according to the Hazardous Products Regulations



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SECTION 1. IDENTIFICATION

Product name : Flunixin Injection Formulation

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 3

Serious eye damage : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure

Category 1 (Gastrointestinal tract, Kidney, Blood)

GHS label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.

H318 Causes serious eye damage.

H331 Toxic if inhaled.

H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Gastrointestinal tract, Kidney,

Blood) through prolonged or repeated exposure.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

according to the Hazardous Products Regulations



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and understood.

P260 Do not breathe mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel

unwell. Rinse mouth.

P304 + P340 + P311 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. Call a doctor.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON

CENTER.

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Propylene glycol	1,2-Propanediol	57-55-6	>= 10 - < 30 *
1-deoxy-1- (methylamino)-D- glucitol 2-[2-methyl-3- (perfluorome- thyl)anilino]nicotinate	No data availa- ble	42461-84-7	>= 5 - < 10 *
Phenol	Monohy- droxybenzene	108-95-2	>= 0.1 - < 1 *
2,2'-Iminodiethanol	Ethanol, 2,2'- iminobis-	111-42-2	>= 0.1 - < 1 *
Sodium hy- droxymethanesulphi- nate	Methanesulfinic acid, hydroxy-, monosodium salt, dihydrate	6035-47-8	>= 0.1 - < 1 *

* Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

according to the Hazardous Products Regulations



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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

idvice.

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delayed

Harmful if swallowed.

Causes serious eye damage.

Toxic if inhaled.

Suspected of damaging fertility or the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Fluorine compounds

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-

ucte

Carbon oxides

Specific extinguishing methods

Nitrogen oxides (NOx)

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

according to the Hazardous Products Regulations



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SO.

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

If sufficient ventilation is unavailable, use with local exhaust Local/Total ventilation

ventilation.

Do not breathe mist or vapors. Advice on safe handling

> 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

according to the Hazardous Products Regulations



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environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Propylene glycol	57-55-6	TWA (Va- pour and 155 mg/m³ aerosols)		CA ON OEL	
		TWA (aero- sol)	10 mg/m³	CA ON OEL	
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 inform	rmation: Skin			
		Wipe limit	400 μg/100 cm ²	Internal	
Phenol	108-95-2	TWA	5 ppm 19 mg/m³	CA AB OEL	
		TWA	5 ppm	CA BC OEL	
		TWAEV	5 ppm 19 mg/m³	CA QC OEL	
		TWA	5 ppm	ACGIH	
2,2'-Iminodiethanol	111-42-2	TWA	2 mg/m³	CA AB OEL	
		TWA	2 mg/m³	CA BC OEL	
		TWAEV (in- halable frac- tion and va- pour)	1 mg/m³	CA QC OEL	
		TWA (Inhalable fraction and vapor)	1 mg/m³	ACGIH	

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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

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

Chemical-resistant gloves Material

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.

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

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,

according to the Hazardous Products Regulations



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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear

Odor : No data available

Odor Threshold : No data available

pH : 7.8 - 9.0

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

according to the Hazardous Products Regulations



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Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Harmful if swallowed. Toxic if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: 604.68 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 0.5964 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 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

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Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

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

Acute oral toxicity : LD50 (Rat): 53 - 157 mg/kg

LD50 (Mouse): 176 - 249 mg/kg

LD50 (Guinea pig): 488.3 mg/kg

LD50 (Monkey): 300 mg/kg

Acute inhalation toxicity : LC50 (Rat): < 0.52 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute toxicity (other routes of :

administration)

LD50 (Rat): 59.4 - 185.3 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 164 - 363 mg/kg Application Route: Intraperitoneal

Phenol:

Acute oral toxicity : LD50 (Rat): 650 mg/kg

Method: OECD Test Guideline 401

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

Method: Expert judgment

Acute inhalation toxicity : LC0 (Rat): 0.9 mg/l

Exposure time: 8 h

Test atmosphere: dust/mist

Assessment: Corrosive to the respiratory tract.

Acute toxicity estimate (Humans): > 0.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : LD50 (Rabbit): 660 mg/kg

Method: OECD Test Guideline 402

Acute toxicity estimate (Humans): 300 mg/kg

Method: Expert judgment

2,2'-Iminodiethanol:

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

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Acute inhalation toxicity : LC50 (Rat, male): > 3.35 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Sodium hydroxymethanesulphinate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

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

Species : Rabbit

Result : Mild skin irritation

Phenol:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

2,2'-Iminodiethanol:

Species : Rabbit Result : Skin irritation

Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

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

Species : Rabbit

Result : Irreversible effects on the eye

Phenol:

Species : Rabbit

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

2.2'-Iminodiethanol:

Species : Rabbit

Result : Irreversible effects on the eye

Sodium hydroxymethanesulphinate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Propylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitization.

