# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078071153

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078073195 078074229 078074237 078591323

Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

# MATERIAL SAFETY DATA SHEET

*Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.*

## SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

**MSDS NAME:** **Flunixin Meglumine Solution**

**SYNONYM(S):** Flunixin Meglumine Solution
Banamine Injectable Solution
Finadyne Injectable Solution
Finixin Solution
Bedozane Solution

**MSDS NUMBER:** SP000351

**EMERGENCY NUMBER(S):** (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

**INFORMATION:** Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

**MERCK MSDS HELPLINE:** (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

## SECTION 2. HAZARDS IDENTIFICATION

### EMERGENCY OVERVIEW

Solution
Clear, Colorless to light yellow
Odor unknown
May be severely irritating to the eyes.
Highly toxic by inhalation.
Harmful if swallowed.
Prolonged exposure may cause serious health effects.
Harmful to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

**POTENTIAL HEALTH EFFECTS:**

## SECTION 2. HAZARDS IDENTIFICATION

The following summary is based upon available information about the individual ingredients of the mixture, or of the expected properties of the mixture.

Flunixin meglumine is a potent non-narcotic, non-steroidal agent with pain killing, anti-inflammatory, and fever-reducing activity. Based on animal studies, flunixin meglumine may cause severe eye irritation or irreversible ocular effects. It may also cause irritation of the skin, mucous membranes, respiratory tract, and gastrointestinal tract. Repeated dermal contact to high concentrations may cause severe skin irritation. Prolonged inhalation may produce serious lung effects. Repeated ingestion or inhalation of high doses may cause internal bleeding, predominantly of the gastrointestinal tract.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

### LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

## SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**PRODUCT USE:** Veterinary product

**CHEMICAL FORMULA:** Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

### CHEMICAL COMPOSITION

| INGREDIENT | CAS NUMBER | PERCENT |
|---|---|---|
| Flunixin Meglumine | 42461-84-7 | 8.5 |
| Propylene Glycol | 57-55-6 | 20-30 |

**ADDITIONAL INFORMATION:** This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

## SECTION 4. FIRST AID MEASURES

**INHALATION:** Remove to fresh air. Administer artificial respiration if breathing has ceased. IMMEDIATELY consult a physician.

**SKIN CONTACT:** In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

**EYE CONTACT:** In case of eye contact, IMMEDIATELY rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. Get IMMEDIATE medical attention.

**INGESTION:** Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

**NOTE TO PHYSICIAN:** Flunixin meglumine is a potent Non-Steroidal Anti-inflammatory Drug (NSAID), and overexposure may cause gastrointestinal irritation and bleeding, kidney and central nervous system effects.

## SECTION 5. FIRE FIGHTING MEASURES

**FLAMMABILITY DATA:**

Flash Point: Not determined (liquids) or not applicable (solids).

**SPECIAL FIRE FIGHTING PROCEDURES:**
Wear full protective clothing and self-contained breathing apparatus (SCBA).

## SECTION 5. FIRE FIGHTING MEASURES

**SUITABLE EXTINGUISHING MEDIA:**
Carbon dioxide (CO2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:**
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

**SPILL RESPONSE / CLEANUP:**
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

**ENVIRONMENTAL PRECAUTIONS:**
This product is harmful to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

## SECTION 7. HANDLING AND STORAGE

**HANDLING:**
Avoid contact with eyes. Avoid splashing or spraying. Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

**STORAGE:**
Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

## SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

**OCCUPATIONAL EXPOSURE BAND (OEB):**
OEB 4: 1-10 mcg/$m^3$. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

**OCCUPATIONAL EXPOSURE GUIDELINE (OEG):**
An Occupational Exposure Guideline (OEG) of 18 mcg/$m^3$ (8-hr TWA) has been established for flunixin. Consult your site safety and industrial hygiene professional(s) for additional guidance.

**HHC/OEG NOTATION(S):**
This material has a notation of "C" for corrosivity.

**EXPOSURE CONTROLS**
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

**RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):**

| | |
|---|---|
| Respiratory Protection: | Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance. |
| Skin Protection: | Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance. |
| Eye Protection: | Safety glasses with side shields. Use of goggles or full face protection is required if there is potential for contact with this material. Consult your site safety staff for guidance. |
| Body Protection: | In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.<br><br>In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. |

### EXPOSURE LIMIT VALUES

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **FORM:** | Solution |
| **COLOR:** | Clear, Colorless to light yellow |
| **ODOR:** | Odor unknown |
| **pH:** | 7.8 to 9.0 |
| **SPECIFIC GRAVITY:** | 1.041 to 1.047 at 20 deg C |
| **SOLUBILITY:** | |
| Water: | Not determined |

See Section 5 for flammability/explosivity information.

