

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Flunixin Injection Formulation

Version 8.0 Revision Date: 06/17/2025 SDS Number: 1308645-00019 Date of last issue: 04/14/2025
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 - repeated exposure | : Category 1 (Gastrointestinal tract, Kidney, Blood) |

Other hazards

None known.

GHS label elements

| | |
|--------------------------------|--|
| Hazard pictograms | : |
| Signal Word | : Danger |
| Hazard Statements | : H302 Harmful if swallowed. H318 Causes serious eye damage. H331 Toxic if inhaled. H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure. |
| Supplemental Hazard Statements | : Corrosive to the respiratory tract. |

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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 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS No./Unique ID | Concentration (% w/w) | Trade secret |
|---|-------------------|-----------------------|--------------|
| Propylene glycol | 57-55-6* | >= 10 - <= 30 | TSC |
| 1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluorome-thyl)anilino]nicotinate | 42461-84-7* | >= 5 - <= 10 | TSC |
| Phenol | 108-95-2* | >= 0.1 - <= 1 | TSC |
| 2,2'-Iminodiethanol | 111-42-2* | >= 0.1 - <= 1 | TSC |
| Sodium hydroxymethanesulphonate | 6035-47-8* | >= 0.1 - <= 1 | TSC |

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
Causes serious eye damage.
Toxic if inhaled.
Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Corrosive to the respiratory tract.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

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- 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 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

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|-----------------------------|---|
| | 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 (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--|------------|-------------------------------------|--|-----------|
| 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 | | | | |
| Phenol | 108-95-2 | Wipe limit | 400 µg/100 cm ² | Internal |
| | | TWA | 5 ppm | ACGIH |
| | | | 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 | Sampl- ing time | Permissible concentra- tion | Basis |
|------------|----------|--------------------|---------------------|---------------------------|--------------------------------|-----------|
| Phenol | 108-95-2 | Phenol | Urine | End of shift (As soon as) | 250 mg/g creatinine | ACGIH BEI |

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|--|--|--|--|--|--|--|
| | | | | possible after exposure ceases) | | |
|--|--|--|--|--|--|--|

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 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

Eye protection

- : Consider double gloving.

- : 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,

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industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|--|---|-------------------|
| Appearance | : | liquid |
| Color | : | clear |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 7.8 - 9.0 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| 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 |

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| | |
|--------------------------|--|
| Explosive properties | : Not explosive |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Molecular weight | : No data available |
| Particle characteristics | |
| Particle size | : Not applicable |

SECTION 10. STABILITY AND REACTIVITY

| | |
|------------------------------------|--|
| Reactivity | : Not classified as a reactivity hazard. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : Can react with strong oxidizing agents. |
| Conditions to avoid | : None known. |
| Incompatible materials | : Oxidizing agents |
| Hazardous decomposition products | : No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.
Toxic if inhaled.

Product:

| | |
|---------------------------|--|
| Acute oral toxicity | : Acute toxicity estimate: 604.68 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : Acute toxicity estimate: 0.5964 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |
| Acute dermal toxicity | : Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method |

Components:

Propylene glycol:

| | |
|---------------------------|----------------------------|
| Acute oral toxicity | : LD50 (Rat): 22,000 mg/kg |
| Acute inhalation toxicity | : LC50 (Rat): > 44.9 mg/l |

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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:

Acute oral toxicity : LD50 (Rat): 650 mg/kg
Method: OECD Test Guideline 401

Acute toxicity estimate (Humans): 140 - 290 mg/kg
Method: Expert judgment

Acute inhalation toxicity : LC0 (Rat): 0.9 mg/l
Exposure time: 8 h
Test atmosphere: dust/mist
Assessment: Corrosive to the respiratory tract.

Acute toxicity estimate (Humans): > 0.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity : LD50 (Rabbit): 660 mg/kg
Method: OECD Test Guideline 402

Acute toxicity estimate (Humans): 300 mg/kg
Method: Expert judgment

2,2'-Iminodiethanol:

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

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

Sodium hydroxymethanesulphinate:

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

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

Skin corrosion/irritation

||| Not classified based on available information.

Components:

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

2,2'-Iminodiethanol:

||| Species : Rabbit
Result : Skin irritation

Sodium hydroxymethanesulphinate:

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

Serious eye damage/eye irritation

||| Causes serious eye damage.

