

Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs,  
Unit No- A- 205&206 Second floor, Plot No: G-6, G-20 to G 24, Talaja- MIDC, Opp. Dena Bank  
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## Material Safety Data Sheet

| Section 1 : Chemical Product and Company information |                                                                                                                                                                                                                                                                           |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Name                                         | Tibolone EP Impurity E                                                                                                                                                                                                                                                    |
| CAS No.                                              | 105186-33-2                                                                                                                                                                                                                                                               |
| Identified uses                                      | Pharmaceutical Reference Standard                                                                                                                                                                                                                                         |
| Details of the Supplier Company                      | Chemicea Pharmaceuticals Pvt Ltd,<br>2nd floor, A-205 Plot Number G-6, G-20 to G-24, Platinum Spring, Vavanje Panvel Road, Talaja MIDC, Navi Mumbai, Raigad, Maharashtra, 410208, Email- <a href="mailto:info@chemicea.com">info@chemicea.com</a><br>Mob- +91-92848979789 |
| Telephone                                            | +91-9284897978                                                                                                                                                                                                                                                            |

| Section 2 : Chemical Information |                                                                                             |
|----------------------------------|---------------------------------------------------------------------------------------------|
| Chemical Name                    | 3,3-dimethoxy-7 $\alpha$ -methyl-19-nor-17 $\alpha$ -pregn-5(10)-en-20-yn-17-ol (as per EP) |
| CAS No.                          | 105186-33-2                                                                                 |
| CAT No.                          | CP-T155004                                                                                  |
| Synonyms                         | NA                                                                                          |
| Molecular Weight                 | 358.52                                                                                      |
| Molecular Formula                | C23H34O3                                                                                    |

| Section 3 : Hazards Identification |     |
|------------------------------------|-----|
| <b>Emergency Overview:</b>         |     |
| Appearance                         |     |
| Target Organs                      | NA  |
| <b>Potential Health Effects:</b>   |     |
| Eye                                | NIL |
| Skin                               | NIL |
| Ingestion                          | NIL |
| Inhalation                         | NIL |
| Chronic                            | NIL |

**Section 4 : First Aid Measures**

|                    |                                                                                                                                                                    |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye                | After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist. Remove contact lenses.                                                     |
| Skin               | Take off immediately all contaminated clothing. Rinse skin with water/ shower. Call a physician immediately                                                        |
| Swallowed          | After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise. |
| Inhalation         | Remove to fresh air, artificial respiration or oxygen if necessary.                                                                                                |
| Notes to Physician | 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      | Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. |
| Spills/Leaks              | Wash with plenty of water, provide adequate ventilation.                                                                                                                                              |
| Environmental precautions | Do not let product enter drains.                                                                                                                                                                      |

**Section 7 : Handlings and Storage**

|          |                                                                                         |
|----------|-----------------------------------------------------------------------------------------|
| Handling | Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols. |
| 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 |  |
|------------|--|

|                          |                          |
|--------------------------|--------------------------|
| 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                       |
| <b>Explosion Limits</b>  |                          |
| Lower                    | NA                       |
| Upper                    | NA                       |
| Solubility               | Soluble in Methanol/DMSO |
| 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 |
|-------------|---------------------------|

#### Special precautions for users

#### Further information

### Section 15 : Regulatory Information

|                                |                                      |
|--------------------------------|--------------------------------------|
| TSCA                           | Attached the letter                  |
| Health & 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.