

# Safety Data Sheet

|                                                     |                                                                                                                         |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| Section 1 : Chemical Product Company Identification |                                                                                                                         |
| Product Name                                        | Ivacaftor Impurity 25                                                                                                   |
| CAS No.                                             | NA                                                                                                                      |
| 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                                                                                                          |

|                                  |                                                                                                                 |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------|
| Section 2 : Chemical Information |                                                                                                                 |
| Chemical Name                    | N-(4,6-Di- tert-butyl-6- hydroperoxy-3-oxo- cyclohexa-1,4-diene-1-yl)-4-oxo-1,4-dihydro-quinoline-3-carboxamide |
| CAS No.                          | NA                                                                                                              |
| Molecular Weight                 | 424.5                                                                                                           |
| Molecular Formula                | C24H28N2O5                                                                                                      |

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

|                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard Statement:                                                                                                                                          |
| <b>H302:</b> Harmful if swallowed.                                                                                                                         |
| <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.                                                                                 |

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

|                                    |
|------------------------------------|
| Hazard Statement:                  |
| <b>H302:</b> Harmful if swallowed. |

|                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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.                                                                                 |

|                                |                                                                                  |
|--------------------------------|----------------------------------------------------------------------------------|
| 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             | Ivacaftor Impurity 25 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 |  |
|---------|--|

|                                                    |                                    |
|----------------------------------------------------|------------------------------------|
| 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 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                    |                         |
| Conditions to avoid                   | Direct contract to skin |

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

|                                        |    |
|----------------------------------------|----|
| 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                  |  |

|                                     |                    |
|-------------------------------------|--------------------|
| 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

**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 and 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.