ORGANON

Progesterone Formulation

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Section 1: Identification

Product name Progesterone Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

+1-551-430-6000 Telephone

Emergency telephone number: +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical Restrictions on use Not applicable

Section 2: Hazard identification

GHS Classification

Carcinogenicity Category 2

Reproductive toxicity Category 1

Effects on or via lactation

Hazardous to the aquatic environment - chronic hazard Category 1

GHS label elements

Hazard pictograms

Signal word

Hazard statements H351 Suspected of causing cancer.

H360FD May damage fertility. May damage the unborn child.

H362 May cause harm to breast-fed children.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements Prevention:

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P201 Obtain special instructions before use.

P260 Do not breathe dust.

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

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosible dust-air mixture if dispersed.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Progesterone	57-83-0	>= 25 -< 30	
Glycerine	56-81-5	>= 1 -< 10	
Titanium dioxide	13463-67-7	>= 0.1 -< 1	

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

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 : If in eyes, rinse well with water.





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Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. Suspected of causing cancer.

Most important symptoms and effects, both acute and

. Susp d May

May damage fertility. May damage the unborn child.

May cause harm to breast-fed children.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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

Protection of first-aiders

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

High volume water jet

Dry chemical

Unsuitable extinguishing

media

delayed

. .

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Do not use a solid water stream as it may scatter and spread

fire.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

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

Use personal protective equipment.

: 2Z

Section 6: Accidental release measures

Personal precautions, protective 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

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cannot be contained.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

Section 7: Handling and storage

Static electricity may accumulate and ignite suspended dust Technical measures

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

If sufficient ventilation is unavailable, use with local exhaust Local/Total ventilation

ventilation.

Avoid contact during pregnancy and while nursing. Advice on safe handling

Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Avoid contact with eves.

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.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. 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.

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

use of administrative controls.

Conditions for safe storage Keep in properly labelled containers.

Store locked up.

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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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis
		exposure)	concentration	
Progesterone	57-83-0	TWA	6 μg/m3 (OEB 4)	Internal
		Wipe limit	60 μg/100 cm2	Internal
Glycerine	56-81-5	WES-TWA	10 mg/m3	NZ OEL
		(Mist)		
Titanium dioxide	13463-67-7	WES-TWA	10 mg/m3	NZ OEL
		TWA (Res-	2.5 mg/m3	ACGIH
		pirable par-	(Titanium dioxide)	
		ticulate mat-		
		ter)		

This substance(s) is not bioavailable and therefore does not contribute to a dust inhalation hazard.

Titanium dioxide

Engineering measures : Containment technologies suitable for controlling compounds

are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from

stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

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.

Filter type

Combined particulates and organic vapour type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a





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potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 9: Physical and chemical properties

Appearance : Crystalline powder

Colour : white to off-white

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : 126 °C

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : 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 : No data available

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature

: No data available

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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 : No data available

Particle size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Dust can form an explosive mixture in air.

tions

Conditions to avoid : Avoid dust formation.

Incompatible materials : None.

Hazardous decomposition

products

None.No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Progesterone:

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

Remarks: Based on data from similar materials

Glycerine:

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

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Titanium dioxide:

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

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l



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Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Progesterone:

Species Rabbit

Result No skin irritation

Remarks Based on data from similar materials

Glycerine:

Species Rabbit

Result No skin irritation

Titanium dioxide:

Species Rabbit

Result No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Progesterone:

Species Rabbit

Result No eye irritation

: OECD Test Guideline 405 Method

Remarks Based on data from similar materials

Glycerine:

Species Rabbit

Result No eye irritation

Titanium dioxide:

Species Rabbit

Result No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.



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Respiratory sensitisation

Not classified based on available information.

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

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
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 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

Glycerine:



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Genotoxicity in vitro Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

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thesis in mammalian cells (in vitro)

Result: negative

Titanium dioxide:

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

Result: negative

Test Type: In vivo micronucleus test Genotoxicity in vivo

> Species: Mouse Result: negative

Carcinogenicity

Suspected of causing cancer.

Components:

Progesterone:

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

Carcinogenicity - Assess-

ment

: Limited evidence of carcinogenicity in animal studies

Glycerine:

Species Rat **Application Route** Ingestion Exposure time 2 Years Result : negative

Titanium dioxide:

Species Rat

Application Route inhalation (dust/mist/fume)

Exposure time 2 Years

Method : OECD Test Guideline 453

positive Result

Remarks The mechanism or mode of action may not be relevant in hu-

This substance(s) is not bioavailable and therefore does not

contribute to a dust inhalation hazard.

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Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in inhalation studies with

animals.

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

Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Glycerine:

Species : Rat

NOAEL : 0.167 mg/l



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LOAEL 0.622 mg/l

Application Route inhalation (dust/mist/fume)

Exposure time 13 Weeks

Species Rat

NOAEL 8,000 - 10,000 mg/kg

Application Route Ingestion Exposure time 2 yr

Rabbit **Species** NOAEL 5,040 mg/kg **Application Route** Skin contact Exposure time 45 Weeks

Titanium dioxide:

Species Rat

NOAEL 24,000 mg/kg Application Route Ingestion Exposure time 28 Days

Species Rat **NOAEL** 10 mg/m3

Application Route inhalation (dust/mist/fume)

Exposure time 2 yr

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:

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



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> Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

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NOEC (Pimephales promelas (fathead minnow)): 0.000010

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ma/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

Glycerine:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,955 mg/l

Exposure time: 48 h

NOEC (Pseudomonas putida): > 10,000 mg/l Toxicity to microorganisms

> Exposure time: 16 h Method: DIN 38 412 Part 8

Titanium dioxide:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h

Toxicity to algae/aquatic plants

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l Exposure time: 72 h

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability

Components:

Progesterone:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Glycerine:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 92 % Exposure time: 30 d



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Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

Progesterone:

Partition coefficient: n-Pow: 3.65

octanol/water Method: OECD Test Guideline 117

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1.75

Mobility in soil No data available

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 han-

dling 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 Ш 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 Ш Packing group

Miscellaneous Labels

Packing instruction (cargo 956



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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.

National Regulations

NZS 5433

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Progesterone)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z
Marine pollutant : no

Special precautions for user

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

Section 15: Regulatory information

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

HSNO Approval Number

not allocated

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

IECSC : not determined

AICS : not determined

DSL : not determined

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Section 16: Other information

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Further information

Sources of key data used to

compile the Safety Data

Sheet

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

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

ic Contaminants

ACGIH / 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



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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