


Safety Data Sheet



1. Identification

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| Product Identifier | Finasteride |
| Other means of identification | |
| Internal item number | 82393-0306 |
| CAS number | 98319-26-7 |
| Chemical name | N-tert-Butyl-3-oxo-4-aza-5alpha-androst-1-ene-17beta-carboxamide |
| Relevant use and restrictions: | No further information available. |
| Application of substance: | Active pharmaceutical ingredient. |
| Manufacturer/Supplier information | |
| Company name | Pharma Source Direct |
| Address | 8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112 |
| Website | www.pharmasd.com |
| Emergency phone number | Infotrac: 1-800-535-5053 |

2. Hazard(s) Identification

| | | |
|------------------------------|---|-------------|
| Physical hazards | Not classified | |
| Health hazards | Acute toxicity, oral | Category 4 |
| | Serious eye damage/eye irritation | Category 2B |
| | Reproductive toxicity | Category 1 |
| Environmental hazards | Not classified | |
| OSHA defined hazards | Not classified | |
| Label elements |  | |

| | |
|--------------------------------|--|
| Signal word | Danger |
| Hazard statement | Harmful if swallowed. Causes eye irritation. May damage fertility or the unborn child. |
| Precautionary statement | |
| Prevention | Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. |
| Response | If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. |
| Storage | Store locked up. |

Safety Data Sheet



Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards not otherwise classified (HNOC)

None known.

Supplemental information

Potent pharmacologically active material.

3. Composition/Information on Ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|---------------|--------------------------|------------|-----|
| Finasteride | | 98319-26-7 | 100 |

4. First-aid Measures

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed

Potent pharmacologically active material. Occupational exposure may cause physiological effects. Reproductive system effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

General Information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

Safety Data Sheet



Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

| Material | Type | Value |
|---------------------------------|------|-------------------|
| Finasteride (CAS 98319-26-7) | TWA | 0.5 micrograms/m3 |

Biological limit values

No biological exposure limits noted for the ingredient(s)

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of

Safety Data Sheet



exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice. Pharmacological effects may be seen with occupational exposure.

9. Physical and Chemical Properties

Appearance

Appearance descriptions are general information and not specific to any lot.

Physical state

Solid.

Form

Powder.

Color

White.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

485.6 – 494.6 °F (252 - 257 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Safety Data Sheet



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| Vapor density | Not available. |
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Very slightly soluble. |
| Solubility (other) | Alcohol: Freely soluble. Chloroform: Freely soluble. |
| Partition coefficient (n-octanol/water) | 3.5 |
| Auto-ignition temperature | 716 – 734 °F (380 – 390 °C) |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Chemical family | 4-Azasteroid. |
| Molecular formula | C23H36N2O2 |
| Molecular weight | 372.54 |

10. Stability and Reactivity

| | |
|------------------------------------|--|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage, and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | None known. |
| Hazardous decomposition products | NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

11. Toxicological Information

Information on likely routes of exposure

| | |
|--------------|---|
| Inhalation | Knowledge about health hazard is incomplete. |
| Skin contact | Knowledge about health hazard is incomplete. |
| Eye contact | Causes eye irritation. |
| Ingestion | Harmful if swallowed. Based on information from therapeutic use, this material may cause: Reproductive effects. |

Symptoms related to the physical, chemical, and toxicological characteristics
5 α -Reductase inhibitors: Chills. Cold sweats. Confusion. Dizziness. Swelling. Breast enlargement. Skin rash. Weight gain. Decreased libido. Impotence. Headache. Gastrointestinal disturbances.

Information on toxicological effects

Acute toxicity
Harmful if swallowed.

| Product | Species | Test Results |
|------------------------------|---------|--------------|
| Flinasteride (CAS 9831926-7) | | |
| | Dermal | |
| | LD50 | |
| | Mouse | 486 mg/kg |
| | Rat | 373 mg/kg |

Safety Data Sheet



Skin corrosion/irritation

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Local effects

Eye irritation

Result: Slightly irritating.

Species: Rabbit

Local effects

Skin irritation

Result: Not irritating.

Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Mutagenicity

Chromosome aberration

Result: Negative

In vitro alkaline elution assay

Result: Negative.

In vitro bacterial mutagenicity assay

Result: Negative.

In vitro chromosome aberration assay in Chinese hamster

ovary cells

Result: Positive.

Severity: Slight increase

Mammalian cell mutagenicity assay

Result: Negative.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

160 – 320 mg/kg/day Carcinogenicity

Result: No tumorigenic effects.

Species: Rat

Test Duration: 24 months

250 mg/kg/day Carcinogenicity

Result: Increased incidence of testicular Leydig cell adenomas

Species: Mouse

Test Duration: 219 months

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage fertility or the unborn child.

5 alpha-reductase inhibitors prevent conversion of testosterone to dihydrotestosterone (DHT), a hormone necessary for normal development of male genitalia. In animal reproduction and developmental toxicity studies, 5 alpha-reductase inhibitors inhibited normal development of external genitalia in male fetuses.

Reproductivity

Safety Data Sheet



0.1 - 100 mg/kg/day Reproductivity and development study, administered during gestation
Result: Dose-dependent development of hypospadias in male offspring.
Species: Rat
2 mg/kg/day Reproductivity and development study, oral administration during gestation.
Result: External genital abnormalities in male fetuses.
Species: Rhesus monkey

| | |
|---|---|
| Specific target organ toxicity - single exposure | Knowledge about health hazard is incomplete. |
| Specific target organ toxicity - repeated exposure | Knowledge about health hazard is incomplete. |
| Aspiration hazard | Based on available data, the classification criteria are not met. |
| Further information | Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. |

12. Ecological Information

Ecotoxicity

| Product | Species | Test Results |
|------------------------------|--|---------------------|
| Finasteride (CAS 98319-26-7) | | |
| Aquatic | | |
| Crustacea | LC50 Water flea (<i>Daphnia magna</i>) | 21 mg/l, 48 hours |
| Fish | LC50 Rainbow Trout | 19.6 mg/l, 96 hours |

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

3.5

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Safety Data Sheet



Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safety Data Sheet



Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Phillipines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| Unites States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product regarding handling, storage, and/or disposal.

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