

SAFETY DATA SHEET

SERESTO COLLAR



Version Revision Date: SDS Number: Date of last issue: -
1.0 23.06.2020 122000005913 Date of first issue: 23.06.2020

Section 1: Identification

1.1 Product identifier

SERESTO COLLAR

HSNO Approval Number : HSR100529

ACVM number : A010750

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- : Veterinary medicine
stance/Mixture

1.3 Details of the supplier of the safety data sheet

Company

Elanco New Zealand
88 Shortland Street
1010 AUCKLAND
NEW ZEALAND
+64 0800 352 626
elanco_sds@elancoah.com

1.4 Emergency telephone number

In case of emergency: CHEMTREC International: +1 703-527-3887 (24 hours)
or +64-98010034 (local)

Section 2: Hazard identification

GHS Classification

Acute toxicity (Oral) : 6.1D

Specific Target Organ Toxicity : 6.9B
(Oral)

Aquatic toxicity (Acute or : 9.1A
Chronic)

Ecotoxic to soil environment : 9.2B

Ecotoxic to terrestrial verte- : 9.3B
brates

Ecotoxic to terrestrial inverte- : 9.4A
brates

GHS label elements

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Hazard pictograms :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H373 May cause damage to organs through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.
H422 Toxic to the soil environment.
H432 Toxic to terrestrial vertebrates.
H441 Very toxic to terrestrial invertebrates.

Precautionary statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
Response:
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
P309 + P311 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/ physician.

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)
Dibutyl adipate	105-99-7	>= 10 -< 20
Imidacloprid	138261-41-3	>= 10 -< 20
Decanoic acid, mixed diesters with octanoic acid and propylene glycol	68583-51-7	>= 1 -< 10
Flumethrin	69770-45-2	>= 2,5 -< 10
Soybean oil, epoxidized	8013-07-8	>= 1 -< 2,5
Stearic acid	57-11-4	>= 1 -< 10

Section 4: First-aid measures

General advice : Take off all contaminated clothing immediately.

You should call the National Poisons Centre if you feel that you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).

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- If inhaled : Remove to fresh air.
If symptoms persist, call a physician.
 - In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.
If skin reactions occur, contact a physician.
 - In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 - If swallowed : If swallowed, seek medical advice immediately and show this container or label.
 - Most important symptoms and effects, both acute and delayed : No information available.
 - Notes to physician : No information available.
-

Section 5: Fire-fighting measures

- Suitable extinguishing media : Any
 - Specific hazards during fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)
 - Specific extinguishing methods : Prevent fire extinguishing water from contaminating surface water or the ground water system.
 - Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
-

Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
 - Environmental precautions : Do not flush into surface water or sanitary sewer system.
 - Methods and materials for containment and cleaning up : Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13).
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Section 7: Handling and storage

- Advice on protection against fire and explosion : No special protective measures against fire required.
 - Advice on safe handling : Industrial uses:
Avoid dust formation.
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Use with local exhaust ventilation.
Avoid contact with skin, eyes and clothing.

Hygiene measures : Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Conditions for safe storage : For storage suitable stores with adequate product-reception volume must be used.
During handling local official regulations must be observed in order to avert impairment of water by the product.

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyvinylchloride	9002-86-2	TWA (Respirable fraction)	1 mg/m ³	ACGIH
		TWA (Respirable fraction)	1 mg/m ³	ACGIH
Imidacloprid	138261-41-3	Bayer OES	0,7 mg/m ³	TRGS901
Flumethrin	69770-45-2	Bayer OES	0,02 mg/m ³	
Stearic acid	57-11-4	TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Inhalable fraction)	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH
		TWA (Respirable fraction)	3 mg/m ³	ACGIH

Personal protective equipment

Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection
Material : Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

Remarks : Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection : Safety glasses

Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff

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or patients.
Wear suitable protective equipment.
The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.

Section 9: Physical and chemical properties

Appearance	:	solid
Colour	:	grey
pH	:	neutral
Melting point / range	:	140 °C Method: DIN ISO 3146
Burning number	:	3 (20 °C) Local combustion without spreading 5 (100 °C) Complete combustion with flames
Bulk density	:	550 kg/m ³ Method: ISO 697
Auto-ignition temperature	:	No data available
Decomposition temperature	:	185 °C Heating rate: 3 K/min Decomposition energy (mass): 440 KJ/kg
Explosive properties	:	No statements available.
Oxidizing properties	:	No data available
Impact sensitivity	:	No data available
Dust explosion class	:	St 2 (= dust explosion tendency)
Minimum ignition energy	:	No data available

Section 10: Stability and reactivity

Reactivity	:	No data available
Chemical stability	:	No data available
Possibility of hazardous reactions	:	No data available

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Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : Carbon monoxide (CO)
Carbon dioxide (CO₂)

Section 11: Toxicological information

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): 99,65 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg
Method: Calculation method

