# **Material Safety Data Sheet**

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

| Section 2: Chemical Information |  |
|---------------------------------|--|
| Chemical Name                   | (S)-3,3'-((((3,4-dimethoxybicyclo[4.2.0]octa-1,3,5-trien-7-yl)methyl)az anediyl)bis(propane-3,1-diyl))bis(7,8-dimethoxy-1,3,4,5-tetrahydro-2 H-benzo[d]azepin-2-one) hydrochloride |
| CAS No.                         | NA   |
| Synonyms                        | N-(Demethyl)diithabradine  |
| Molecular Weight                | 715.9:36.5   |
| Molecular Formula               | C41H53N3O8: HCI  |

| Section 3: Hazards Identification      |     |  |
|--|-----|--|
| Emergency Overview:                    |     |  |
| Appearance Off White Hygroscopic Solid |     |  |
| Target Organs                          | NA  |  |
| Potential Health Effects:              |     |  |
| Eye                                    | NIL |  |
| Skin                                   | NIL |  |
| Ingestion NIL                          |     |  |
| nhalation 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 | Ivabradine Dimer Impurity (HCl salt) 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 Hygroscopic Solid |  |
| Odor  | Odor less                   |  |
| Melting Point                               | NA                          |  |
| Н   | 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 Stable              |                         |
| 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                             | NA  |  |  |
| 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 | on 13: Disposal Consideration |  |
|------------------------------------|-------------------------------|--|
| RCRA P-Series                      | Can be incinerated            |  |
| RCRA U-Series                      | NA                            |  |

|         |           | _        |        |       |
|---------|-----------|----------|--------|-------|
| Section | 14: Trans | sport Co | nsider | ation |

## **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 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.