according to the Globally Harmonized System



Flunixin Injection Formulation

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1. PRODUCT AND COMPANY IDENTIFICATION

Product name Flunixin Injection Formulation

Manufacturer or supplier's details

Company MSD

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

+1-908-740-4000 Telephone

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Veterinary product Recommended use Restrictions on use Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Toxic

GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) Category 3

Serious eye damage/eye irri-

tation

Category 1

repeated exposure

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

GHS label elements

Hazard pictograms





Signal word Danger

H302 Harmful if swallowed. Hazard statements

H318 Causes serious eye damage.

H331 Toxic if inhaled.

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H373 May cause damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Precautionary statements :

Prevention:

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 eye protection/ face protection.

Response:

P301 + P317 + P330 IF SWALLOWED: Get medical help.

Rinse mouth.

P304 + P340 + P316 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get emergency medical

help immediately.

P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help.

P319 Get medical help if you feel unwell.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (%
	10101 01 -	w/w)
1-deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-	42461-84-7	>= 5 - < 10
(perfluoromethyl)anilino]nicotinate		
Phenol	108-95-2	>= 0.25 - < 1
2,2'-Iminodiethanol	111-42-2	>= 0.25 - < 1
Sodium hydroxymethanesulphinate	6035-47-8	>= 0.1 - < 1

4. FIRST AID MEASURES

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

vice 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.

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Get medical attention.

In case of contact, immediately flush skin with soap and plenty In case of skin contact

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 Harmful if swallowed. Causes serious eye damage.

delayed Toxic if inhaled.

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).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING 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 prod-

ucts

Carbon oxides

Fluorine compounds Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

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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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

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 as-

sessment

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 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	

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1-deoxy-1-(methylamino)-D- glucitol 2-[2-methyl-3- (perfluorome- thyl)anilino]nicotinate	42461-84-7	TWA	40 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	400 μg/100 cm ²	Internal
Phenol	108-95-2	TWA	5 ppm 19 mg/m3	IN OEL
	Further information: Potential contribution to the overall exposure			
	by the cutaneous route including mucous membranes and eye.			
		TWA	5 ppm	ACGIH
2,2'-Iminodiethanol	111-42-2	TWA (Inhal- able fraction and vapor)	1 mg/m3	ACGIH

Biological occupational exposure limits

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

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., 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 contain-

ment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection : Particulates type

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

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aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

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

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Not applicable

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Auto-ignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

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

Molecular weight No data available

Particle size Not applicable

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Can react with strong oxidizing agents.

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

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Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

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 : 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 judgement

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

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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:

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:

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

Species : Rabbit

Result : Irreversible effects on the eye

Phenol:

Species : Rabbit

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

2,2'-Iminodiethanol:

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Species : Rabbit

Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

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:

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

Germ cell mutagenicity

Not classified based on available information.

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Components:

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 muta-

genicity 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 mam-

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malian 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

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity -

Assessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Carcinogenicity

Not classified based on available information.

Components:

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

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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 hu-

mans.

Species : Rat

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

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

Not classified based on available information.

Components:

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 develop-

ment were detected.

Effects on foetal develop-

ment

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:

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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 develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 443

Result: positive

Reproductive toxicity - As-

sessment

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 develop-

ment

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 - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT - single exposure

Not classified based on available information.

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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:

Target Organs : Central nervous system, Kidney, Liver, Skin

Assessment : May cause damage to organs through prolonged or repeated

exposure.

2,2'-Iminodiethanol:

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Liver, Nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations 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 con-

centrations 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 con-

centrations of >20 to 200 mg/kg bw.

Repeated dose toxicity

Components:

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

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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 (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

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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, hyperten-

sion, Kidney disorders

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

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Components:

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

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l

according to the Globally Harmonized System



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> 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:

LC50 (Pimephales promelas (fathead minnow)): 24.9 mg/l Toxicity to fish

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 microorganisms IC50 (Nitrosomonas sp.): 21 mg/l

Exposure time: 24 h

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.077 mg/l Exposure time: 60 d

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 10 mg/l

Exposure time: 16 d

Species: Daphnia magna (Water flea)

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

Toxicity to algae/aguatic

plants

Exposure time: 48 h

ErC50 (Pseudokirchneriella subcapitata (green algae)): 9.5

Exposure time: 72 h

EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1

Exposure time: 72 h

according to the Globally Harmonized System



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EC10 (activated sludge): > 1,000 mg/l Toxicity to microorganisms

Exposure time: 30 min

Method: OECD Test Guideline 209

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

EC10: 1.05 mg/l Exposure time: 21 d

ic toxicity)

Species: Daphnia magna (Water flea)

Sodium hydroxymethanesulphinate:

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

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

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 4 h

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

NOEC: 13.5 mg/l

Exposure time: 35 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 5.6 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

Persistence and degradability

Components:

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

according to the Globally Harmonized System



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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

Bioaccumulative potential

Components:

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

log Pow: -2.46

2,2'-Iminodiethanol:

Partition coefficient: n-

octanol/water Method: OECD Test Guideline 107

Mobility in soil

Components:

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

Distribution among environ-

mental compartments

: log Koc: 1.92

Other adverse effects

No data available

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 han-

according to the Globally Harmonized System



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dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 30.09.2023

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 Agen-

cy, 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)

IN OEL : India. Permissible levels of certain chemical substances in

work environment.

ACGIH / TWA : 8-hour, time-weighted average

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

according to the Globally Harmonized System



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AIIC - 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; 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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