

Progesterone Formulation (Veterinary)

Version Revision Date: SDS Number: Date of last issue: 2023/09/30 6.2 2024/09/28 2183766-00015 Date of first issue: 2017/11/15

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Progesterone Formulation (Veterinary)

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

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 (Inhala-

tion)

Category 1 (Lungs)

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.

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/ vapours/ spray.

P263 Avoid contact during pregnancy/ 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Quartz	14808-60-7	>= 30 -< 60
Progesterone	57-83-0	>= 2.5 -< 10
Bis(alpha,alpha-dimethylbenzyl) peroxide	80-43-3	>= 0.3 -< 2.5

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.



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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.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.
May cause cancer by inhalation.
Suspected of causing cancer.

Most important symptoms and effects, both acute and

delayed

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.

5. FIREFIGHTING 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 firefighters

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

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES



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Personal precautions, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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 con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

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, vapours 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 as-

sessment

Keep container tightly closed.

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

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

environment.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Compensation Control C	Components	CAS-No.	Value type	Control parame-	Basis
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		(Form of exposure)	ters / Permissible concentration		
Quartz	14808-60-7	NAB (Respirable particulate matter)	0.025 mg/m3	ID OEL	
	Further information: Suspected human carcinogen				
		TWA (Res- pirable par- ticulate mat- ter)	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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Self-contained breathing apparatus

Filter type

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).

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

eye flushing systems and safety showers close to the work-

ing place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid



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Colour : light green

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/cm³

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.



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Molecular weight : Not applicable

Particle characteristics

Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
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

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-

icity

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

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

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



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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)

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 foetal develop-

ment

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 lacta-

tion period

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Effects on foetal develop- : Test Type: Embryo-foetal development



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Species: Rat ment

> **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:

Exposure routes 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.

Bis(alpha,alpha-dimethylbenzyl) peroxide:

Exposure routes 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 200 mg/kg LOAEL **Application Route** Ingestion 28 Days Exposure time

OECD Test Guideline 407 Method

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Quartz:

LC50 (Danio rerio (zebra fish)): 508 mg/l Toxicity to fish

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 tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.000010

mg/l

Exposure time: 21 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

NOEC (Daphnia magna (Water flea)): 0.1 mg/l

Exposure time: 26 d

ic toxicity)

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 (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 % 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 soil

No data available



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Other adverse effects

No data available

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.

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 : 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.



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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.

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable

control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control, Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to compile the Safety Data

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



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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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.

ID / EN