

Flunixin Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 04/09/2022
6.3 10/01/2022 1308645-00015 Date of first issue: 02/21/2017

SECTION 1. IDENTIFICATION

Product name : Flunixin Injection Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
 : Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4
Acute toxicity (Inhalation) : Category 3
Serious eye damage : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity : Category 1 (Gastrointestinal tract, Kidney, Blood)
- repeated exposure

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
 : H318 Causes serious eye damage.
 : H331 Toxic if inhaled.
 : H361d Suspected of damaging the unborn child.
 : H372 Causes damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
 : P201 Obtain special instructions before use.
 : P202 Do not handle until all safety precautions have been read and understood.
 : P260 Do not breathe mist or vapors.

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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 protective gloves, protective clothing, eye protection and face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
 P304 + P340 + P311 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a 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.
 P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| Propylene glycol | 57-55-6 | 20.72 |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | 8.5 |
| Phenol | 108-95-2 | 0.5 |
| 2,2'-Iminodiethanol | 111-42-2 | 0.4 |
| Sodium hydroxymethanesulphinate | 6035-47-8 | 0.25 |

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.

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| | | |
|---|---|--|
| | | 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. Suspected of damaging the unborn child. Causes 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 (CO ₂) 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 | |
|--|------------|------------------------------------|----------------------------------|-----------|
| Propylene glycol | 57-55-6 | TWA | 10 mg/m ³ | US WEEL |
| 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 | TWA | 5 ppm | ACGIH |
| | | TWA | 5 ppm 19 mg/m ³ | NIOSH REL |
| | | C | 15.6 ppm 60 mg/m ³ | NIOSH REL |
| | | TWA | 5 ppm 19 mg/m ³ | OSHA Z-1 |
| 2,2'-Iminodiethanol | 111-42-2 | TWA (Inhalable fraction and vapor) | 1 mg/m ³ | ACGIH |
| | | TWA | 3 ppm 15 mg/m ³ | NIOSH REL |

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sam-pling time | Permissible concentra-tion | Basis |
|------------|----------|--------------------|---------------------|--|----------------------------|-----------|
| Phenol | 108-95-2 | 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any

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hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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

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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 : 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

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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:

Propylene glycol:

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity |

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

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 53 - 157 mg/kg LD50 (Mouse): 176 - 249 mg/kg LD50 (Guinea pig): 488.3 mg/kg LD50 (Monkey): 300 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): < 0.52 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 59.4 - 185.3 mg/kg Application Route: Intraperitoneal LD50 (Mouse): 164 - 363 mg/kg Application Route: Intraperitoneal |

Phenol:

| | | |
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| Acute oral toxicity | : | LD50 (Rat): 650 mg/kg |
|---------------------|---|-----------------------|

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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:

Acute oral toxicity : LD50 (Rat): 1,600 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3.35 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Sodium hydroxymethanesulphinat:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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

Species : Rabbit
Result : Mild skin irritation

Phenol:

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

2,2'-Iminodiethanol:

Species : Rabbit
Result : Skin irritation

Sodium hydroxymethanesulphinat:

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

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Propylene glycol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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

Species : Rabbit
Result : Irreversible effects on the eye

Phenol:

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

2,2'-Iminodiethanol:

Species : Rabbit
Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinat:

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.

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Components:

Propylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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.

Components:

Propylene glycol:

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

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)

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Species: Mouse
 Application Route: Intraperitoneal injection
 Result: negative

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

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

Test Type: in vitro 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: Chromosome aberration test in vitro
 Result: negative

Test Type: In vitro sister chromatid exchange assay in mammalian cells

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Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

Sodium hydroxymethanesulphinate:

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

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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

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

Species : Mouse
Application Route : oral (feed)
Exposure time : 97 w
NOAEL : 0.6 mg/kg body weight
Result : negative

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Target Organs : Gastrointestinal tract
 Remarks : Significant toxicity observed in testing

Phenol:

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

2,2'-Iminodiethanol:

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

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

IARC Group 2B: Possibly carcinogenic to humans
 2,2'-Iminodiethanol 111-42-2

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Mouse
 Application Route: Ingestion
 Result: negative

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

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral

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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

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: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Sodium hydroxymethanesulphinate:

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

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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.

