

Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 6.3 28.09.2024 2190078-00015 Date of first issue: 15.11.2017

SECTION 1. IDENTIFICATION

Product name : Progesterone Formulation (Veterinary)

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 2

Carcinogenicity (Inhalation) : Category 1A

Reproductive toxicity : Category 1A

Effects on or via lactation

Specific target organ toxicity - :

repeated exposure

(Inhalation)

Category 1 (Lungs)

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

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. H402 Harmful to aquatic life.

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 dust/ fume/ gas/ mist/ vapors/ spray. 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 protec-

tion/ 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	>= 5 -< 10
Bis(alpha,alpha-dimethylbenzyl) peroxide	80-43-3	>= 0,3 -< 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.



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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

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.

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 cancer by inhalation.

Most important symptoms and effects, both acute and

In case of eye contact

delayed

Suspected of causing cancer.

May damage fertility. May damage the upbo

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 (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 Silicon oxides

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.

Special protective equipment:

for fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

Use personal protective equipment.

tive equipment and emer- Follow safe handling advice (see section 7) and personal



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gency procedures 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 breathe dust, fume, gas, mist, vapors or spray.

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.

Conditions for safe storage : Keep in properly labeled 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

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	



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		exposure)	concentration			
Quartz	14808-60-7	CMP (Respirable fraction)	0,05 mg/m³	AR OEL		
	Further inform	Further information: A2 - Suspected human carcinogen				
		TWA (Respirable particulate matter)	0,025 mg/m³ (Silica)	ACGIH		
Progesterone	57-83-0	TWA	6 μg/m3 (OEB 4)	Internal		
		Wipe limit	60 μg/100 cm2	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 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).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Color : light green

Odor : No data available

Odor 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 : 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

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : 1,1 g/cm³

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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

Particle characteristics

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.



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Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

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

Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Skin contact exposure 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 tox-

icitv

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

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:



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Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

 ${\bf Bis (alpha, alpha-dimethylbenzyl)\ peroxide:}$

Result : Skin irritation

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 sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Progesterone:

Test Type : Maximization Test Routes of exposure : 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)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429



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Result : negative

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 syn-

thesis 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

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 - Assess-

ment

Positive evidence from human epidemiological studies (inhala-

tion)



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Progesterone:

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

Carcinogenicity - Assess-

ment

: 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 fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Subcutaneous

Result: positive

Reproductive toxicity - As-

sessment

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

Bis(alpha,alpha-dimethylbenzyl) peroxide:

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

Species: Rat

Application Route: Ingestion
Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

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:

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

Target Organs : Lungs

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

centrations of 0.02 mg/l/6h/d or less.



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Bis(alpha,alpha-dimethylbenzyl) peroxide:

Routes of exposure : Ingestion

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Quartz:

Species : Humans LOAEL : 0,053 mg/m³ 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.

Experience with human exposure

Components:

Progesterone:

General Information : Target Organs: Endocrine system

Symptoms: Effects on fertility.

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



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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 tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0,000010

mg/l

Exposure time: 21 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 20

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 (Chron-

ic 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

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 20,2 %



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Exposure time: 28 d

Method: OECD Test Guideline 301F

Bioaccumulative potential

Components:

Progesterone:

Partition coefficient: n- : Pow: 3,65

octanol/water Method: OECD Test Guideline 117

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 soilNo data available

NO data avallable

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



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Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

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.

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

Argentina. Carcinogenic Substances and Agents : Quartz

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Further information

Sources of key data used to

compile the Material Safety

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

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

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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods: IMO - International Maritime Organization: ISHL - Industrial Safety and Health Law (Japan): ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New 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.

AR / Z8