## SECTION 10. STABILITY AND REACTIVITY

**STABILITY/ REACTIVITY:**
Stable under normal conditions.

**INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:**
Open flames and high temperatures.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**
Carbon monoxide (CO). Carbon dioxide (CO2).

## SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s). The information presented for the active ingredient in this formulation, flunixin meglumine, is either for flunixin (free acid) or the meglumine salt. The toxicity is considered equivalent, except for differences in mutagenicity, based on studies conducted using both forms of the drug.

**ACUTE TOXICITY DATA**

**INHALATION:**
Flunixin Meglumine: Inhalation LC50 (4hr): <0.52 mg/L (rat)
Mortality occurred in all rats (10/10) between days 3 and 6 following a single 4-hour exposure to an average analytical concentration of 0.52 mg/L (maximum attainable exposure). Signs exhibited following exposure included lacrimation, nasal discharge, dried red material around facial area, and yellow anogenital staining. Significant weight loss was noted following exposure in all animals.

Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

**SKIN:**
Flunixin meglumine: Slightly irritating
Flunixin meglumine produced mild, transient dermal irritation in rabbits. Dose-related skin irritation effects were observed in rabbits during a 21-day repeat skin application study (see below under Subchronic to Chronic Toxicity).

Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

**EYE:**
Flunixin Meglumine: Severely irritating
All six animals exhibited severe conjunctival irritation including redness, swelling, discharge, and necrosis, as well as corneal opacity, ulceration and iridial damage. Severe ocular irritation was irreversible in most animals.

Propylene glycol was slightly irritating to the eyes of rabbits.

**ORAL:**
Flunixin Meglumine: Oral LD50: 53 to 157 mg/kg (rat), 176 to 249 mg/kg (male mouse, female estimated)
Flunixin (free acid): Oral LD50: 468.3 mg/kg (guinea pig)
Common effects observed in acute oral studies across species include gastrointestinal effects (perforation/ulceration and hemorrhage), hypoactivity, pallor, spleen enlargement, congestion of kidneys, lungs, or gastrointestinal tract, and respiratory distress. Necropsy of animals that died from flunixin meglumine revealed abnormalities of the brain, epididymides, abdominal cavity, thymus, liver, mesenteric lymph nodes, esophagus, mesentery, pancreas, and lungs. No signs of toxicity were observed following acute oral administration of 100 & 200 mg/kg to rhesus monkeys. However, 1 of 3 monkeys died following administration of 300 mg/kg. That monkey showed lethargy, prostration, and salivation prior to death, and signs of hyperemic mucosa in gastrointestinal tract and lungs at necropsy. Flunixin administered orally to mice at a dose of 300 mg/kg (100x the projected clinical dose) caused slight tremors and ataxia which resolved within 24 hours. Effects from acute oral and IV treatment of horses with 1.1 mg/kg flunixin were limited to sporadic incidence of fecal occult blood.

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

**DERMAL AND RESPIRATORY SENSITIZATION:**
Flunixin Meglumine was found not to be sensitizing in guinea pigs when tested by intradermal induction at 1% and topically at 100%.

Propylene glycol did not cause sensitization in a human patch test.

## REPEAT DOSE TOXICITY DATA

**SUBCHRONIC / CHRONIC TOXICITY:**
Repeat oral dosing studies have been performed with flunixin across multiple species. The most common adverse effect seen in these studies is gastrointestinal irritation/ulceration and bleeding as indicated by blood in the stools. Other common adverse effects observed across species from oral, IV or IM routes of exposure include nephrotoxicity, emesis, anorexia, and bleeding. Blood cell count changes, blood coagulation effects, and immune organ effects were observed secondary to gastrointestinal erosion and bleeding. Liver, nervous system and behavioral effects were also noted in mice. In addition to ulceration and bleeding, significant mortality was observed in rats at 8 and 16 mg/kg dosed for six weeks. [6-week oral toxicity NOAEL: 2 mg/kg (rats); 90-day oral toxicity NOAEL: 5 mg/kg (monkeys), 3.0 mg/kg (rats); one year oral toxicity NOEL: 1 mg flunixin/kg (rats)]

In several 21-day repeat skin application studies in rabbits using up to 80 mg/kg flunixin meglumine or the free acid in spray or cream formulations, no conclusive treatment-related toxicity could be established. The incidence and severity of dermal irritation increased in a dose-related manner with severe irritation seen at 80 mg/kg/day.

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**
Reproductive and teratology studies in rats, mice and rabbits were performed with flunixin. Although significant maternal toxicity, including mortality, was reported, these studies indicate that flunixin does not affect offspring development, male or female fertility, or mating behavior. A slight increase in the length of gestation and difficult labor with an increase in stillbirths were observed. No evidence of any drug-related teratogenic effects were observed. Maternal toxicity observed in these studies was consistent with those findings in acute and repeated dose oral toxicity studies with the addition of pale eyes, ears and extremities. [Reproductive or developmental NOELs ranged from 2-21 mg/kg in studies with multiple species. Maternal toxicity NOELs ranged from 3-9 mg/kg in these studies].

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

**MUTAGENICITY / GENOTOXICITY:**
Flunixin meglumine was negative in the Ames and mouse micronucleus assays. It was positive in mouse lymphoma L5178Y cells, both in the absence and presence of S-9 metabolic activation and in the chromosomal abberation assay in CHO cells in vitro both in the absence and presence of S-9 metabolic activation. It has been reported to alter cellular DNA and caused primary DNA damage in E. coli. Flunixin free acid yielded the same results as flunixin meglumine. However, it was inconclusive in the bacterial repair assay in E.coli whereas flunixin meglumine was strongly positive. The meglumine moiety (N-methyl-D glucamine) was negative in all studies performed except the micronucleus study in which it was positive in one study and negative in a second.

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

**CARCINOGENICITY:**
Flunixin meglumine had no carcinogenic effects or increase in tumor incidence relative to controls in either a 104-week study in rats administered 2, 4 and 8 mg flunixin meglumine/kg/day in the diet, or in mice administered 0.6, 2.0 and 6.0 mg flunixin meglumine/kg/day in the diet for 97 weeks. Significant toxicity observed in rats and mice included decreased body weights, increased mortality (high dose groups) and dose-related increases in gastrointestinal lesions in all treated groups. Compound-related lesions observed at necropsy included dose-related gastrointestinal ulcers, ulcer perforation with secondary peritonitis and adhesion formation, and large or edematous lymph nodes. Dose-related nonproliferative lesions were present in the gastrointestinal tract and mesenteric lymph node. Necrosis and ulceration of the mucosa, transmural necrosis, mucosal and mural inflammation, lymphoid hyperplasia, peritonitis and abscess formation were present. Inflammatory lesions and necrosis secondary to the peritonitis were present in other abdominal organs. Splenomegaly (enlarged spleens) were observed at necropsy in mice and were significant in the high dose group only. [Rat NOEL for tumor formation = 8 mg flunixin meglumine/kg/day and the LOEL = 2 mg flunixin meglumine/kg/day based on GI lesions. Mouse NOEL for tumor formation = 6.0 mg flunixin meglumine/kg/day; Toxicity NOEL = 0.6 mg flunixin meglumine/kg/day].

Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

## SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

**ECOTOXICITY DATA**

**INGREDIENT ECOTOXICITY**

Flunixin meglumine: 96-hr LC50 (trout): 9.2 mg/L
Flunixin meglumine: 96-hr LC50 (bluegill): 46 mg/L
Flunixin meglumine: 48-hr EC50 (Daphnia): 25 mg/L
Flunixin meglumine: 72 hr IC50 (Algae): 36-120 mg/L

Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L
Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L
Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L

**ENVIRONMENTAL DATA**

**OTHER INGREDIENT ENVIRONMENTAL DATA:**

Flunixin Meglumine: log Pow (log octanol/water partition coefficient): 1.34

Propylene glycol is expected to be readily biodegradable.

## SECTION 13. DISPOSAL CONSIDERATIONS

**MATERIAL WASTE:**
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

**PACKAGING AND CONTAINERS:**
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

**SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:**
Do not allow product to reach ground water, water courses, sewage or drainage systems.

## SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

## SECTION 15. REGULATORY INFORMATION

### TSCA LISTING

## SECTION 15. REGULATORY INFORMATION

| INGREDIENT | TSCA |
|---|---|
| Propylene Glycol | X |

## U.S. STATE REGULATIONS

| INGREDIENT | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|---|---|---|---|---|---|
| Propylene Glycol | | | 3595 | | |

| INGREDIENT | PARTK | MNRTK | MIRTK | RIRTK |
|---|---|---|---|---|
| Propylene Glycol | X | X | | X |

## SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

**DEPARTMENT ISSUING MSDS:**
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**MERCK MSDS HELPLINE:**
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Monday to Friday, 9am to 5pm (US Eastern Time)

**MSDS CREATION DATE:** 01-Jan-1993

**SUPERSEDES DATE:** 07-May-2010

**SECTIONS CHANGED (US SUBFORMAT):** 2, 11
**SIGNIFICANT CHANGES (US SUBFORMAT):** OEB

# SAFETY DATA SHEET

# Flunixin Injection Formulation (Banamine Injection Formulation)

| Version | Revision Date: | SDS Number: | Date of last issue: 10/11/2017 |
|---|---|---|---|
| 3.1 | 04/12/2018 | 1308645-00005 | Date of first issue: 02/21/2017 |

## SECTION 1. IDENTIFICATION

Product name : Flunixin Injection Formulation (Banamine Injection Formulation)

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033

Telephone : 908-740-4000

Telefax : 908-735-1496

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

## SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with 29 CFR 1910.1200**

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 3

Serious eye damage : Category 1

Carcinogenicity : Category 2

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated exposure : Category 1 (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.

H351 Suspected of causing cancer.
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.
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/ 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous ingredients**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Propylene glycol | 57-55-6 | >= 20 - < 30 |
| 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | >= 5 - < 10 |
| Phenol | 108-95-2 | >= 0.1 - < 1 |
| Diethanolamine | 111-42-2 | >= 0.1 - < 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.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | Harmful if swallowed.<br>Causes serious eye damage.<br>Toxic if inhaled.<br>Suspected of causing cancer.<br>Suspected of damaging the unborn child.<br>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. |
| Notes to physician | : | Treat symptomatically and supportively. |

## SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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<br>Fluorine compounds<br>Nitrogen oxides (NOx) |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 | : | Use with local exhaust ventilation. |

| | | |
|---|---|---|
| Advice on safe handling | : | Do not breathe vapors or spray mist.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Organic peroxides<br>Explosives<br>Gases |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| Propylene glycol | 57-55-6 | TWA | 10 mg/m³ | US WEEL |
| 1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate | 42461-84-7 | TWA | 40 µg/m3 (OEB 3) | Internal |
| | | Wipe limit | 400 µg/100 cm² | Internal |
| Phenol | 108-95-2 | TWA | 5 ppm | ACGIH |
| | | TWA | 5 ppm<br>19 mg/m³ | NIOSH REL |
| | | C | 15.6 ppm<br>60 mg/m³ | NIOSH REL |
| | | TWA | 5 ppm<br>19 mg/m³ | OSHA Z-1 |
| Diethanolamine | 111-42-2 | TWA (Inhalable fraction and vapor) | 1 mg/m³ | ACGIH |
| | | TWA | 3 ppm<br>15 mg/m³ | NIOSH REL |

**Biological occupational exposure limits**

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | 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., dripless 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 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.<br>Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Hygiene measures | : | Ensure that eye flushing systems and safety showers are located close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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 information 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<br>Method: Calculation method |

| | | |
|---|---|---|
| Acute inhalation toxicity | : | Acute toxicity estimate: 0.6 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: > 5,000 mg/kg<br>Method: Calculation method |

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rabbit): > 159 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>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<br><br>LD50 (Mouse): 176 - 249 mg/kg<br><br>LD50 (Guinea pig): 488.3 mg/kg<br><br>LD50 (Monkey): 300 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): < 0.52 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : | LD50 (Rat): 59.4 - 185.3 mg/kg<br>Application Route: Intraperitoneal<br><br>LD50 (Mouse): 164 - 363 mg/kg<br>Application Route: Intraperitoneal |

**Phenol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 650 mg/kg<br>Method: OECD Test Guideline 401<br><br>Acute toxicity estimate (Humans): 140 - 290 mg/kg<br>Method: Expert judgment |
| Acute inhalation toxicity | : | LC0 (Rat): 0.9 mg/l<br>Exposure time: 8 h<br>Test atmosphere: dust/mist<br>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

**Diethanolamine:**

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

**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:**

**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:**

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

**Diethanolamine:**

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:**

**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

**Diethanolamine:**

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:**

**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 |

**Diethanolamine:**

| | | |
|---|---|---|
| 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)<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>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)<br>Result: negative<br><br>Test Type: in vitro test<br>Test system: mouse lymphoma cells<br>Result: positive<br><br>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.

