further information**Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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 abbreviationsACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
AR BEI : Argentina. Biological Exposure Indices
AR OEL : Argentina. Occupational Exposure LimitsACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)AIC - Australian Inventory of Industrial Chemicals; 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); EC_x - Concentration associated with x% response; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule;

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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; TECI - Thailand Existing Chemicals Inventory; 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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