Components:

Dibutyl adipate:

Acute oral toxicity : LD50 (Rat): 12.900 mg/kg
Method: OECD 401

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

Imidacloprid:

Acute oral toxicity : LD50 (Rat): 424 mg/kg
Method: OECD 401

Acute inhalation toxicity : LC50 (Rat): > 5,323 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol
Method: OECD 403

Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : > 2.000 mg/kg
Remarks: Based on data from similar materials

Flumethrin:

Acute oral toxicity : LD50 (Rat): 175 mg/kg
Test substance: in corn oil

Acute inhalation toxicity : LC50 (Rat): 0,572 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist/aerosol

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Method: OECD 403

Acute dermal toxicity : LD50 (Rat, female): 1.436 mg/kg

Soybean oil, epoxidized:

Acute oral toxicity : LD50 (Rat): > 20.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 20.000 mg/kg

Stearic acid:

Acute oral toxicity : LD50 (Rat): 4.640 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute toxicity (other routes of administration) : LD50 (Mouse): 23 mg/kg
Application Route: intravenous

Skin corrosion/irritation

Components:

Dibutyl adipate:

Result : Mild skin irritation

Imidacloprid:

Species : Rabbit
Result : No skin irritation

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Flumethrin:

Species : Rabbit
Result : No skin irritation

Soybean oil, epoxidized:

Species : Rabbit
Result : Mild skin irritation

Stearic acid:

Species : Rabbit
Exposure time : 24 h
Result : Moderate skin irritation

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Serious eye damage/eye irritation

Components:

Dibutyl adipate:

Result : No eye irritation

Imidacloprid:

Species : Rabbit
Result : No eye irritation

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Result : No eye irritation

Flumethrin:

Species : Rabbit
Result : No eye irritation

Soybean oil, epoxidized:

Species : Rabbit
Result : No eye irritation

Stearic acid:

Result : No eye irritation
Test substance : Data on a comparable substance

Respiratory or skin sensitisation

Components:

Dibutyl adipate:

Result : Does not cause skin sensitisation.

Imidacloprid:

Test Type : Skin sensitisation
Species : Guinea pig
Method : Magnusson and Kligmann maximization test
Result : Did not cause sensitisation on laboratory animals.

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Species : Guinea pig
Assessment : The available study results do not lead to a GHS classification
Method : OECD 406
Remarks : Based on data from similar materials
Assessment : An acute toxic effect is not expected.

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Flumethrin:

Test Type : Skin sensitisation
Species : Guinea pig
Method : Magnusson and Kligmann maximization test
Result : Did not cause sensitisation on laboratory animals.

Soybean oil, epoxidized:

Result : Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Components:

Dibutyl adipate:

Genotoxicity in vitro : Test Type: Bacterial mutagenicity
Method: OECD 471
Result: negative

Imidacloprid:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Remarks: In vitro tests did not show mutagenic effects

Genotoxicity in vivo : Result: No indication of mutagenic effects., No evidence of a genotoxic effect.

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Genotoxicity in vitro : Test Type: Ames test
Method: OECD 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD 473
Result: negative

Test Type: Micronucleus test
Method: OECD 474
Result: negative

Flumethrin:

Genotoxicity in vitro : Result: No evidence of a genotoxic effect.

Genotoxicity in vivo : Result: No evidence of a genotoxic effect.

Soybean oil, epoxidized:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

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Stearic acid:

Genotoxicity in vitro : Test Type: Ames test
Result: negative
Test substance: Data on a comparable substance

Carcinogenicity

Components:

Imidacloprid:

Result : Animal testing did not show any carcinogenic effects.

Flumethrin:

Species : Rat
Result : Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

Imidacloprid:

Flumethrin:

Effects on fertility : Species: Rat
Result: Animal testing did not show any effects on fertility.

STOT - single exposure

Components:

Flumethrin:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

Components:

Imidacloprid:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Flumethrin:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Dibutyl adipate:

Species : Rat

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NOAEL : 1.000 mg/kg
Application Route : Oral
Exposure time : 28-day

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Repeated dose toxicity - Assessment : An acute toxic effect is not expected.

Further information

Components:

Imidacloprid:

Pharmaceutic effects
Remarks : Insecticide

Flumethrin:

Pharmaceutic effects
Remarks : Antiparasitic agent

Section 12: Ecological information

Ecotoxicity

Components:

Dibutyl adipate:

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): 3,7 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Method: OECD 203

Toxicity to algae/aquatic plants : IC50 (*Selenastrum Capricornutum* (Green algae)): 2,8 mg/l
Test Type: Growth inhibition
Method: OECD 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC50 (*Daphnia magna* (Water flea)): > 8,9 mg/l
Exposure time: 48 h
Test Type: Immobilization
Method: OECD 202

Toxicity to microorganisms : EC50: > 10.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD 209

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic to aquatic life.

