

Finasteride (3.25%) Formulation



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 03/23/2020

 2.4
 10/10/2020
 2160713-00008
 Date of first issue: 11/09/2017

SECTION 1. IDENTIFICATION

Product name : Finasteride (3.25%) Formulation

Manufacturer or supplier's details

Company name of supplier : 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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity : Category 1B

Specific target organ toxicity

- repeated exposure (Oral)

Category 1 (Testis)

GHS label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H360D May damage the unborn child.

H372 Causes damage to organs (Testis) through prolonged or

repeated exposure if swallowed.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust, fume, gas, mist, vapors or spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:



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P501 Dispose of contents and container to an approved waste

disposal plant.

Other hazards

None known.

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 - < 5

Actual concentration is withheld as a trade secret

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 Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and May damage the unborn child.

exposure if swallowed.

delayed Protection of first-aiders Causes damage to organs through prolonged or repeated

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

None known.

Specific hazards during fire Exposure to combustion products may be a hazard to health.

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fighting

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.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

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

Do not breathe dust, fume, gas, mist, vapors or spray.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

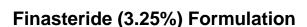
Do not eat, drink or smoke when using this product.

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

environment.

Conditions for safe storage : Keep in properly labeled 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 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
		TWA (Res- pirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Res- pirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Finasteride	98319-26-7	TWA	0.5 μg/m3 (OEB 5)	Internal
		Wipe limit	5 μg/100 cm ²	Internal

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 : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where

concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn.

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> Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Chemical-resistant gloves Material

Remarks Consider double gloving.

Wear safety glasses with side shields or goggles. Eye protection

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.

Work uniform or laboratory coat. Skin and body protection

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance solid

Color blue

Odor odorless

Odor Threshold No data available

No data available pН

Melting point/freezing point No data available

Initial boiling point and boiling :

range

No data available

Flash point Not applicable

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Evaporation rate Not applicable

Flammability (solid, gas) Not classified as a flammability hazard

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure Not applicable

Relative vapor density Not applicable

Relative density No data available

No data available Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

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 size No data available

SECTION 10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact Ingestion Eye contact

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Acute toxicity

Not classified based on available information.

Product:

Acute toxicity estimate: > 5,000 mg/kg Acute oral toxicity

Method: Calculation method

Components:

Cellulose:

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

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

Not classified based on available information.

Components:

Finasteride:

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

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Finasteride:

Species : Rabbit

Remarks : slight irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Starch:

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



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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

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)

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

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

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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

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

Components:

Finasteride:

Routes of exposure Ingestion **Target Organs** Testis

Assessment Causes damage to organs through prolonged or repeated

exposure.



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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

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

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



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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/

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

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



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♣ ORGANON

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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

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Finasteride)

Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Finasteride)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen-

ger aircraft)

956

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Finasteride)

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.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Finasteride)

Class : 9 Packing group : III



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Labels : CLASS 9 ERG Code : 171

Marine pollutant : yes(Finasteride)

Remarks : Above applies only to containers over 119 gallons or 450

liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard

classification to facilitate multi-modal transport involving ICAO

(IATA) or IMO.

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate
Cellulose
9004-34-6
Starch
Starch, carboxymethyl ether, sodium salt
Finasteride
98319-26-7

California Permissible Exposure Limits for Chemical Contaminants

 Cellulose
 9004-34-6

 Starch
 9005-25-8

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

AICS : not determined

DSL : not determined

IECSC : not determined

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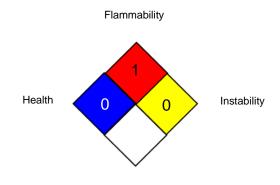


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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



Special hazard

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable



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Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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 Agen-

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

Revision Date : 10/10/2020

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.

US / Z8