

# Safety Data Sheet

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|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Section 1 : Chemical Product Company Identification |                                                                                                                         |
| Product Name                                        | Buprenorphine EP Impurity D                                                                                             |
| CAS No.                                             | 16524-65-5                                                                                                              |
| Identified uses                                     | Pharmaceutical Reference Standard                                                                                       |
| Details of the Supplier Company                     | SynZeal Research Pvt Ltd<br>Survey No. - 355/404/407,<br>Rajoda, Bavla,<br>Dist. Ahmedabad - 382 220,<br>Gujarat, INDIA |
| Telephone                                           | +91-7969225400                                                                                                          |

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| Section 2 : Chemical Information |                                                                                                                                      |
| Chemical Name                    | (2S)-2-[17-(Cyclopropylmethyl)-4,5-Alpha-epoxy-3,6-dimethoxy-6-Alpha,14-ethano-14-Alpha-morphinan-7-Alpha-yl]-3,3-dimethylbutan-2-ol |
| CAS No.                          | 16524-65-5                                                                                                                           |
| Synonyms                         | 3-O-Methylbuprenorphine                                                                                                              |
| Molecular Weight                 | 481.7                                                                                                                                |
| Molecular Formula                | C30H43NO4                                                                                                                            |

|                                    |                                                                                     |  |
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| Section 3 : Hazards Identification |                                                                                     |  |
| Emergency Overview:                |                                                                                     |  |
| Appearance                         | Light Yellow Thick Oil                                                              |  |
| Target Organs                      | NA                                                                                  |  |
| Potential Health Effects:          |                                                                                     |  |
| Eye                                | NA                                                                                  |  |
| Skin                               | NA                                                                                  |  |
| Ingestion                          | NA                                                                                  |  |
| Inhalation                         | NA                                                                                  |  |
| Chronic                            | NA                                                                                  |  |
| Label Elements:                    |                                                                                     |  |
| Pictogram                          |  |  |

|                                                                                                                                                    |
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| Hazard Statement:                                                                                                                                  |
| H302:Harmful if swallowed.                                                                                                                         |
| H312:Harmful in contact with skin.                                                                                                                 |
| H315:Causes skin irritation.                                                                                                                       |
| H319:Causes serious eye irritation.                                                                                                                |
| H332:Harmful if inhaled.                                                                                                                           |
| H335:May cause respiratory irritation.                                                                                                             |
| Precautionary Statement:                                                                                                                           |
| P261:Avoid breathing dust/fume/gas/mist/vapours/spray.                                                                                             |
| P262:Do not get in eyes, on skin, or on clothing.                                                                                                  |
| P271:Use only outdoors or in a well-ventilated area.                                                                                               |
| P280:Wear protective gloves/protective clothing/eye protection/face protection.                                                                    |
| P302 + P352:IF ON SKIN: Wash with plenty of water                                                                                                  |
| P304 + P340:IF INHALED: Remove person to fresh air and keep comfortable for breathing.                                                             |
| P305 + P351 +P338:IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P308 + P313:IF exposed or concerned: Get medical advice/attention.                                                                                 |

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|-----------------|--------------------------------------------------------------------------------------|--|
| Label Elements: |                                                                                      |  |
| Pictogram       |  |  |

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| Hazard Statement:          |
| H302:Harmful if swallowed. |

|                                                                                                                                                            |
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| <b>H312:</b> Harmful in contact with skin.                                                                                                                 |
| <b>H315:</b> Causes skin irritation.                                                                                                                       |
| <b>H319:</b> Causes serious eye irritation.                                                                                                                |
| <b>H332:</b> Harmful if inhaled.                                                                                                                           |
| <b>H335:</b> May cause respiratory irritation.                                                                                                             |
| Precautionary Statement:                                                                                                                                   |
| <b>P261:</b> Avoid breathing dust/fume/gas/mist/vapours/spray.                                                                                             |
| <b>P262:</b> Do not get in eyes, on skin, or on clothing.                                                                                                  |
| <b>P271:</b> Use only outdoors or in a well-ventilated area.                                                                                               |
| <b>P280:</b> Wear protective gloves/protective clothing/eye protection/face protection.                                                                    |
| <b>P302 + P352:</b> IF ON SKIN: Wash with plenty of water                                                                                                  |
| <b>P304 + P340:</b> IF INHALED: Remove person to fresh air and keep comfortable for breathing.                                                             |
| <b>P305 + P351 +P338:</b> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| <b>P308 + P313:</b> IF exposed or concerned: Get medical advice/attention.                                                                                 |

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| 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             | Buprenorphine EP Impurity D can be washed with plenty of water in case of any exposure |

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

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| 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.       |

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| Section 7 : Handlings and Storage |                      |
| Handling                          | Wear surgical gloves |

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| Storage |  |
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| 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                                   | Light Yellow Thick Oil |
| 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                    |                         |
| Conditions to avoid                   | Direct contract to skin |

|                                        |           |
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| Incompatibilities with other Materials | Keep away |
| Hazardous Decomposition Products       | NA        |
| Hazardous Polymerization               | NA        |

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

|                                     |  |
|-------------------------------------|--|
| Section 12 : Ecological Information |  |
| Data not available                  |  |

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| Section 13 : Disposal Consideration |                    |
| RCRA P-Series                       | Can be incinerated |
| RCRA U-Series                       | NA                 |

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| Section 14 : Transport Consideration                                                   |  |
| <b>UN-Number</b>                                                                       |  |
| ADR/RID: IMDG: IATA:                                                                   |  |
| <b>UN proper shipping name</b>                                                         |  |
| ADR/RID: Not dangerous goods<br>IMDG: Not dangerous goods<br>IATA: Not dangerous goods |  |
| <b>Transport hazard class(es)</b>                                                      |  |
| ADR/RID: IMDG: IATA:                                                                   |  |
| <b>Packaging Group</b>                                                                 |  |
| ADR/RID: IMDG: IATA:                                                                   |  |
| <b>Environmental hazards</b>                                                           |  |

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|------------------------------------------------|
| ADR/RID: No IMDG Marine pollutant: No IATA: No |
| <b>Special precautions for users</b>           |
| <b>Further information</b>                     |

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