

## Flunixin Injection Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 1308647-00016      Date of last issue: 04.04.2023  
Date of first issue: 21.02.2017

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### Section 1: Identification

Product name : Flunixin Injection Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800 CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 3

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 2

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

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H318 Causes serious eye damage.  
H331 Toxic if inhaled.

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H361 Suspected of damaging fertility or the unborn child.  
 H373 May cause 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 vapours.  
 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 which do not result in classification**

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol	57-55-6	>= 20 -< 30
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 3 -< 10
Phenol	108-95-2	>= 0.25 -< 1
2,2'-Iminodiethanol	111-42-2	>= 0.1 -< 1
Sodium hydroxymethanesulphinate	6035-47-8	>= 0.1 -< 1

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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.  
May cause damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
 Use personal protective equipment.

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### 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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

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

### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	WES-TWA (particulate)	10 mg/m <sup>3</sup>	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m <sup>3</sup>	NZ OEL
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Phenol	108-95-2	WES-TWA	1 ppm 3.8 mg/m <sup>3</sup>	NZ OEL
	Further information: Skin absorption			
		WES-STEL	2 ppm 7.7 mg/m <sup>3</sup>	NZ OEL
	Further information: Skin absorption			
		TWA	5 ppm	ACGIH
2,2'-Iminodiethanol	111-42-2	WES-TWA	3 ppm 13 mg/m <sup>3</sup>	NZ OEL
	Further information: Skin absorption			
		TWA (Inhalable fraction and vapor)	1 mg/m <sup>3</sup>	ACGIH

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**Biological occupational exposure limits**

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Phenol	108-95-2	Total phenol	Urine	End of shift	100 mg/l	NZ BEI
		Phenol	Urine	End of shift (As soon as possible after exposure ceases)	250 mg/g creatinine	ACGIH BEI

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
 Minimize open handling.

**Personal protective equipment**

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

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

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

**Section 9: Physical and chemical properties**

Appearance : liquid

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Colour : clear

Odour : No data available

Odour 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

Vapour pressure : No data available

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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Molecular weight                   : No data available  
Particle size                         : Not applicable

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**Section 10: Stability and reactivity**

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

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**Section 11: Toxicological information**

Exposure routes                    : 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: 0.5661 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method  
Acute dermal toxicity               : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

**Components:****Propylene glycol:**

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



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**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 judgement

Acute inhalation toxicity : Acute toxicity estimate: 0.0501 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Expert judgement  
Remarks: Based on national or regional regulation.

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

**2,2'-Iminodiethanol:**

Acute oral toxicity : LD50 (Rat): 1,600 mg/kg  
Acute inhalation toxicity : LC50 (Rat, male): > 3.35 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

**Sodium hydroxymethanesulphinate:**

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

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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

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

Species : Rabbit  
Result : Irreversible effects on the eye

**Phenol:**

Species : Rabbit

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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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Propylene glycol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

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

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative

**Phenol:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**2,2'-Iminodiethanol:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

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**Sodium hydroxymethanesulphinat:**

Test Type : Maximisation Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Chronic toxicity****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 assay  
Test system: mouse lymphoma cells  
Result: positive

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: positive

Test Type: in vitro assay  
Test system: Escherichia coli  
Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

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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 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

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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.

Species : Rat

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

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

### 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 foetal development : Test Type: Embryo-foetal 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 foetal abnormalities  
 Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Development  
 Species: Rat  
 Application Route: Oral  
 General Toxicity Maternal: LOAEL: 2 mg/kg body weight  
 Embryo-foetal 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-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 General Toxicity Maternal: LOAEL: 3 mg/kg body weight  
 Embryo-foetal 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

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Application Route: Ingestion  
 Method: OECD Test Guideline 414  
 Result: negative

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

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

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

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

### Sodium hydroxymethanesulphinate:

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

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

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



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### STOT - single exposure

Not classified based on available information.

#### Components:

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

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

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

#### Components:

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

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

#### **Phenol:**

Assessment : Causes damage to organs through prolonged or repeated exposure.  
 Remarks : Based on national or regional regulation.

#### **2,2'-Iminodiethanol:**

Exposure routes : 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.

Exposure routes : 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.

Exposure routes : 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 yr

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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 :  $\geq 0.1$  mg/l  
 Application Route : inhalation (vapour)  
 Exposure time : 74 Days

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

### 2,2'-Iminodiethanol:

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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

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## 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

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

#### **Phenol:**

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

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 3.1 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): 61.1 mg/l  
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC: 0.077 mg/l  
Exposure time: 60 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 16 d

Toxicity to microorganisms : IC50 (Nitrosomonas sp.): 21 mg/l  
Exposure time: 24 h

**2,2'-Iminodiethanol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 460 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 30.1 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5 mg/l  
Exposure time: 72 h

EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1 mg/l  
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 1.05 mg/l  
Exposure time: 21 d

Toxicity to microorganisms : EC10 (activated sludge): > 1,000 mg/l  
Exposure time: 30 min  
Method: OECD Test Guideline 209

**Sodium hydroxymethanesulphinate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l  
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 : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

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plants  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): 13.5 mg/l  
Exposure time: 35 d  
Method: OECD Test Guideline 210  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 5.6 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50: > 1,000 mg/l  
Exposure time: 4 h  
Remarks: Based on data from similar materials

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

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

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

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

**Phenol:**

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

**2,2'-Iminodiethanol:**

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

**Sodium hydroxymethanesulphinate:**

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

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**Bioaccumulative potential****Components:****Propylene glycol:**

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

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

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

**Phenol:**

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

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

**2,2'-Iminodiethanol:**

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

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**Section 13: Disposal considerations****Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

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**Section 14: Transport information****International Regulations****UNRTDG**

UN number : Not applicable

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Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable

**IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

**National Regulations****NZS 5433**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

**Special precautions for user**

Not applicable

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**Section 15: Regulatory information**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard



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**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

**The components of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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**Section 16: Other information**

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**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
NZ BEI	:	New Zealand. Biological Exposure Indices
NZ OEL	:	New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NZ OEL / WES-TWA	:	Workplace Exposure Standard - Time Weighted average
NZ OEL / WES-STEL	:	Workplace Exposure Standard - Short-Term Exposure Limit

AIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships;

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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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