

Progesterone Formulation (Veterinary)

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
9.0	14.04.2025	2183759-00017	Date of first issue: 15.11.2017

Section 1: Identification

Product name : Progesterone Formulation (Veterinary)

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**

Carcinogenicity : Category 2

Carcinogenicity (Inhalation) : Category 1

Reproductive toxicity : Category 1

Effects on or via lactation

Specific target organ toxicity - repeated exposure (Inhalation) : Category 1 (Lungs)

Hazardous to the aquatic environment - chronic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

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Hazard statements : H350 May cause cancer by inhalation.
H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.
H362 May cause harm to breast-fed children.
H372 Causes damage to organs (Lungs) through prolonged or repeated exposure if inhaled.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P263 Avoid contact during pregnancy and while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ 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)
Quartz	14808-60-7	>= 30 -< 50
Progesterone	57-83-0	>= 2.5 -< 10
Bis(alpha,alpha-dimethylbenzyl) peroxide	80-43-3	>= 0.25 -< 1

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

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

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	of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: May cause cancer by inhalation. Suspected of causing cancer. May damage fertility. May damage the unborn child. May cause harm to breast-fed children. Causes damage to organs through prolonged or repeated exposure if inhaled.
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 (CO ₂) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Silicon oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances 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	: 2Z

Section 6: Accidental release measures

Personal precautions, protec-	: Use personal protective equipment.
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tive equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

Section 7: Handling and storage

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Avoid contact during pregnancy and while nursing. Do not get on skin or clothing. 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 assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the 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. Wash contaminated clothing before re-use.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents

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Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Quartz	14808-60-7	WES-TWA (Respirable dust)	0.025 mg/m ³	NZ OEL
Further information: Confirmed carcinogen				
		TWA (Respirable particulate matter)	0.025 mg/m ³ (Silica)	ACGIH
Progesterone	57-83-0	TWA	6 µg/m ³ (OEB 4)	Internal
		Wipe limit	60 µg/100 cm ²	Internal

Engineering measures : Minimize workplace exposure concentrations.
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Self-contained breathing apparatus

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
Safety glasses

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Section 9: Physical and chemical properties

Appearance : solid

Colour : light green

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Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
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	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	1.1 g/cm ³
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	Not applicable

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Particle characteristics
Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Quartz:**

Acute oral toxicity : LD50 (Rat): > 22,500 mg/kg

Progesterone:

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 401
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity : LC50 (Rat): > 0.224 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

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Skin corrosion/irritation

Not classified based on available information.

Components:**Quartz:**

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation
Remarks	: Based on data from similar materials

Progesterone:

Species	: Rabbit
Result	: No skin irritation
Remarks	: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Result	: Skin irritation
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Serious eye damage/eye irritation

Not classified based on available information.

Components:**Quartz:**

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

Progesterone:

Species	: Rabbit
Result	: No eye irritation
Method	: OECD Test Guideline 405
Remarks	: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 7 days
Method	: OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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Components:**Progesterone:**

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Rabbit
Method	: OECD Test Guideline 406
Result	: negative
Remarks	: Based on data from similar materials

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Progesterone:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Method: OECD Test Guideline 482 Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Monkey Application Route: Subcutaneous Result: negative Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo Species: Rat Application Route: Ingestion Result: negative

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Carcinogenicity

May cause cancer by inhalation.
Suspected of causing cancer.

Components:**Quartz:**

Species : Humans
Application Route : inhalation (dust/mist/fume)
Result : positive

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies (inhalation)

Progesterone:

Species : Mouse, female
Application Route : Subcutaneous
Exposure time : 104 weeks
Result : positive

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies

Reproductive toxicity

May damage fertility. May damage the unborn child.
May cause harm to breast-fed children.

Components:**Progesterone:**

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Result: positive

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Result: positive

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Clear evidence of adverse effects on development, based on animal experiments., Studies indicating a hazard to babies during the lactation period

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Bis(alpha,alpha-dimethylbenzyl) peroxide:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: positive
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Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on development, based on animal experiments.
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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs (Lungs) through prolonged or repeated exposure if inhaled.

Components:**Quartz:**

Exposure routes	:	inhalation (dust/mist/fume)
Target Organs	:	Lungs
Assessment	:	Shown to produce significant health effects in animals at concentrations of 0.02 mg/l/6h/d or less.

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Exposure routes	:	Ingestion
Assessment	:	No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Repeated dose toxicity**Components:****Quartz:**

Species	:	Humans
LOAEL	:	0.053 mg/m ³
Application Route	:	Inhalation

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Species	:	Rat
NOAEL	:	60 mg/kg
LOAEL	:	200 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Method	:	OECD Test Guideline 407

Aspiration toxicity

Not classified based on available information.

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Experience with human exposure

Components:

Progesterone:

General Information	:	Target Organs: Endocrine system Symptoms: Effects on fertility
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Section 12: Ecological information

Ecotoxicity

Components:

Quartz:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 508 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)): 731 mg/l Exposure time: 48 h Remarks: Based on data from similar materials

Progesterone:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 1 - 10 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to fish (Chronic toxicity)	:	NOEC (Pimephales promelas (fathead minnow)): 0.000010 mg/l Exposure time: 21 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.1 mg/l Exposure time: 26 d
M-Factor (Chronic aquatic toxicity)	:	1,000

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.397 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility
Toxicity to algae/aquatic	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20

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plants	mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility NOEC (Pseudokirchneriella subcapitata (green algae)): 8 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.177 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	: NOEC: > 1,000 mg/l Exposure time: 30 min Remarks: No toxicity at the limit of solubility

Persistence and degradability**Components:****Progesterone:**

Biodegradability	: Result: Readily biodegradable. Remarks: Based on data from similar materials
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Bis(alpha,alpha-dimethylbenzyl) peroxide:

Biodegradability	: Result: Not readily biodegradable. Biodegradation: 20.2 % Exposure time: 28 d Method: OECD Test Guideline 301F
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Bioaccumulative potential**Components:****Progesterone:**

Partition coefficient: n-octanol/water	: Pow: 3.65 Method: OECD Test Guideline 117
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Bis(alpha,alpha-dimethylbenzyl) peroxide:

Bioaccumulation	: Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 137 - 1,470 Method: OECD Test Guideline 305C
Partition coefficient: n-octanol/water	: log Pow: 5.6

Mobility in soil

No data available

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Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

Section 14: Transport information**International Regulations****UNRTDG**

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

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Progesterone)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Progesterone)
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.

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National Regulations**NZS 5433**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Progesterone)

II

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z
Marine pollutant : yes

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**

not allocated

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 14.04.2025

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 Agency, <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.

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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 Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN