

Flunixin Injection Formulation

Version 5.0 Revision Date: 04.04.2023 SDS Number: 1308647-00015 Date of last issue: 01.10.2022
 Date of first issue: 21.02.2017

Section 1: Identification

Product name : Flunixin Injection Formulation

Manufacturer or supplier's details

Company : MSD

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

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use :
 Not applicable

Section 2: 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.
 H361 Suspected of damaging fertility or the unborn child.
 H373 May cause damage to organs (Gastrointestinal tract,

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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

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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		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 ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Fluorine compounds Nitrogen oxides (NO _x)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for 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.

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.
- 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

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- Conditions for safe storage : use of administrative controls.
 : 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 ³	NZ OEL
		WES-TWA (Vapour and particulates)	150 ppm 474 mg/m ³	NZ OEL
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m ³ (OEB 3)	Internal
		Further information: Skin		
		Wipe limit	400 µg/100 cm ²	Internal
Phenol	108-95-2	WES-TWA	1 ppm 3.8 mg/m ³	NZ OEL
		Further information: Skin absorption		
		WES-STEL	2 ppm 7.7 mg/m ³	NZ OEL
		Further information: Skin absorption		
		TWA	5 ppm	ACGIH
2,2'-Iminodiethanol	111-42-2	WES-TWA	3 ppm 13 mg/m ³	NZ OEL
		Further information: Skin absorption		
		TWA (Inhalable fraction and vapor)	1 mg/m ³	ACGIH

Biological occupational exposure limits

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

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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.
Molecular weight	:	No data available
Particle size	:	Not applicable

Section 10: Stability and reactivity

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

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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

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

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

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

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

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

- Species : Rabbit
 Result : Mild skin irritation

Phenol:

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

2,2'-Iminodiethanol:

Species : Rabbit
Result : Skin irritation

Sodium hydroxymethanesulphinate:

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

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Propylene glycol:

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

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

Species : Rabbit
Result : Irreversible effects on the eye

Phenol:

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

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

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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

Sodium hydroxymethanesulphinate:

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

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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

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

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		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:

		Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials
	Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: positive Remarks: Based on data from similar materials
	Germ cell mutagenicity - Assessment	: Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:

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

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

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

	Species	: Mouse
	Application Route	: oral (feed)
	Exposure time	: 97 w

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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
 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.

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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
 Application Route: Ingestion
 Method: OECD Test Guideline 416
 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

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		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.

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

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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 : $\geq 1,700$ mg/kg
 Application Route : Ingestion
 Exposure time : 2 yr

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

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Species : Rat
 NOAEL : ≥ 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:

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
- 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

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Method: FDA 4.08

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

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

Phenol:

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

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

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

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

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

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

2,2'-Iminodiethanol:

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

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

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

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

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

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

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
 Exposure time: 96 h

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	Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	: NOEC (Danio rerio (zebra fish)): 13.5 mg/l Exposure time: 35 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 5.6 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: Based on data from similar materials
Toxicity to microorganisms	: EC50: > 1,000 mg/l Exposure time: 4 h Remarks: Based on data from similar materials

Persistence and degradability

Components:

Propylene glycol:

Biodegradability	: Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F
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1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

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

Biodegradability	: Result: Readily biodegradable. Biodegradation: 62 % Exposure time: 10 d Method: OECD Test Guideline 301C
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2,2'-Iminodiethanol:

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

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

Bioaccumulative potential

Components:

Propylene glycol:

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

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UNRTDG

UN number : Not applicable
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

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

Section 16: Other information

Revision Date : 04.04.2023

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/>

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

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

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

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