

# Flunixin Injection Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 1308611-00017 Date of first issue: 2017/02/21

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name Flunixin Injection Formulation

Supplier's company name, address and phone number

Company name of supplier MSD

Address Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone 048-588-8411

E-mail address EHSDATASTEWARD@msd.com

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

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Not applicable Restrictions on use

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

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

Hazard statements H302 Harmful if swallowed.

H318 Causes serious eye damage.

H331 Toxic if inhaled.

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



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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 + 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.

P314 Get medical advice/ attention 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 (% w/w)	ENCS No.
Propylene glycol	57-55-6	>= 20 - < 30	2-234
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	3-481
2,2'-Iminodiethanol	111-42-2	>= 0.25 - < 1	2-302, 2-354
Sodium hydroxymethanesulphinate	6035-47-8	>= 0.1 - < 1	2-1633
Ethylenediaminetetraacetic acid disodium salt	139-33-3	< 0.1	2-1265

#### 4. FIRST AID MEASURES



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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.

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.

May cause damage to organs through prolonged or repeated

exposure.

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

> 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

Water spray Suitable extinguishing media

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

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.



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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, protective 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.

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

Handling

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.

Avoidance of contact

Hygiene measures

Oxidizing agents

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



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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.

**Storage** 

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:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Reference concentration / Permissible concentration	Basis	
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 <sup>2</sup>	Internal	
Phenol	108-95-2	OEL-M	5 ppm 19 mg/m3	JP OEL JSOH	
	Further information: Group 3: Substances suspected to cause reproductive toxicity in humans, Skin absorption				
		TWA	5 ppm	ACGIH	
2,2'-Iminodiethanol	111-42-2	TWA (Inhalable fraction and vapor)	1 mg/m3	ACGIH	

### Biological occupational exposure limits

Components	CAS-No.	Target sub-	Biological	Sam-	Permissible	Basis
		stance	specimen	pling	concentra-	
				time	tion	
Phenol	108-95-2	Phenol	Urine	End of	250 mg/g	JSOH



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		shift	creatinine	
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 con-

tainment 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

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : liquid

Colour : clear

Odour : No data available

Odour Threshold : No data available



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Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit No data available

No data available Flash point

No data available Decomposition temperature

pΗ 7.8 - 9.0

**Evaporation rate** No data available

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density

Relative density No data available

Density No data available

Relative vapour density No data available

Explosive properties Not explosive

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

Molecular weight No data available



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Particle characteristics

Particle size Not applicable

### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

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

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

LC50 (Rat): > 44.9 mg/l Acute inhalation toxicity

Exposure time: 4 h

Test atmosphere: dust/mist

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

Assessment: The substance or mixture has no acute dermal

toxicity



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

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

LD50 (Mouse): 176 - 249 mg/kg

LD50 (Guinea pig): 488.3 mg/kg

LD50 (Monkey): 300 mg/kg

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

Exposure time: 4 h

Test atmosphere: dust/mist

Acute toxicity (other routes of:

administration)

LD50 (Rat): 59.4 - 185.3 mg/kg

Application Route: Intraperitoneal

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

Phenol:

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

Method: OECD Test Guideline 401

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

Method: Expert judgement

Acute inhalation toxicity : 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

Exposure time: 4 h

Test atmosphere: dust/mist

Sodium hydroxymethanesulphinate:



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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

Ethylenediaminetetraacetic acid disodium salt:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 1 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 412

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.



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#### **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

Ethylenediaminetetraacetic acid disodium salt:

Species : Rabbit

Result : No eye irritation

### Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

Propylene glycol:

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

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

Test Type : Maximisation Test



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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

Ethylenediaminetetraacetic acid disodium salt:

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.

**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



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> 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 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



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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) 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.

### Ethylenediaminetetraacetic acid disodium salt:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

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: Ingestion Method: OECD Test Guideline 474

Result: negative



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### 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

NÖAEL 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 positive Result

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 - Assess-

Weight of evidence does not support classification as a car-

ment cinogen



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### Ethylenediaminetetraacetic acid disodium salt:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Remarks : Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

### Components:

### Propylene glycol:

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

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

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 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.

Ethylenediaminetetraacetic acid disodium salt:

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

Species: Rat



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**Application Route: Ingestion** 

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

### 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:

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.



