

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

SECTION 1. IDENTIFICATION

Product identifier : Finasteride (1%) Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054

Telephone : +1 551-430-6000 US | +55 (19) 3758-2000 BR

Emergency telephone : For 24/7 emergency response advice, call CHEMTREC at +55 11 4349-1359 (local) or 0800 892 0479 (toll-free). Global 24/7: +1-800-424-9300 (United States, English only).

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION


GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Testes)

Long-term (chronic) aquatic hazard : Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.
H373 May cause damage to organs (Testes) 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.
P260 Do not breathe dust.
P273 Avoid release to the environment.

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
 Date of first issue: 2015/01/26

P280 Wear protective gloves/ protective clothing/ eye protection/ 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.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 5 -< 10
Starch	9005-25-8		>= 5 -< 10
Finasteride	98319-26-7	Acute Tox. (Oral), 4 Repr., 1B STOT RE, (Oral)(Testes) , 1 Aquatic Acute, 3 Aquatic Chronic, 1	>= 1 -< 2,5

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.

In case of eye contact : If in eyes, rinse well with water.
 Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

Most important symptoms and effects, both acute and delayed	:	<p>Get medical attention. Rinse mouth thoroughly with water.</p> <p>Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.</p>
Protection of first-aiders	:	<p>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).</p>
Notes to physician	:	<p>Treat symptomatically and supportively.</p>

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	<p>Water spray Alcohol-resistant foam Carbon dioxide (CO₂) Dry chemical</p>
Unsuitable extinguishing media	:	<p>None known.</p>
Specific hazards during fire fighting	:	<p>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.</p>
Hazardous combustion products	:	<p>Carbon oxides Metal oxides</p>
Specific extinguishing methods	:	<p>Use extinguishing measures that are appropriate to local circumstances 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.</p>
Special protective equipment for fire-fighters	:	<p>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</p>

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	<p>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</p>
Environmental precautions	:	<p>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.</p>

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

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 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.

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 labeled containers.
 Store locked up.

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
 Date of first issue: 2015/01/26

Materials to avoid : Keep tightly closed.
 Store in accordance with the particular national regulations.
 : Do not store with the following product types:
 Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
Finasteride	98319-26-7	TWA	0.5 µg/m ³ (OEB 5)	Internal
		Wipe limit	5 µg/100 cm ²	Internal
titanium dioxide	13463-67-7	TWA (Respirable particulate matter)	2,5 mg/m ³ (Titanium dioxide)	ACGIH
		TWA (Respirable particulate matter)	0,2 mg/m ³ (Titanium dioxide)	ACGIH

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 : Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	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

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

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

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

Particle characteristics
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 reactions : 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.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Based on available data, the classification criteria are not met.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

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
LD50 (Mouse): 486 mg/kg

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Components:**Finasteride:**

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Components:**Starch:**

Species : Rabbit
Result : No eye irritation

Finasteride:

Species : Rabbit
Remarks : slight irritation

Respiratory or skin sensitization**Skin sensitization**

Based on available data, the classification criteria are not met.

Respiratory sensitization

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Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

Components:**Starch:**

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

Finasteride:

Test Type : Skin sensitization
Remarks : Not classified due to lack of data.

Test Type : Respiratory sensitization
Remarks : Not classified due to lack of data.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Components:**Cellulose:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay
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
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
Result: negative

Test Type: Alkaline elution assay
Result: negative

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Application Route: Oral
Result: negative

Carcinogenicity

Based on available data, the classification criteria are not met.

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)

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 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

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

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 relevant 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 - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Based on available data, the classification criteria are not met.

Components:**Finasteride:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

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

Components:**Finasteride:**

Routes of exposure : Ingestion
Target Organs : Testes
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Cellulose:**

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

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 : Testes

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

Aspiration toxicity

Based on available data, the classification criteria are not met.

Components:**Finasteride:**

Not applicable

Experience with human exposure**Components:****Finasteride:**

Ingestion : Symptoms: breast tenderness, breast enlargement, impotence, lip swelling, skin rash

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
Exposure time: 96 h

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

Remarks: Based on data from similar materials

Ecotoxicology Assessment

Acute aquatic toxicity : No toxicity at the limit of solubility.

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 : EC50 (Pseudokirchneriella subcapitata (green algae)): > 49 mg/l
Exposure time: 14 h
Method: FDA 4.01

NOEC (Pseudokirchneriella subcapitata (green algae)): 49 mg/l
Exposure time: 14 h
Method: FDA 4.01

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Orange-red killifish)): 0,05 mg/l
Exposure time: 105 d

Toxicity to daphnia and other aquatic invertebrates (Chronic 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

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

Finasteride (1%) Formulation

Version 10.0 Revision Date: 2025/07/01 SDS Number: 300000001605 Date of last issue: 2023/09/30
Date of first issue: 2015/01/26

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 : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

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.

Domestic regulation**ANTT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans
13463-67-7

Titanium dioxide

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

Group 2B: Possibly carcinogenic to humans
14807-96-6

Talc

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 2025/07/01
Date format : yyyy/mm/dd

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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; 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; KECl - 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

Finasteride (1%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/09/30
10.0	2025/07/01	300000001605	Date of first issue: 2015/01/26

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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