

# **Enrofloxacin (2.5%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 8.1 28.09.2024 633922-00020 Date of first issue: 27.04.2016

**Section 1: Identification** 

Product name : Enrofloxacin (2.5%) Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

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

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Section 2: Hazard identification

**GHS Classification** 

Skin sensitisation : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure

Category 2 (cartilage, Testis)

Hazardous to the aquatic environment - acute hazard

: Category 1

Hazardous to the aquatic environment - chronic hazard

: Category 1

**GHS** label elements

Hazard pictograms

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.



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H361f Suspected of damaging fertility.

H373 May cause damage to organs (cartilage, Testis) through

prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P391 Collect spillage.

# Storage:

P405 Store locked up.

# Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### Other hazards which do not result in classification

None known.

### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
Enrofloxacin	93106-60-6	>= 2.5 -< 10	
Benzyl alcohol	100-51-6	>= 1 -< 10	
Potassium hydroxide	1310-58-3	>= 0.1 -< 0.5	

#### Section 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.



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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. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction. Suspected of damaging fertility.

Most important symptoms and effects, both acute and

delayed

May cause damage to organs through prolonged or repeated

exposure.

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

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

Notes to physician Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (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

Specific extinguishing meth-

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.

Hazchem Code 3Z

Section 6: Accidental release measures

Personal precautions, protec- : Use personal protective equipment.



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tive equipment and emer-

gency procedures

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.

### Section 7: Handling and storage

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

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

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

Take care to prevent spills, waste and minimize release to the

environment.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

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



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use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

#### Section 8: Exposure controls/personal protection

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Enrofloxacin	93106-60-6	TWA	0.2 mg/m3 (OEB	Internal
			2)	
Potassium hydroxide	1310-58-3	WES-Ceiling	2 mg/m3	NZ OEL
		С	2 mg/m3	ACGIH

**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.

Laboratory operations do not require special containment.

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. Combined particulates and organic vapour type

Filter type
Hand protection

nd protection

Material : Chemical-resistant gloves

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.

#### Section 9: Physical and chemical properties

Appearance : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available



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pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle size : Not applicable

#### Section 10: Stability and reactivity



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

Possibility of hazardous reac-

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### **Section 11: Toxicological information**

Exposure routes Inhalation

> Skin contact Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute toxicity estimate: > 2,000 mg/kg Acute dermal toxicity

Method: Calculation method

#### **Components:**

**Enrofloxacin:** 

Acute oral toxicity : LD50 (Rabbit): 500 - 800 mg/kg

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

LD50 (Mouse): > 5,000 mg/kg

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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute toxicity estimate: 1,100 mg/kg Acute dermal toxicity

Method: Expert judgement

Remarks: Based on national or regional regulation.



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Potassium hydroxide:

Acute oral toxicity : Acute toxicity estimate: 100 mg/kg

Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

**Enrofloxacin:** 

Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Potassium hydroxide:

Species : Rabbit

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

**Enrofloxacin:** 

Result : Mild eye irritation

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Potassium hydroxide:

Species : Rabbit

Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.



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Components:

**Enrofloxacin:** 

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Potassium hydroxide:

Test Type : Intracutaneous test Exposure routes : Skin contact

Species : Guinea pig Result : negative

**Chronic toxicity** 

Germ cell mutagenicity

Not classified based on available information.

Components:

**Enrofloxacin:** 

Genotoxicity in vitro : Test Type: Chromosomal aberration

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Mammalian bone marrow sister chromatid ex-

change

Species: Hamster Result: negative

Test Type: Chromosomal aberration

Species: Rat Result: negative

Benzyl alcohol:

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

Result: negative



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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Potassium hydroxide:

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

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

**Enrofloxacin:** 

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

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

Suspected of damaging fertility.

**Components:** 

**Enrofloxacin:** 

Effects on fertility : Test Type: Two-generation study

Species: Rat

Application Route: Oral

Fertility: LOAEL: 15 mg/kg body weight

Result: Effects on fertility, alteration in sperm morphology

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

**Application Route: Oral** 

Developmental Toxicity: LOAEL: 210 mg/kg body weight



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Result: Reduced foetal weight, No teratogenic effects

Remarks: Maternal toxicity observed.

Test Type: Development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: No fetotoxicity, No teratogenic effects

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments.

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

#### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs (cartilage, Testis) through prolonged or repeated exposure.

#### **Components:**

#### **Enrofloxacin:**

Target Organs : cartilage, Testis

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

#### **Components:**

#### **Enrofloxacin:**

Species : Rat
NOAEL : 36 mg/kg
LOAEL : 150 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Testis

Species : Dog NOAEL : 3 mg/kg



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LOAEL : 9.6 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : cartilage

Species : Cat
NOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 30 Days

Remarks : No significant adverse effects were reported

Benzyl alcohol:

Species : Rat NOAEL : 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

**Aspiration toxicity** 

Not classified based on available information.

Experience with human exposure

**Components:** 

**Enrofloxacin:** 

Ingestion : Symptoms: Gastrointestinal disturbance, central nervous sys-

tem effects, Sensitivity to light

**Section 12: Ecological information** 

**Ecotoxicity** 

**Components:** 

**Enrofloxacin:** 

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 79.5 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): > 196 mg/l

Exposure time: 96 h

LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Hyalella azteca (Amphipod)): > 206 mg/l

Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 79.9 mg/l

Exposure time: 48 h



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Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 3.1

mg/l

10

Exposure time: 72 h

EC50 (Microcystis aeruginosa (blue-green algae)): 0.049 mg/l

Exposure time: 5 d

M-Factor (Acute aquatic tox- :

icity)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.8 mg/l

Exposure time: 21 d

NOEC (Daphnia magna (Water flea)): 5 mg/l

Exposure time: 21 d

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

Exposure time: 21 d

M-Factor (Chronic aquatic

toxicity)

10

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Persistence and degradability

**Components:** 

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d



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#### Bioaccumulative potential

**Components:** 

Enrofloxacin:

Partition coefficient: n- : log Pow: 0.5

octanol/water

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1.05

Mobility in soil

Components:

**Enrofloxacin:** 

Distribution among environ-

mental compartments

Other adverse effects
No data available

Koc: 5.55

Section 13: Disposal considerations

**Disposal methods** 

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

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**Section 14: Transport information** 

**International Regulations** 

**UNRTDG** 

Class

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

() 9 III

Packing group : III Labels : 9 Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

()

Class : 9 Packing group : III

Labels : Miscellaneous



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Packing instruction (cargo : 964

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

Class : 9
Packing group : III
Labels : 9

EmS Code : F-A, S-F Marine pollutant : yes

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

Not applicable for product as supplied.

### **National Regulations**

**NZS 5433** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

() 9

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : no

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### Section 15: Regulatory information

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

#### **HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable



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#### **HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### Section 16: Other information

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**Further information** 

Sources of key data used to

compile the Safety Data

Sheet

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / C : Ceiling limit

NZ OEL / WES-Ceiling : Workplace Exposure Standard - Ceiling

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 Develop-



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ment; 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.

NZ / EN