# Flunixin Injection Formulation

Version Revision Date: SDS Number: Date of last issue: 2023/04/04 8.0 2023/09/30 1308611-00017 Date of first issue: 2017/02/21

### Ethylenediaminetetraacetic acid disodium salt:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

### Propylene glycol:

Species : Rat, male

NOAEL : >= 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</td>

 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:



# Flunixin Injection Formulation

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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
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

### Ethylenediaminetetraacetic acid disodium salt:

Species : Rat
NOAEL : 500 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Species : Rat LOAEL : 0.03 mg/l

Application Route : inhalation (dust/mist/fume)



# Flunixin Injection Formulation

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Exposure time : 4 Weeks

Method : OECD Test Guideline 412

**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

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 : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l



# Flunixin Injection Formulation

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aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Skeletonema cos

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 (Chron-

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

ic toxicity) Toxicity to microorganisms

: NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

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

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

Exposure time: 96 h Method: FDA 4.11

LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 15 mg/l

Exposure time: 48 h Method: FDA 4.08

Toxicity to algae/aquatic

plants

NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l

Exposure time: 13 d Method: FDA 4.01

NOEC (Selenastrum capricornutum (green algae)): 96 mg/l

Exposure time: 12 d

Phenol:

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

NOEC (Daphnia magna (Water flea)): 10 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 tox-

icity)

NOEC: 0.077 mg/l

Exposure time: 60 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

dualic liliverteprates (C

Exposure time: 16 d

ic toxicity)

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

Exposure time: 24 h



# Flunixin Injection Formulation

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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

Exposure time: 72 h

Toxicity to daphnia and other :

ic toxicity)

aquatic invertebrates (Chron-

EC10 (Daphnia magna (Water flea)): 1.05 mg/l

Exposure time: 21 d

Toxicity to microorganisms

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

Exposure time: 30 min

Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

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

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

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 :

aquatic invertebrates (Chron-

ic 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



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Ethylenediaminetetraacetic acid disodium salt:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 140 mg/l

Exposure time: 48 h Method: DIN 38412

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 25 mg/l

Exposure time: 21 d

Toxicity to microorganisms : EC10 (activated sludge): > 500 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

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 %



# Flunixin Injection Formulation

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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

Ethylenediaminetetraacetic acid disodium salt:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

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:

Partition coefficient: nlog Pow: 1.34

octanol/water

Phenol:

Bioaccumulation Species: Fish

> Bioconcentration factor (BCF): 17.5 Method: OECD Test Guideline 305

Partition coefficient: n-

2,2'-Iminodiethanol:

log Pow: 1.47

octanol/water

Partition coefficient: nlog Pow: -2.46

octanol/water Method: OECD Test Guideline 107

Ethylenediaminetetraacetic acid disodium salt:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

: log Pow: -4.3



# Flunixin Injection Formulation

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### Mobility in soil

### **Components:**

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

Distribution among environ- : log Koc: 1.92

mental compartments

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

### International Regulations

**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

Not applicable UN/ID No. Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels Not applicable

Packing instruction (cargo

aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Proper shipping name Not applicable Not applicable Class Subsidiary risk Not applicable Packing group Not applicable



# Flunixin Injection Formulation

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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**

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

ERG Code : 171

### 15. REGULATORY INFORMATION

### **Related Regulations**

#### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.

### **Chemical Substance Control Law**

### Priority Assessment Chemical Substance

Chemical name	Number
Propane-1,2-diol	106
Phenol	62
Diethanolamine	91
Sodium salt of 2,2',2",2"'-(ethane-1,2-diyldinitrilo)tetraacetic acid	268

### **Industrial Safety and Health Law**

#### Harmful Substances Prohibited from Manufacture

Not applicable

### **Harmful Substances Required Permission for Manufacture**

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

### **Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
propane-1,2-diol	>=20 - <30	From April 1st, 2025
Phenol	>=0.1 - <1	-



# Flunixin Injection Formulation

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Diethanolamine >=0.1 - <1 -

#### **Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
propane-1,2-diol	From April 1st, 2025
phenol	-

### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

### **Ordinance on Prevention of Lead Poisoning**

Not applicable

### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# **Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

### **High Pressure Gas Safety Act**

Not applicable

### **Explosive Control Law**

Not applicable

### **Vessel Safety Law**

Not regulated as a dangerous good

#### **Aviation Law**

Not regulated as a dangerous good

### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable



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### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

#### **Further information**

Sheet

Sources of key data used to compile the Safety Data

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

cy, 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 : yyyy/mm/dd

### Full text of other abbreviations

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

JP OEL JSOH : Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

JSOH : Occupational exposure limits based on biological monitoring

(JSOH).

ACGIH / TWA : 8-hour, time-weighted average
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean

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



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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.

JP / EN