**Diethanolamine:**

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

Suspected of causing cancer.

**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 |
| 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 |

**Diethanolamine:**

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Skin contact |
| Exposure time | : | 103 weeks |
| Result | : | positive |

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Skin contact |
| Exposure time | : | 103 weeks |

Result : negative

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

**IARC** Group 2B: Possibly carcinogenic to humans
Diethanolamine 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: Three-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
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<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: negative |

**Diethanolamine:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 416<br>Result: negative |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Inhalation<br>Result: negative |

**Sodium hydroxymethanesulphinate:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative<br>Remarks: Based on data from similar materials |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: positive<br>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.

**Diethanolamine:**

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.

**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 |

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

**Diethanolamine:**

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 14 - 25 mg/kg |
| Application Route | : | Ingestion |
| 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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 32 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l<br>Exposure time: 48 h |
| Toxicity to algae | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l<br>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<br>Exposure time: 96 h<br>Method: FDA 4.11<br><br>LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 15 mg/l<br>Exposure time: 48 h<br>Method: FDA 4.08 |
| Toxicity to algae | : | NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l<br>Exposure time: 13 d<br>Method: FDA 4.01<br><br>NOEC (Selenastrum capricornutum (green algae)): 96 mg/l<br>Exposure time: 12 d |

**Phenol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 3.1 mg/l<br>Exposure time: 48 h |
| Toxicity to algae | : | EC50 (Selenastrum capricornutum (green algae)): 61.1 mg/l<br>Exposure time: 96 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0.077 mg/l<br>Exposure time: 60 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 10 mg/l<br>Exposure time: 16 d |
| Toxicity to microorganisms | : | IC50 (Nitrosomonas sp.): 21 mg/l<br>Exposure time: 24 h |

**Diethanolamine:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 1,460 mg/l<br>Exposure time: 96 h |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 55 mg/l<br>Exposure time: 48 h<br>Method: EPA-660/3-75-009 |
| Toxicity to algae | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 2.2 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.78 mg/l<br>Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10: > 1,000 mg/l<br>Exposure time: 30 min<br>Method: OECD Test Guideline 209 |

**Sodium hydroxymethanesulphinate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: Based on data from similar materials |
| Toxicity to algae | : | ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Danio rerio (zebra fish)): 13.5 mg/l<br>Exposure time: 35 d<br>Method: OECD Test Guideline 210<br>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<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC50: > 1,000 mg/l<br>Exposure time: 4 h<br>Remarks: Based on data from similar materials |

**Persistence and degradability**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>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

**Diethanolamine:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 99 %
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

**Bioaccumulative potential**

**Components:**

**Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07

**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

**Diethanolamine:**

Partition coefficient: n-octanol/water : log Pow: -1.71

**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**

**49 CFR**

| | | |
|---|---|---|
| UN/ID/NA number | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (Diethanolamine) |
| 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

**EPCRA - Emergency Planning and Community Right-to-Know**

**CERCLA Reportable Quantity**

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|---|---|---|---|
| Diethanolamine | 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)
Serious eye damage or eye irritation
Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

**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-(perfluoromethyl)anilino]nicotinate | 42461-84-7 |
| Phenol | 108-95-2 |
| Diethanolamine | 111-42-2 |

**California Prop. 65**

WARNING: This product can expose you to chemicals including Diethanolamine, 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

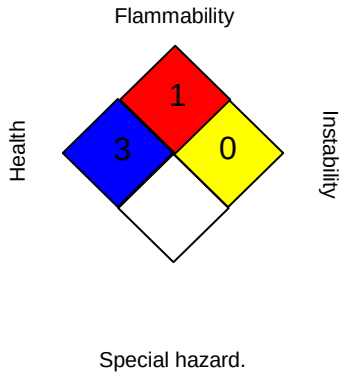
DSL : not determined

| | | |
|---|---|---|
| IECSC | : | not determined |

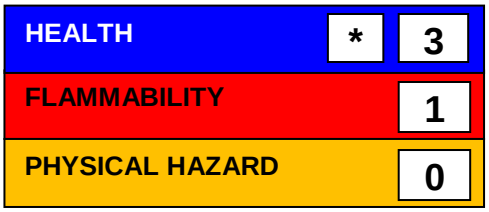
## SECTION 16. OTHER INFORMATION

### Further information

**NFPA 704:**




**HMIS® IV:**




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 |

AICS - Australian Inventory of Chemical Substances; 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; 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 | : | 04/12/2018 |

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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