

Material Safety Data Sheet

| Section 1: Chemical Product Company Identification | |
|--|---|
| Product Name | Dutasteride EP Impurity I |
| CAS No. | 1648593-70-7 |
| Identified uses | Pharmaceutical Reference Standard |
| Details of the Supplier Company | SynZeal Research Pvt Ltd Plot No. F, Ganesh Industrial Estate 423/24/8, MahagujaratInd Estate Sarkhej-Bavla Road, Ahmedabad-382 213. Gujarat, India. |
| Telephone | +91-7969225400 |

| Section 2: Chemical Information | |
|---------------------------------|---|
| Chemical Name | (4aR,4bS,6aS,7S,9aS,9bS,11aR)-N-(2,5-Bis(trifluoromethyl)phenyl)-1-((4aR,4bS,6aS,7S,9aS,9bS,11aR)-4a,6a-dimethyl-2-oxo-2,4a,4b,5,6,6a,7,8,9,9a,9b,10,11,11a-tetradecahydro-1H-indeno[5,4-f]quinoline-7-carbonyl)-4a,6a-dimethyl-2-oxo-2,4a,4b,5,6,6a,7,8,9,9a,9b,10,11,11a-tetradecahydro-1H-indeno[5,4-f]quinoline-7-carboxamide |
| CAS No. | 1648593-70-7 |
| Synonyms | Dutasteride b-Dimer |
| Molecular Weight | 828.0 |
| Molecular Formula | C46H55F6N3O4 |

| Section 3: Hazards Identification | |
|-----------------------------------|-----------------|
| Emergency Overview: | |
| Appearance | Off White Solid |
| Target Organs | NA |
| Potential Health Effects: | |
| Eye | NIL |
| Skin | NIL |
| Ingestion | NIL |
| Inhalation | NIL |
| Chronic | NIL |

| Section 4: First Aid Measures | |
|-------------------------------|--|
| Eye | Wash with plenty of water |
| Skin | Wash with plenty of water |
| Ingestion | Medical assistance for gastric lavage. |
| Inhalation | Remove to fresh air, artificial respiration or oxygen if necessary. |
| Notes to Physician | Dutasteride EP Impurity I can be washed with plenty of water in case of any exposure |

| Section 5: Firefighting Measures | |
|------------------------------------|---|
| Extinguishing Media | Carbon dioxide, dry chemical powder, foam, water. |
| Unusual Fire and Explosion Hazards | None indicated |

| Section 6: Accidental Release Measures | |
|--|--|
| Personal Precautions | Wear self-contained breathing apparatus, avoid dust formation. |
| Spills/Leaks | Wash with plenty of water, provide adequate ventilation. |

| Section 7: Handlings and Storage | |
|----------------------------------|-----------------------------------|
| Handling | Wear surgical gloves |
| Storage | Can be stored at room temperature |

| Section 8: Exposure Controls, Personal Protection | |
|---|------------------------------------|
| Respiratory Protection | Self-contained breathing apparatus |
| Exposure Limits | NA |
| Eye Protection | Wear safety goggles |
| Other Protective Equipment | Protective clothing |
| Skin | Full sleeves apron |
| Clothing | Cotton |

| Section 9: Physical and Chemical Properties | |
|---|-----------------|
| Appearance | Off White Solid |
| Odor | Odor less |
| Melting Point | NA |
| pH | Basic |

| | |
|--------------------------|----------------------|
| Vapor Pressure | NA |
| Vapor Density | NA |
| Evaporation Rate | NA |
| Viscosity | NA |
| Boiling Point | NA |
| Decomposition Temp | NA |
| Auto ignition Temp. | NA |
| Flash Point | NA |
| NFPA Rating | NA |
| Explosion Limits | |
| Lower | NA |
| Upper | NA |
| Solubility | Chloroform, Methanol |
| Specific Gravity/Density | NA |

| | |
|--|------------------------|
| Section 10: Stability and Reactivity | |
| Chemical Stability | Stable |
| Conditions to avoid | Direct contact to skin |
| Incompatibilities with other Materials | Keep away |
| Hazardous Decomposition Products | NIL |
| Hazardous Polymerization | NIL |

| | |
|---------------------------------------|-----|
| Section 11: Toxicological Information | |
| CAS | NA |
| LD50/LC50 | NA |
| Carcinogenicity | NIL |
| Epidemiology | NIL |
| Teratogenicity | NIL |
| Reproductive Effects | NIL |
| Neurotoxicity | NIL |
| Mutagenicity | NIL |
| Other Studies | NA |

Section 12: Ecological Information

Data not available

Section 13: Disposal Consideration

RCRA P-Series

Can be incinerated

RCRA U-Series

NA

Section 14: Transport Consideration

UN-Number

ADR/RID: IMDG: IATA:

UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

Transport hazard class(es)

ADR/RID: IMDG: IATA:

Packaging Group

ADR/RID: IMDG: IATA:

Environmental hazards

ADR/RID: No IMDG Marine pollutant: No IATA: No

Special precautions for users

Further information

Section 15: Regulatory Information

TSCA

Attached the letter

Health and Safety Reporting List

No data available

Chemical Test Rules

Chemical analysis report is attached

Section 16: Additional Information

This product is not bioactive, non-radioactive. It is for R/D use only. Not for drug, household or other uses.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge. It does not represent any guarantee of the product.