

PRODUCT SAFETY DATA SHEET

Cipla

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Reference	: —	Date	: September 2008
Edition	: 03		

1 IDENTIFICATION OF SUBSTANCE

Trade Name : FINASTERIDE
Company : Cipla Limited
*Manufacturing division - M.I.D.C. Patalganga, District – Raigad
Maharashtra, India (Pin Code - 410 220)*

Telephone : +91 2192 250811 / 250822
Fax : +91 2192 250819
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Web site : www.cipla.com
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2 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name : 4 – Azaandrost – 1 – ene – 17 – Carboxamide, N (1,1 - dimethylethyl) 3 – oxo – 5, (5 α , 17 β)
Molecular Formula : C₂₃H₃₆N₂O₂
Molecular Weight : 372.55
CAS No. : 98319 - 26 - 7
EINECS – No. : Data not available.

3 HAZARD IDENTIFICATION

Fire & Explosion - Product is not highly flammable. Packing may be combustible
Health - Exposure might occur via inhalation, ingestion, skin absorption and eyes.
Material may be harmful by inhalation, ingestion, skin absorption and eyes. May cause eye, skin and respiratory tract irritation.
Environment - May harmful to aquatic organisms

4 FIRST AID MEASURES

General advice

Inhalation : Remove victim to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Receive immediate medical attention.
Skin Contact : May cause irritation. Remove contaminated clothing. Flush with copious quantities of water. Receive immediate medical attention.

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Eye Contact : May cause irritation. Flush eyes with copious quantities of water for at least 15 minutes. Receive immediate medical attention.

Ingestion : May cause irritation. Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Receive immediate medical attention.

Notes to Health Professionals

Medical Treatment : Medical treatment in cases of overexposure should be treated as an overdose of the product. Treat according to locally approved protocols.

Medical conditions Caused or Aggravated by exposure : No specific data available

Antidote : No specific data available

5 FIRE FIGHTING MEASURES

Fire & Explosion hazard : Product is not highly flammable. Packing may be combustible. This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build up of static electricity. Dust may cause explosion at proper concentration.

Extinguishing media : Water spray, Foam, Carbon dioxide as appropriate for surrounding fire and material.

Special fire fighting procedure : As with all fires, evacuate persons to safe area. Fire fighter should use self – contained breathing apparatus and protective clothing. If possible, contain and collect fire fighting water for later disposal.

Hazardous Combustion Products : Under fire conditions - May emit toxic fumes. Toxic, corrosive or flammable thermal decomposition products are expected under fire condition.

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6 ACCIDENTAL RELEASE MEASURES

- Personal Precautions** : Avoid unwanted exposure. Wear self – contained breathing apparatus / approved respirator, Personal clothing including chemical compatible suit, hand gloves & boots, consistent and compatible with the degree of hazard.
- Environmental Precaution** : Vacuum or Sweep up the material, place in a bag / container and hold for waste disposal. Avoid raising dust. Take precautions to prevent entry into waterways, sewers or surface drain systems.
- Clean - up Procedure** : Place spillage in appropriate and labeled container / bag for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Dispose off waste in accordance with applicable federal, state and local laws.
- Decontamination Procedure** : No specific decontamination procedure has been identified.

7 HANDLING AND STORAGE

- Handling** : Handle material with care. Avoid exposure to moisture, humid conditions and direct sunlight. This material should be handled as per instructions to ensure product integrity. Avoid contact with skin, eyes and clothing. Avoid breathing dust or mist. Use with adequate dust control. Handle product with wearing proper personal protective equipment mentioned in section 8. Wear fresh clothing daily. Wash contaminated clothing before reuse. Wash thoroughly after handling. Do not permit eating, drinking or smoking near the material.
- Storage** : **1. Bulk Storage -** Store in well – closed Container at the demarcated place. Store material in cool dry place protected from light. Avoid exposure to moisture, humid conditions and direct sunlight. This material should be handled and stored as per instructions to ensure product integrity.
- 2. Department Storage -** As mentioned above

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8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Hazard category and Exposure Limits

Refer section 9, 10, 11 and 12

Personal protective equipment

Ensure before use - Personal Protective Equipment selected are consistent and compatible with degree of hazard.

- Respiratory protection** : Self Contained Breathing Apparatus, Respirator or Pressure suit
Hand protection : Chemically compatible hand gloves
Eye protection : Safety Goggle or Face Shield
Skin protection : Protective clothing including apron / suit, shoes

Exposure control

- Ventilation** : Adequate ventilation is required. Provide local exhaust and mechanical ventilation.

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : White to off – white, crystalline solid.

- | | |
|--|--|
| Vapour pressure : Not applicable | Vapour density : Not applicable |
| Flash point : Not applicable | Viscosity : Not applicable |
| Melting range : Between 254°C to 258°C | Boiling point : Not applicable |
| Specific gravity : Not applicable | Auto-ignition : Data not available. |
| Relative density : Data not available. | Flammability : Data not available. |
| Solubility : Freely soluble in chloroform and in alcohol. | |

10 STABILITY AND REACTIVITY

- Stability** : Stable at ambient temperature.
Incompatibilities / Conditions to avoid : Data not available
Hazardous decomposition products : When heated to decomposition it may emit toxic fumes.

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11 TOXICOLOGICAL INFORMATION

Material may be harmful by inhalation, ingestion or skin absorption. May cause eye and skin irritation.

- Oral Toxicity : Data Not available
- Inhalation Toxicity : Data Not available
- Skin Effects : May cause irritation
- Eye Effects : May cause irritation
- Target Organ Effects : Data Not available
- Sensitization : Data Not available
- Genetic Toxicity : Data Not available
- Carcinogenicity : Data Not available
- Reproductive Effects : Data Not available

Material may be harmful by inhalation, ingestion, skin absorption. May cause eye & skin irritation.

Toxicity data

- ORL - RAT LD 50 : Data not available. SCU - RAT LD 50 : Data not available.
- ORL -MICE LD 50 : Data not available. SCU - MUS LD 50 : Data not available.

12 ENVIRONMENTAL / ECOLOGICAL INFORMATION

Summary : This product may be harmful if releases directly to the environment. No information is available about the potential of this product to produce adverse environmental effects. Appropriate precautions should be taken to limit release of this material in the environment.. Local regulations and procedures should be consulted prior to environmental release.

Ecotoxicity

- Aquatic Daphnid : May be toxic to daphnids

13 DISPOSAL CONSIDERATION

- Disposal Recommendations** : Dispose material as per local, state and federal regulatory procedures and laws.
- Regulatory Requirements** : Dispose material as per local, state and federal regulatory procedures and laws.

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14 TRANSPORT INFORMATION

Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release.

UN Classification & Labeling : Data not available

Transport Information : Transportation of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose.

15 REGULATORY INFORMATION

Labeling according to EEC directives : Data not available.

National legislation / regulations

Any other regulatory information : ---

16 OTHER INFORMATION

Material Use and Category

Use : It is Used as Benign prostatic hypertrophy

Therapeutic category : Benign prostatic hypertrophy

Reference : Active Pharmaceutical Ingredient specification No.
APGF 002 Of Cipla, Patalganga, Version No. 02
dated 28. 02. 2008

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