# Material Safety Data Sheet (MSDS)

**Effective Date:** **Due Date:**

## Section 1: Chemical Product and Company Identification

| | |
|---|---|
| Product Name | Ivacaftor Impurity 16 |
| CAT No. | KMI006019 |
| CAS No. | NA |
| Identified uses | Pharmaceutical Reference Standard |
| Details of the Supplier Company | K. M. PHARMA SOLUTION PRIVATE LIMITED<br>Unit No.101, Shivam Industrial park,<br>Sarkhej-bavala NH=8A, At-Moraiya, Changodar,<br>Ahmedabad (Gujarat), India-382213 |
| Telephone | +91 9898822121 |

## Section 2: Chemical Information

| | |
|---|---|
| Chemical Name | 4-(3-((2,4-Di-tert-butyl-5-hydroxyphenyl)carbamoyl)-4-oxoquinolin-1(4H)-yl)-4-oxobutanoic acid |
| CAS No. | NA |
| Molecular Weight | 492.6 |
| Molecular Formula | C28H32N2O6 |

## Section 3: Hazards Identification

| | |
|---|---|
| **Emergency Overview:** | |
| Appearance | NA |
| Target Organs | NA |
| **Potential Health Effects:** | |
| Eye (Hazard) | NIL |
| Skin (Hazard) | NIL |
| Ingestion (Hazard) | NIL |
| Inhalation (Hazard) | NIL |
| Chronic (Hazard) | NIL |

## Section 4: First Aid Measures

| | |
|---|---|
| Eye | Wash with plenty of water |
| Skin | Wash with plenty of water |

K.M. Pharma Solution Private Limited



| | |
|---|---|
| Ingestion | Medical assistance for gastric lavage. |
| Inhalation | Remove to fresh air, artificial respiration or oxygen if necessary. |
| Notes to Physician | Ivacaftor Impurity 16 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: Handling and Storage

| | |
|---|---|
| Handling | Wear surgical gloves |
| Storage | ~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 | NA |
| Odor | NA |
| Melting Point | NA |
| pH | NA |
| Vapor Pressure | NA |
| Vapor Density | NA |
| Evaporation Rate | NA |
| Viscosity | NA |
| Boiling Point | NA |

K.M. Pharma Solution Private Limited



| | |
|---|---|
| Decomposition Temp | NA |
| Auto ignition Temp. | NA |
| Flash Point | NA |
| NFPA Rating | NA |
| **Explosion Limits** | |
| Lower | NA |
| Upper | NA |
| Solubility | NA |
| Specific Gravity/Density | NA |

## Section 10: Stability and Reactivity

| | |
|---|---|
| Chemical Stability | ~ChemicalStability |
| Conditions to avoid | Direct contract to skin |
| Incompatibilities with other Materials | Keep away |
| Hazardous Decomposition Products | NIL |
| Hazardous Polymerization | NIL |

## Section 11: Toxicological Information

| | |
|---|---|
| CAS | NA |
| LD50/LC50 | >10,000 mg/kg<br>Remarks: Behavioral:Somnolence (general depressed activity) |
| Carcinogenicity | NIL |
| Epidemiology | NIL |
| Teratogenicity | NIL |
| Reproductive Effects | NIL |
| Neurotoxicity | NIL |
| Mutagencity | NIL |
| Other Studies | NA |

## Section 12 : Ecological Information

Data not available

## Section 13: Disposal Consideration

| | |
|---|---|
| RCRA P-Series | Can be incinerated |

K.M. Pharma Solution Private Limited



| | |
|---|---|
| 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
IATA: 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.

K.M. Pharma Solution Private Limited

