

# Material Safety Data Sheet

|  |   |
|--|---|
| Section 1: Chemical Product Company Identification |   |
| Product Name                                       | Tolvaptan Impurity 31   |
| CAS No.  | NA  |
| Identified uses                                    | Pharmaceutical Reference Standard   |
| Details of the Supplier Company                    | SynZeal Research Pvt Ltd<br>Plot No. F, Ganesh Industrial Estate<br>423/24/8, MahagujaratInd Estate<br>Sarkhej-Bavla Road,<br>Ahmedabad-382 213.<br>Gujarat, India. |
| Telephone  | +91-7969225400  |

|                                 |  |
|---------------------------------|--|
| Section 2: Chemical Information |  |
| Chemical Name                   | (R)-N-(4-(7-Chloro-5-hydroxy-2,3,4,5-tetrahydro-1H-benzo[b]azepin e-1-carbonyl)phenyl)-2-methylbenzamide |
| CAS No.                         | NA   |
| Molecular Weight                | 434.9  |
| Molecular Formula               | C25H23ClN2O3   |

|                                   |                 |
|-----------------------------------|-----------------|
| Section 3: Hazards Identification |                 |
| <b>Emergency Overview:</b>        |                 |
| Appearance                        | Off White Solid |
| Target Organs                     | NA              |
| <b>Potential Health Effects:</b>  |                 |
| 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 | Tolvaptan Impurity 31 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                   |
| <b>Explosion Limits</b>  |                      |
| 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  |  |
| <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>   |  |
| ADR/RID: No IMDG Marine pollutant: No IATA: No   |  |
| <b>Special precautions for users</b>   |  |
| <b>Further information</b>   |  |

|                                    |                                      |
|------------------------------------|--------------------------------------|
| 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. |  |