according to the Globally Harmonized System



# Finasteride (1%) Formulation

Revision Date: Date of last issue: 04.04.2023 Version SDS Number: 7.1 30.09.2023 51665-00023 Date of first issue: 26.01.2015

#### 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 +1-551-430-6000

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

## 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**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

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.

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Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P318 IF exposed or concerned, get medical advice.

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.

## 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

## 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.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

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Rinse mouth thoroughly with water.

Most important symptoms 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.

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.

#### 5. FIREFIGHTING MEASURES

Protection of first-aiders

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

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 firefighters

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

Use personal protective equipment.

### 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

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.

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 re-

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leased 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

certain local or national requirements.

#### 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 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.

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 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Finasteride	98319-26-7	TWA	0.5 μg/m3 (OEB 5)	Internal
		Wipe limit	5 μg/100 cm <sup>2</sup>	Internal
Titanium dioxide	13463-67-7	TWA (Res-	2.5 mg/m3	ACGIH

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pirable particulate matter) (Titanium dioxide)

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

vent 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended 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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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : tan

Odour : odourless

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

dling 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

Vapour pressure : Not applicable

Relative vapour 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

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

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Explosive properties : Not explosive

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

Particle size : No data available

### 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, han-

dling 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.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

: Inhalation 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

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Finasteride:

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

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 sensitisation

## Skin sensitisation

Not classified based on available information.

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### Respiratory sensitisation

Not classified based on available information.

## **Components:**

Starch:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Exposure routes : 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

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

cytogenetic test, chromosomal analysis)

Application Route: Oral Result: negative

.........9--

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.

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 the unborn child.

**Components:** 

Cellulose:

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

Species: Rat

**Application Route: Ingestion** 

Result: negative

Effects on foetal develop-

ment

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: There is no evidence that these findings are rele-

vant to humans.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Developmental Toxicity: LOAEL: 0.003 mg/kg body weight

Result: Teratogenic effects, Embryotoxic effects.

Test Type: Embryo-foetal 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.

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#### 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:

Exposure routes : Ingestion Target Organs : Testis

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 yr
Target Organs : Testis

Species: DogNOAEL: 45 mg/kgApplication Route: OralExposure time: 1 yrTarget Organs: Testis

#### Titanium dioxide:

Species : Rat

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

Species : Rat

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NOAEL 10 ma/m3

**Application Route** inhalation (dust/mist/fume)

Exposure time 2 yr

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Finasteride:

Ingestion Symptoms: breast tenderness, breast enlargement, impo-

tence, lip swelling, skin rash

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

mq/l

Exposure time: 14 h Method: FDA 4.01

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.05 mg/l

Exposure time: 105 d

Species: Oryzias latipes (Orange-red killifish)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

NOEC: 0.12 mg/l Exposure time: 21 d

ic toxicity)

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1

Titanium dioxide:

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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/

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:**

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

#### 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.

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If not otherwise specified: Dispose of as unused product.

#### 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 IMO instruments

Not applicable for product as supplied.

### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

### **16. OTHER INFORMATION**

Revision Date : 30.09.2023

**Further information** 

Sources of key data used to compile the Safety Data

Sheet

Data farmed

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)

ACGIH / TWA : 8-hour, 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;

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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.

IN / EN