STOT-repeated exposure

Causes 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 : inhalation (dust/mist/fume)
 Assessment : No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

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

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

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Repeated dose toxicity**Components:****Propylene glycol:**

Species : Rat, male
NOAEL : >= 1,700 mg/kg
Application Route : Ingestion
Exposure time : 2 y

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

Phenol:

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

Species : Rat
NOAEL : >= 0.1 mg/l
Application Route : inhalation (vapor)
Exposure time : 74 Days

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

2,2'-Iminodiethanol:

Species : Rat
LOAEL : 14 - 25 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Species : Rat
LOAEL : 0.015 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 90 Days
Method : OECD Test Guideline 413

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

Sodium hydroxymethanesulphinate:

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

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 32 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Components:

Propylene glycol:

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h

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

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l
Exposure time: 96 h
Method: FDA 4.11

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 15 mg/l
Exposure time: 48 h
Method: FDA 4.08

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

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

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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)): 1.4 mg/l
Exposure time: 72 h
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 1.05 mg/l
Exposure time: 21 d
- Toxicity to microorganisms : EC10: > 1,000 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
Exposure time: 72 h

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- Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 13.5 mg/l
Exposure time: 35 d
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 4 h
Remarks: Based on data from similar materials

Persistence and degradability**Components:****Propylene glycol:**

- Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

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

Phenol:

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

2,2'-Iminodiethanol:

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

Sodium hydroxymethanesulphinate:

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

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Bioaccumulative potential

Components:

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

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

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

Phenol:

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

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

2,2'-Iminodiethanol:

Partition coefficient: n-octanol/water : log Pow: -2.46

Mobility in soil

Components:

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

Distribution among environmental compartments : log Koc: 1.92

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

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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.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3082
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (2,2'-Iminodiethanol)
 Class : 9
 Packing group : III
 Labels : CLASS 9
 ERG Code : 171
 Marine pollutant : no
 Remarks : THE ABOVE INFORMATION ONLY APPLIES TO PACKAGE SIZES WHERE THE HAZARDOUS SUBSTANCE MEETS THE REPORTABLE QUANTITY.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|---------------------|----------|--------------------|-----------------------------|
| 2,2'-Iminodiethanol | 111-42-2 | 100 | 25000 |
| Phenol | 108-95-2 | 1000 | 200000 |

SARA 304 Extremely Hazardous Substances Reportable Quantity

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|------------|----------|--------------------|-----------------------------|
| Phenol | 108-95-2 | 1000 | 200000 |

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
 Reproductive toxicity
 Specific target organ toxicity (single or repeated exposure)
 Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water 7732-18-5
 Propylene glycol 57-55-6
 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3- 42461-84-7

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| | |
|-------------------------------------|----------|
| (perfluoromethyl)anilino]nicotinate | |
| Phenol | 108-95-2 |
| 2,2'-Iminodiethanol | 111-42-2 |

California Prop. 65

WARNING: This product can expose you to chemicals including 2,2'-Iminodiethanol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

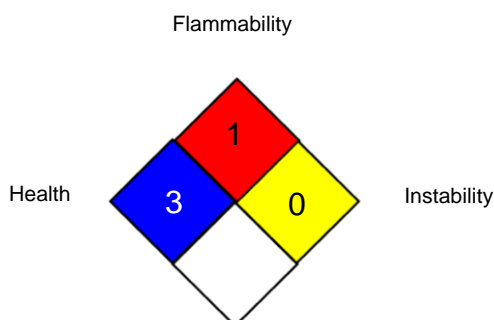
The ingredients of this product are reported in the following inventories:

| | | |
|-------|---|----------------|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

| | | |
|------------------------|---|----------|
| HEALTH | * | 3 |
| FLAMMABILITY | | 1 |
| PHYSICAL HAZARD | | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

| | | |
|-----------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH BEI | : | ACGIH - Biological Exposure Indices (BEI) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| US WEEL | : | USA. Workplace Environmental Exposure Levels (WEEL) |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| NIOSH REL / C | : | Ceiling value not be exceeded at any time. |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |
| US WEEL / TWA | : | 8-hr TWA |

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AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

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/>

Revision Date : 10/01/2022

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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