Result : negative

Phenol:

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

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2,2'-Iminodiethanol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Sodium hydroxymethanesulphinate:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Components:

Propylene glycol:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

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

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

Result: negative

Test Type: in vitro test

Test system: mouse lymphoma cells

Result: positive

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

Result: positive

Test Type: in vitro test Test system: Escherichia coli

Result: positive

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Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Phenol:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Remarks: Annex VI From 1272/2008

Germ cell mutagenicity -

Assessment

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

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)

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Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity -

Assessment

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

genicity tests.

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:

Species: RatApplication Route: IngestionExposure time: 2 YearsResult: 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 hu-

mans.

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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

Suspected of damaging fertility or the unborn child.

Components:

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

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

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity Parent: LOAEL: 1 - 1.5 mg/kg body weight

Symptoms: No fetal abnormalities.

Result: No effects on fertility and early embryonic

development were detected.

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 2 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 2 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Oral

General Toxicity Maternal: LOAEL: 3 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Phenol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

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Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 416

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

2,2'-Iminodiethanol:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: positive

Effects on fetal development : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: positive

Reproductive toxicity - 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 fetal development: Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - 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

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

Components:

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

Target Organs : Gastrointestinal tract, Kidney, Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Phenol:

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

Assessment : May cause damage to organs through prolonged or repeated

exposure.

2,2'-Iminodiethanol:

Routes of exposure : Ingestion

Target Organs : Kidney, Blood, Liver, Nervous system

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

centrations of >10 to 100 mg/kg bw.

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Kidney, Blood

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

centrations of >0.02 to 0.2 mg/l/6h/d.

Routes of exposure : Skin contact

Target Organs : Blood, Liver, Kidney

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

centrations of >20 to 200 mg/kg bw.

Repeated dose toxicity

Components:

Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 y

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

 Species
 : Rat

 NOAEL
 : 2 mg/kg

 LOAEL
 : < 4 mg/kg</td>

according to the Hazardous Products Regulations



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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 21 d Exposure time

Symptoms : Severe irritation

Species Dog LOAEL 11 mg/kg Application Route Exposure time : Oral : 9 d

Target Organs : Gastrointestinal tract

Symptoms Vomiting

Phenol:

Species Rat LOAEL 300 mg/kg Application Route Exposure time Ingestion 90 Days

Method **OECD Test Guideline 408**

Species Rat NOAEL >= 0.1 mg/l

Application Route
Exposure time inhalation (vapor)

74 Days

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

2,2'-Iminodiethanol:

Species Rat, female : 14 mg/kg : Ingestion LOAEL Application Route Exposure time 13 Weeks

according to the Hazardous Products Regulations



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Species Rat

NOAEL 0.015 mg/l

inhalation (dust/mist/fume) Application Route

Exposure time 90 Days

Method **OECD Test Guideline 413**

Species Rat LOAEL 32 mg/kg Skin contact Application Route Exposure time 13 Weeks

Sodium hydroxymethanesulphinate:

Species Rat NOAEL 600 mg/kg Application Route Ingestion Exposure time 90 Days

OECD Test Guideline 408 Method

Based on data from similar materials Remarks

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

Symptoms: Skin irritation Skin contact Eye contact Symptoms: Severe irritation

Ingestion Symptoms: Gastrointestinal disturbance, bleeding, hyperten-

sion, Kidney disorders

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l

plants

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 32

mg/l

according to the Hazardous Products Regulations



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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

aquatic invertebrates

Toxicity to daphnia and other : 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: aguatic invertebrates (Chron-

ic 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:

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

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:

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

according to the Hazardous Products Regulations



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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 (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

aquatic invertebrates

Toxicity to daphnia and other : 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

ma/l

Exposure time: 72 h

EC10 (Pseudokirchneriella subcapitata (green algae)): 1.1

Exposure time: 72 h

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic 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

aquatic invertebrates

Toxicity to daphnia and other : 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 tox-

icity)

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 : NOEC (Daphnia magna (Water flea)): 5.6 mg/l

according to the Hazardous Products Regulations



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aquatic invertebrates (Chron- Exposure time: 21 d

ic toxicity) Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

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

Exposure time: 4 h

Remarks: Based on data from similar materials

Persistence and degradability

Components:

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

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

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

Phenol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 62 % Exposure time: 10 d

Method: OECD Test Guideline 301C

2,2'-Iminodiethanol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 93 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Remarks: The test was conducted according to guideline

Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Propylene glycol:

Partition coefficient: n- : log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

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

according to the Hazardous Products Regulations



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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 environ-

mental compartments

: log Koc: 1.92

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

TDG

Not regulated as a dangerous good

according to the Hazardous Products Regulations



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Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA ON OEL : Ontario Table of Occupational Exposure Limits made under

the Occupational Health and Safety Act.

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average
CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value

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

according to the Hazardous Products Regulations



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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

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

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