

# Material Safety Data Sheet

|                                                           |                                                                                                                                                                     |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Section 1: Chemical Product Company Identification</b> |                                                                                                                                                                     |
| Product Name                                              | Ivacaftor Impurity 7                                                                                                                                                |
| CAS No.                                                   | 1643-39-6                                                                                                                                                           |
| 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                                                                                                                                                      |

|                                        |                                    |
|----------------------------------------|------------------------------------|
| <b>Section 2: Chemical Information</b> |                                    |
| Chemical Name                          | 2-Amino-4,6-di-Tert-Butylphenol    |
| CAS No.                                | 1643-39-6                          |
| Molecular Weight                       | 221.3                              |
| Molecular Formula                      | C <sub>14</sub> H <sub>23</sub> NO |

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

|                                      |                           |
|--------------------------------------|---------------------------|
| <b>Section 4: First Aid Measures</b> |                           |
| 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 | Ivacaftor Impurity 7 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                                  | Grey 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. |  |