Imidacloprid:

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- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 237 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 85 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
- EC50 (Desmodesmus subspicatus (green algae)): > 10 mg/l
Exposure time: 72 h
- Toxicity to microorganisms : EC50 (Activated sludge micro-organism): > 10.000 mg/l
Method: OECD 209

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

- Toxicity to fish : (Danio rerio (zebra fish)): Exposure time: 96 h
Method: OECD 203
Remarks: No toxicity at the limit of solubility
- Toxicity to daphnia and other aquatic invertebrates : (Daphnia magna (Water flea)): Exposure time: 48 h
Method: OECD 202
Remarks: No toxicity at the limit of solubility
- Toxicity to algae/aquatic plants : (Desmodesmus subspicatus (green algae)): Exposure time: 72 h
Method: OECD 201
Remarks: No toxicity at the limit of solubility
- Toxicity to microorganisms : EC10 (Pseudomonas putida): > 0,99 g/l
Exposure time: 16 h
Test Type: Cell multiplication inhibition test
Method: DIN 38412

Flumethrin:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,17 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity
Method: OECD 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,0027 mg/l
Exposure time: 48 h
Method: OECD 202
- Toxicity to algae/aquatic plants : IC50 (Desmodesmus subspicatus (green algae)): 0,59 mg/l
Exposure time: 72 h
Method: OECD 201

Soybean oil, epoxidized:

- Toxicity to microorganisms : EC0 (Pseudomonas putida): > 10.000 mg/l
Exposure time: 0,5 h

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Method: DIN 38412

Stearic acid:

Toxicity to microorganisms : EC0 (Pseudomonas putida): > 100 mg/l
Test substance: Data on a comparable substance

Persistence and degradability

Components:

Dibutyl adipate:

Biodegradability : Biodegradation
Result: Readily biodegradable.
Biodegradation: 60 %
Exposure time: 28 d

Biodegradation
Result: rapidly biodegradable
Biodegradation: 86 - 95 %
Exposure time: 28 d
Method: OECD 301 C

Biochemical Oxygen Demand (BOD) : Biochemical oxygen demand
750 mg/g

Stability in water : Degradation half life: 7 d
Remarks: Readily biodegradable.

Imidacloprid:

Stability in water : Degradation half life: > 1 a (25 °C) pH: 4
Hydrolysis: at25 °C

Degradation half life: > 1 a (25 °C) pH: 7
Hydrolysis: at25 °C

Degradation half life: ca. 1 h (25 °C) pH: 9
Hydrolysis: at25 °C

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Biodegradability : Result: rapidly biodegradable
Biodegradation: 82 %
Exposure time: 28 d
Method: Directive 67/548/EEC Annex V, C.4.C.

Flumethrin:

Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD 301F

Soybean oil, epoxidized:

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Biodegradability : Concentration: 2 mg/l
Biodegradation
Result: rapidly biodegradable
Biodegradation: 78 %
Exposure time: 28 d
Method: OECD 301 D

Stearic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 60 %
Test substance: Data on a comparable substance

Bioaccumulative potential

Components:

Imidacloprid:

Bioaccumulation : Remarks: Low potential for bioaccumulation

Partition coefficient: n-octanol/water : log Pow: 0,57 (21 °C)
Method: OECD 107

Decanoic acid, mixed diesters with octanoic acid and propylene glycol:

Partition coefficient: n-octanol/water : log Pow: 5,21
Method: OECD 123

Flumethrin:

Partition coefficient: n-octanol/water : log Pow: 6,2

Soybean oil, epoxidized:

Partition coefficient: n-octanol/water : log Pow: < 6

Stearic acid:

Partition coefficient: n-octanol/water : log Pow: 7,17 - 8,23

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

Components:

Dibutyl adipate:

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Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

Adsorbed organic bound halogens (AOX) : Remarks: Product does not contain any organic halogens.

Imidacloprid:

Adsorbed organic bound halogens (AOX) : Remarks: The product contains organic halogens.

Section 13: Disposal considerations

Disposal methods

Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.

Section 14: Transport information

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FLUMETHRIN)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (FLUMETHRIN)
Class : 9
Packing group : III
Labels : 9
Marine pollutant : yes

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

Not applicable for product as supplied.

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.

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Section 15: Regulatory information

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

TRGS 500 Precaution: Least standards

HSNO Approval Number

HSR100529

HSW Controls

Approved handler certificate required

HSNO tracking required

Refer to EPA user guide to the HSNO control regulations for further information.

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

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

NZIoC : On the inventory, or in compliance with the inventory

Section 16: Other information

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

TRGS901 : TRGS 901, Explanations and Basis for Exposure Limits in the Workplace Air

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

TRGS901 / Bayer OES : BOES = Bayer Occupational Exposure Standard

AICS - Australian Inventory of Chemical Substances; 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; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships;

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n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

NZ / EN