# Finasteride (1%) Formulation



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#### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Finasteride (1%) Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor

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

Telephone : 551-430-6000

Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Reproductive toxicity : Category 1B

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Testis)

Long-term (chronic) aquatic

hazard

Category 3

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.

H373 May cause damage to organs (Testis) through prolonged

or repeated exposure if swallowed.

H412 Harmful 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.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

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tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

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 explosive dust-air mixture during processing, handling or other means.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 5 -< 10
Starch	9005-25-8	>= 5 -< 10
Finasteride	98319-26-7	>= 1 -< 2,5
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

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

: If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

In case of eye contact

and effects, both acute and

delayed

: May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

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Dust contact with the eyes can lead to mechanical irritation.

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).

Treat symptomatically and supportively. Notes to physician

**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

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.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Metal 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- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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.

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 determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

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certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

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

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. 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.

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

Take precautionary measures against static discharges. 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 Organic peroxides

Explosives Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
Cellulose	9004-34-6	CMP	10 mg/m <sup>3</sup>	AR OEL	
	Further information: Irritation				
		TWA	10 mg/m <sup>3</sup>	ACGIH	
Starch	9005-25-8	CMP	10 mg/m <sup>3</sup>	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen,				
	lung, Dermatitis				
		TWA	10 mg/m <sup>3</sup>	ACGIH	
Finasteride	98319-26-7	TWA	0.5 μg/m3 (OEB	Internal	
			5)		
		Wipe limit	5 μg/100 cm <sup>2</sup>	Internal	



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Titanium dioxide	13463-67-7	CMP	10 mg/m <sup>3</sup>	AR OEL			
	Further inform	Further information: A4 - Not classifiable as a human carcinogen,					
	lung	lung					
		TWA	10 mg/m <sup>3</sup>	ACGIH			
			(Titanium dioxide)				

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard.

Titanium dioxide

**Engineering measures** : Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

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

protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems

are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into

the workplace.

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

Hand protection

Particulates type

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 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,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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.

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#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

Color : tan

Odor : odorless

Odor 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) : May form explosive dust-air mixture during processing,

handling or other means.

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 : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

log Pow: 3,5 pH: 7

Active ingredient

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

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-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of : Inhalation

exposure

Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

### **Components:**

Cellulose:

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

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Starch:

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

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Finasteride:

Acute oral toxicity : LD50 (Rat): 373 - 828 mg/kg



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LD50 (Mouse): 486 mg/kg

Titanium dioxide:

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

Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l

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:** 

Finasteride:

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:** 

Starch:

Species : Rabbit

Result : No eye irritation

Finasteride:

Species : Rabbit

Remarks : slight irritation

Titanium dioxide:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.



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**Components:** 

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Cellulose:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Starch:

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

Result: negative

Finasteride:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Alkaline elution assay

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Application Route: Oral

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Result: negative

Titanium dioxide:

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

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Finasteride:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years

160 mg/kg body weight

Result : negative Target Organs : Testes

Remarks : Benign tumor(s)

Species : Mouse
Application Route : Ingestion
Exposure time : 19 month(s)
Result : negative
Target Organs : Testes

Remarks : Benign tumor(s)

Titanium dioxide:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 Years

Method : OECD Test Guideline 453

Result : positive

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

mans.

Carcinogenicity - Assess-

ment

: Limited evidence of carcinogenicity in inhalation studies with

animals.

Reproductive toxicity

May damage the unborn child.

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**Components:** 

Cellulose:

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

Species: Rat

**Application Route: Ingestion** 

Result: negative

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

Species: Rat

Application Route: Ingestion

Result: negative

Finasteride:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rabbit Application Route: Oral

Fertility: NOAEL: 80 mg/kg body weight

Result: No effects on fertility.

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Fertility: LOAEL: 80 mg/kg body weight

Result: positive

Remarks: These is no evidence that these findings are rele-

vant to humans.

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

Species: Rat

Application Route: Ingestion

Developmental Toxicity: LOAEL: 0,003 mg/kg body weight

Result: Teratogenic effects., Embryotoxic effects.

Test Type: Embryo-fetal development

Species: Monkey

Application Route: Ingestion

Developmental Toxicity: LOAEL: 2 mg/kg body weight

Result: Teratogenic effects.

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

May cause damage to organs (Testis) through prolonged or repeated exposure if swallowed.

Components:

Finasteride:

Routes of exposure : Ingestion Target Organs : Testis



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Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

Cellulose:

Species : Rat

NOAEL : >= 9.000 mg/kg

Application Route : Ingestion Exposure time : 90 Days

Starch:

Species : Rat

NOAEL : >= 2.000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

Finasteride:

Species : Rat
NOAEL : 20 mg/kg
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 1 y
Target Organs : Testis

Species : Dog
NOAEL : 45 mg/kg
Application Route : Oral
Exposure time : 1 y
Target Organs : Testis

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 y

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Finasteride:

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Ingestion : Symptoms: breast tenderness, breast enlargement, impo-

tence, lip swelling, skin rash

#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Finasteride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 20,4 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 17,8 mg/l

Exposure time: 48 h Method: FDA 4.08

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): 49

mg/l

Exposure time: 14 h Method: FDA 4.01

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Orange-red killifish)): 0,05 mg/l

Exposure time: 105 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0,12 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1

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

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### Persistence and degradability

**Components:** 

Cellulose:

Biodegradability : Result: Readily biodegradable.

Finasteride:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 7 d Method: FDA 3.11

Stability in water : Hydrolysis: 0 %(5 d)

Method: FDA 3.09

**Bioaccumulative potential** 

**Components:** 

Finasteride:

Partition coefficient: n-

octanol/water

log Pow: 3,57

**Mobility in soil**No data available

Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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** 

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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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#### **SECTION 15. REGULATORY INFORMATION**

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

Argentina. Carcinogenic Substances and Agents : Not applicable

Registry.

Control of precursors and essential chemicals for the : Not applicable

preparation of drugs.

### International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

### **Further information**

Sources of key data used to compile the Material Safety

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

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

### 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



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Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information 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.

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