**Aspiro Pharma Limited**
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Web: www.aspiropharma.com
**CIN No.:U24100TG2014PLC092771**

# SAFETY DATA SHEET

## Section 1: Identification

| Section 1, Identification | |
|---|---|
| **GHS Product identifier** | Lidocaine Hydrochloride Injection USP |
| **Recommended use** | Pharmaceutical product |
| **Strengths** | **Preservative free: (single dose vial)**<br>1% (10 mg/mL) 20 mg/2mL, 50 mg/5mL &<br>2% (20 mg/mL) 40 mg/2mL, 100 mg/5mL<br><br>Multi Dose vial:<br>1% (10 mg/mL) 200 mg/20 mL<br>2% (20 mg/ML) |
| **Manufacturer** | **Aspiro Pharma Limited,**<br>Sy. No. 321, Biotech Park, Phase-III,<br>Karkapatla Village, Markook Mandal,<br>Telangana (S), Siddipet (Dist.)-502281, India. |
| **Distributor** | **Camber Pharmaceuticals, Inc**, Piscataway, NJ 08854 |

## Section 2: Hazard(s) Identification

| | |
|---|---|
| **Section 2, Hazard(s)identification**<br>**Classified hazards**<br>**Label elements** | Skin Irrit. 2 H315<br>Eye Irrit. 2 H319 |
| **Hazard statement**<br>**Environment** | H315 - Causes skin irritation<br>H319 - Causes serious eye irritation |

## Section 3: Composition/Information on Ingredients

| Ingredients | CAS |
|---|---|
| Lidocaine Hydrochloride | 6108-05-0 |
| Sodium chloride (adjust tonicity) | 7647-14-5 |
| Sodium hydroxide (adjust pH) | 1310-73-2 |
| Hydrochloric acid (adjust pH) | 7647-01-0 |

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| | |
|---|---|
| Methylparaben (preservative) (for Multi Dose Vials) | 99-76-3 |

| **Section 4: First-Aid Measures** | |
|---|---|
| **Eye Contact** | Rinse with water. Get medical attention if irritation develops and persists. |
| **Skin Contact** | Wash contact areas with soap and water. |
| **Ingestion** | Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident. |
| **Inhalation** | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. No special first aid needed. |
| **Section 5: Fire-Fighting Measures** | |
| **Suitable Extinguishing Media** | Use extinguishing media appropriate for surrounding fire. |
| **Unsuitable Extinguishing Media** | None. |
| **Special protective equipment and precautions for firefighters** | Use standard firefighting procedures and consider the hazards of other involved materials |
| **Section 6: Accidental Release Measures** | |
| **Environmental precautions** | Prevent entry to sewers and public waters. |
| **Methods and materials for containment and cleaning up** | Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations. |
| **Section 7: Handling and Storage** | |
| **Handling** | Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. |
| **Conditions for safe storage,** | Store as directed by product packaging. |

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| | |
|---|---|
| **including any incompatibilities** | None known |
| **Section 8: Exposure Controls/Personal Protection** | |
| Appropriate engineering Control | Local exhaust and general ventilation must be adequate to meet exposure standards |
| **Individual protection measures, such as personal protective equipment** | |
| Eye/face protection | No protection is ordinarily required under normal conditions of use |
| Skin protection<br>Hand protection | Wear suitable working clothes.<br>No protection is ordinarily required under normal conditions of use. |
| Respiratory protection | No protection is ordinarily required under normal conditions of use. |
| **Section 9: Physical and Chemical Properties** | |
| **Physical State** | **Liquid** |
| **Colour** | **A clear, colorless solution** |
| **Odor** | **No data available** |
| **Description** | **Lidocaine Hydrochloride Injection USP, 1% (10 mg/mL):**<br>25 x 2 mL Single-Dose Carton NDC 31722-117-31<br>25 x 5 mL Single-Dose Carton NDC 31722-117-32<br>25 x 30 mL Single-Dose Carton NDC 31722-117-33<br><br>**Lidocaine Hydrochloride Injection USP, 2% (20 mg/mL):**<br>25 x 2 mL Single-Dose Carton NDC 31722-118-31<br>25 x 5 mL Single-Dose Carton NDC 31722-118-32<br><br>**Lidocaine Hydrochloride Injection USP, 1% (10 mg/mL):**<br>25 x 20 mL Multiple-Dose Vials NDC 31722-116-31<br>10 x 20 mL Multiple-Dose Vials NDC 31722-116-32<br>25 x 50 mL Multiple-Dose Vials NDC 31722-116-33<br>10 x 50 mL Multiple-Dose Vials NDC 31722-116-34 |

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| | |
|---|---|
| | **Lidocaine Hydrochloride Injection USP, 2% (20 mg/mL):**<br><br>25 x 20 mL Multiple-Dose Vials NDC 31722-217-31<br>10 x 50 mL Multiple-Dose Vials NDC 31722-217-33<br>25 x 50 mL Multiple-Dose Vials NDC 31722-217-32<br><br>Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. |

## Section 10: Stability and Reactivity

| | |
|---|---|
| **Reactivity** | No data available |
| **Chemical stability** | The product is stable at normal handling and storage conditions |
| **Possibility of hazardous reactions** | Will not occur |
| **Conditions to avoid** | Excessive heat. Freezing. |
| **Incompatible materials** | None known |
| **Hazardous decomposition Products** | None known |

## Section 11: Toxicological Information

| | |
|---|---|
| **Information on Toxicological Effects** | |
| **General Information** | The information included in this section describes the potential hazards of the individual ingredients. |
| **Known Clinical Effects** | The most common adverse effects seen during clinical use of this drug include increase in blood pressure (hypertension), decrease in blood pressure (hypotension), respiratory arrest, troubled breathing, irregular heartbeat (cardiac arrhythmia), slow heart rate (bradycardia), increased heart rate (tachycardia), |
| **Acute Toxicity: (Species, Route, End Point, Dose)** | |
| **SODIUM CHLORIDE**<br>Rat Inhalation LC50/1hr > 42 g/m$^3$<br>Rat Oral LD 50 3g/kg | |
| **Methylparaben**<br>ATE US (oral) 2100 mg/kg | |

## Section 12: Ecological Information

| | |
|---|---|
| **Environmental Overview:** | Environmental properties have not been thoroughly investigated. Releases to the environment should be |

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| | |
|---|---|
| | avoided. |
| **Toxicity:** | No data available |
| **Persistence and Degradability:** | No data available |
| **Bio-accumulative Potential:** | No data available |
| **Mobility in Soil:** | No data available |

## Section 13: Disposal Considerations

| | |
|---|---|
| **Waste treatment methods** | Dispose of contents/container in accordance with local/regional/national/international regulations. |

## Section 14: Transport Information

**In accordance with DOT**
**Not a dangerous good as defined in transport regulations**

## Section 15: Regulatory Information

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

| | |
|---|---|
| **SODIUM CHLORIDE**<br>**Sodium hydroxide**<br>**Hydrochloric acid**<br>**Methylparaben** | Listed on the United States TSCA (Toxic Substances Control Act) inventory |

## Section 16: Other Information

**Issue Date : 05-03-2024**

**Version : 00**

**Further information**

**Revision date: New issue**

**Revision note: New issue**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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