Components:

Propylene glycol:

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

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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 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 |

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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) 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 |

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| Genotoxicity in vivo | | : Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative | |
| Germ cell mutagenicity - Assessment | | : Weight of evidence does not support classification as a germ cell mutagen. | |
| Phenol: | | | |
| Genotoxicity in vitro | | : Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: positive | |
| Genotoxicity in vivo | | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: positive Remarks: Annex VI From 1272/2008 | |
| Germ cell mutagenicity - Assessment | | : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests. | |
| 2,2'-Iminodiethanol: | | | |
| Genotoxicity in vitro | | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative | |
| | | Test Type: In vitro mammalian cell gene mutation test Result: negative | |
| | | Test Type: Chromosome aberration test in vitro Result: negative | |
| | | Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative | |
| Genotoxicity in vivo | | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Skin contact Result: negative | |
| Sodium hydroxymethanesulphonate: | | | |
| 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) | |

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| | |
|-------------------------------------|--|
| | 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 |
| 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. |

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| | | |
|------------------------------|--|--|
| Species | : | Rat |
| Application Route | : | Skin contact |
| Exposure time | : | 103 weeks |
| Result | : | negative |
| Carcinogenicity - Assessment | : | Weight of evidence does not support classification as a carcinogen |
| 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 fertility or 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 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 |

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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: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 443 Result: positive |
| Effects on fetal development | : Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Method: OECD Test Guideline 443 Result: positive |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments. |

Sodium hydroxymethanesulphonate:

- | | |
|------------------------------------|--|
| Effects on fertility | : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative Remarks: Based on data from similar materials |
| Effects on fetal development | : Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive Remarks: Based on data from similar materials |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on |

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Assessment animal experiments.

STOT-single exposure

Corrosive to the respiratory tract.

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

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

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

Repeated dose toxicity

Components:

Propylene glycol:

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

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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 |

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2,2'-Iminodiethanol:

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat, female |
| LOAEL | : | 14 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |
| Species | : | Rat |
| NOAEL | : | 0.015 mg/l |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 90 Days |
| Method | : | OECD Test Guideline 413 |
| Species | : | Rat |
| LOAEL | : | 32 mg/kg |
| Application Route | : | Skin contact |
| Exposure time | : | 13 Weeks |

Sodium hydroxymethanesulphinate:

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

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

| | | |
|--------------|---|--|
| Inhalation | : | Symptoms: respiratory tract irritation |
| Skin contact | : | Symptoms: Skin irritation |
| Eye contact | : | Symptoms: Severe irritation |
| Ingestion | : | Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders |

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |

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

Phenol:

| | |
|------------------|---|
| Toxicity to fish | : LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l Exposure time: 96 h |
|------------------|---|

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

2,2'-Iminodiethanol:

| | | |
|--|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l Exposure time: 72 h |
| | | EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1 mg/l Exposure time: 72 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | EC10 (Daphnia magna (Water flea)): 1.05 mg/l Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10 (activated sludge): > 1,000 mg/l Exposure time: 30 min Method: OECD Test Guideline 209 |

Sodium hydroxymethanesulphonate:

| | | |
|---|---|--|
| 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 Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |

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| | | |
|--|---|--|
| 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 Remarks: The test was conducted according to guideline |
|------------------|---|---|

Sodium hydroxymethanesulphonate:

| | | |
|------------------|---|--|
| 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
Method: OECD Test Guideline 107

Mobility in soil

Components:

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

Distribution among environmental compartments : log Koc: 1.92

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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

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IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

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.

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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 |
| 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.

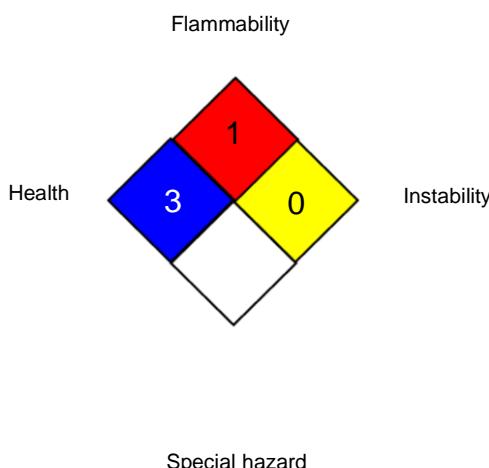
The ingredients of this product are reported in the following inventories:

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:



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 |

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

AIIC - 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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 : 06/17/2025

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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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.

US / Z8