

SAFETY DATA SHEET

Preparation Date: 8/30/2016

Revision Date: Not applicable

Revision Number: Not applicable

1. IDENTIFICATION

Product identifier

Product code: F1300
Product Name: FINASTERIDE, USP

Other means of identification

Synonyms: N-(2-Methyl-2-propyl)-3-oxo-4-aza-5-alpha-androst-1-ene-17-beta-carboxamide

CAS #: 98319-26-7
RTECS # CL5245000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Drug. Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000.

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Reproductive toxicity	Category 2

Label elements

Warning

Hazard statements

Harmful if swallowed
 Suspected of damaging fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Finasteride	98319-26-7	100

4. FIRST AID MEASURES

First aid measures

- General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
- Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
- Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
- Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
- Ingestion:** Harmful if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms May cause nausea and vomiting. May cause bleeding or ulceration from the stomach. Respiratory depression. Central nervous system effects. Somnolence. Ataxia. Dizziness.

Headache. May affect the liver. May affect the cardiovascular system. Hypotension. Suspected of damaging fertility or the unborn child. May cause impotence and decreased libdo. May cause decreased volume of ejaculate in men. May cause breast enlargement and breast tenderness.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray, mist, or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Dioxide, Carbon Monoxide. Nitrogen Oxides.

Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition. Avoid breathing dust.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Use only in well-ventilated areas. Do not ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WHEEL
Finasteride	98319-26-7	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Finasteride	98319-26-7	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Finasteride	98319-26-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Chemical resistant apron. Gloves. Long sleeved clothing.

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust

clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures:

Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Crystalline powder.	Color: White. Off-white.
Odor: No information available.	Taste No information available.	Formula: C23H36N2O2
Molecular/Formula weight: 372.55 g/mol	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 252-254°C/486-489°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): 3.5	Viscosity: No information available
Miscibility: No information available	Solubility: Very slightly soluble in water Freely soluble in Dimethyl Sulfoxide (DMSO) Freely soluble in propyl alcohol Freely soluble in Ethanol Freely soluble in Chloroform Freely soluble in Ethyl alcohol Practically insoluble in propylene glycol	

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Avoid dust formation. Heat. Ignition sources. Incompatible materials.

Incompatible Materials: Oxidizing agents
Hazardous decomposition products: Carbon oxides. Nitrogen oxides (NOx).

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion.

Acute Toxicity

Component Information

Finasteride
CAS-No. 98319-26-7

LD50/oral/rat = 418 mg/kg Oral LD50 Rat
LD50/oral/mouse = 486 mg/kg oral LD50 mouse
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 418 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 486 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause respiratory tract irritation.

Ingestion Harmful if swallowed. Ingestion may cause nausea, vomiting. May cause ulceration or bleeding from the stomach. May affect behavior/central nervous system (dizziness, headache). May affect behavior/central nervous system (ataxia, somnolence), respiration (dyspnea, respiratory depression). May cause skin rash, redness or itching. May affect liver. May affect the cardiovascular system (hypotension).

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated ingestion may affect the liver. Prolonged or repeated ingestion may affect the blood (changes in serum composition).

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Finasteride	98319-26-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity Suspected of damaging fertility or the unborn child

Reproductive Effects: Possible risk of impaired fertility
In men, the most common side effects of finasteride therapy include decreased libido, ejaculatory disorder, impotence and mild decreases in semen endpoints

Developmental Effects: May cause developmental abnormalities
Possible risk of harm to the unborn child
In rats, finasteride produced abnormalities of external genital development hypospadias (the opening of the urethra on the underside of the penis), and a reduction of weight of prostate and seminal vesicles

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Finasteride - 98319-26-7

Freshwater Fish Species Data: 19.6 mg/L LC50 Oncorhynchus mykiss 96h

Water Flea Data: 21 mg/L LC50 Daphnia magna 48h

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Finasteride	98319-26-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class: No information available
Packing group: No information available
Emergency Response Guide Number: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available
Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available

Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions: No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Finasteride	98319-26-7	Not Listed	Not present	Not present	Not present	Not present	Not present	Not present

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Finasteride	98319-26-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous	Section 302 Extremely	Section 302 Extremely	Section 313 - Chemical Category	Section 313 - Reporting
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		Substances and their Reportable Quantities	Hazardous Substances and TPQs	Hazardous Substances and RQs		de minimis
Finasteride	98319-26-7	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) - Health and Safety Reporting
Finasteride	98319-26-7	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D1B Toxic materials

D2A Very toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Finasteride	98319-26-7	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Finasteride	98319-26-7	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Finasteride	98319-26-7	Not listed

EU Classification

R-phrase(s)

R22 - Harmful if swallowed.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

S -phrase(s)

S46 - If swallowed, seek medical advice immediately and show this container or label.

S37/39 - Wear suitable gloves and eye/face protection.

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Finasteride	98319-26-7		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

Xn - Harmful.

Xn



16. OTHER INFORMATION

Preparation Date: 8/30/2016
Revision Date: Not applicable
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet