



## SAFETY DATA SHEET

| Section 1: Identification   |  |
|---|--|
| <b>Material</b>   | Decitabine for Injection 50 mg/vial  |
| <b>Recommended use</b>  | Pharmaceutical   |
| <b>Manufacturer</b>   | Hetero Labs Limited Unit VI,<br>Sy. No.: 410 & 411, TSIIC Formulation SEZ, Polepally<br>Village, Jadcherla Mandal, Mahabubnagar – 509301<br>Telangana, India |
| <b>Distributor</b>  | Camber Pharmaceuticals, Inc., Piscataway, NJ 08854   |
| Section 2: Hazard(s) Identification   |  |
| <ul style="list-style-type: none"><li>• Harmful if swallowed</li><li>• Causes severe skin burns and eye damage</li><li>• Causes serious eye damage</li><li>• May cause respiratory irritation</li><li>• Suspected of causing genetic defects</li><li>• May damage fertility or the unborn child</li><li>• Obtain special instructions before use.</li><li>• Do not handle until all safety precautions have been read and understood.</li><li>• Do not breathe dust/fume/gas/mist/vapors/spray<br/>Avoid breathing dust/fume/gas/mist/vapors/spray.</li><li>• Wash hands, forearms and face thoroughly after handling.</li><li>• Do not eat, drink or smoke when using this product</li><li>• Use only outdoors or in a well-ventilated area.</li><li>• Wear protective gloves/protective clothing/eye protection/face protection</li><li>• If swallowed: Call a poison center or doctor if you feel unwell</li><li>• If swallowed: rinse mouth. Do NOT induce vomiting</li><li>• If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower</li><li>• If inhaled: Remove person to fresh air and keep comfortable for breathing</li><li>• IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li><li>• If exposed or concerned: Get medical advice/attention</li><li>• Immediately call a poison center or doctor</li><li>• Call a poison center or doctor if you feel unwell.</li><li>• Specific treatment (see supplemental first aid instruction on this label)</li><li>• Rinse mouth</li><li>• Wash contaminated clothing before reuse</li></ul> |  |



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|---|--|
| Other hazards   | No additional information available  |
| Unknown acute toxicity (GHS US)   | Not applicable   |
| <b>Section 3: Composition/Information on Ingredients</b>                          |  |
| <b>Ingredients</b>  | <b>CAS-No</b>  |
| Acetonitrile  | 75-05-8  |
| Hydrochloric acid   | 7647-01-0  |
| Nitrogen  | 17778-88-0   |
| Potassium Dihydrogen Phosphate  | 7778-77-0  |
| Sodium Hydroxide  | 1310-73-2  |
| Water for injection   | 7732-18-5  |
| <b>Section 4: First-Aid Measures</b>  |  |
| <b>Description of first aid measures</b>  |  |
| <b>Eye contact</b>  | In case of dust contact with eyes, rinse immediately with plenty of water.                                     |
| <b>Skin contact</b>   | Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse |
| <b>Inhalation</b>   | If not breathing, give artificial respiration  |
| <b>Ingestion</b>  | Go into open air and ventilate suspected area  |
| <b>Most important symptoms and effects, both acute and delayed</b>                |  |
| <b>Symptoms/effects after inhalation</b>  | May cause respiratory irritation   |
| <b>Symptoms/effects after skin contact</b>  | Causes severe skin burns.  |
| <b>Symptoms/effects after eye contact</b>   | Causes eye damage  |
| <b>Symptoms/effects after ingestion</b>   | May be harmful if swallowed.   |
| <b>Indication of any immediate medical attention and special treatment needed</b> |  |
| No additional information available   |  |
| <b>Section 5: Fire-Fighting Measures</b>  |  |
| <b>Extinguishing media</b>  |  |
| <b>Suitable extinguishing media</b>   | Use extinguishing media appropriate for surrounding fire   |



|  |   |
|--|---|
| <b>Unsuitable extinguishing media</b>                                      | None.   |
| <b>Special hazards arising from the substance or mixture</b>               |   |
| <b>Fire hazard</b>   | None known  |
| <b>Advice for firefighters</b>   |   |
| <b>Protection during firefighting</b>                                      | Do not enter fire area without proper protective equipment, including respiratory protection. |
| <b>Section 6: Accidental Release Measures</b>                              |   |
| <b>Personal precautions, protective equipment and emergency procedures</b> |   |
| <b>General measures</b>  | No special measures required  |
| <b>For non-emergency personnel</b>   | No additional information available   |
| <b>For emergency responders</b>  |   |
| <b>Environmental precautions</b>   | Prevent entry to sewers and public waters   |
| <b>Methods and material for containment and cleaning up</b>                |   |
| <b>For containment</b>   | Stop the flow of material, if this is without risk.   |
| <b>Methods for cleaning up</b>   | Place in a suitable container and dispose according to local, state and federal regulations   |
| <b>Reference to other sections</b>   | No additional information available   |
| <b>Section 7: Handling and Storage</b>                                     |   |
| <b>Precautions for safe handling</b>                                       | Do not eat, drink or smoke when using this product.   |
| <b>Conditions for safe storage, including any incompatibilities</b>        | Store vials at 20°C to 25°C (68°F to 77°F)  |
| <b>Section 8: Exposure Controls/Personal Protection</b>                    |   |
| <b>Appropriate engineering controls</b>                                    | Local exhaust and general ventilation must be adequate to meet exposure standards.            |
| <b>Hand protection</b>   | Use neoprene or rubber gloves   |
| <b>Eye protection</b>  | In case of dust production: protective goggles  |
| <b>Skin and body protection</b>  | Wear suitable working clothes.  |
| <b>Respiratory Protection</b>  | Wear NIOSH approved respirator when handling  |



### Section 9: Physical and Chemical Properties

#### Information on basic physical and chemical properties

|                    |  |
|--------------------|--|
| Physical state     | Solid (Lyophilized cake or powder)   |
| <b>Description</b> | Decitabine for injection is a sterile, white to almost white lyophilized powder for intravenous use<br>supplied as:<br>50 mg single-dose vial individually packaged in a carton<br>NDC 31722-304-31<br>Store vials at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. |

### Section 10: Stability and Reactivity

|   |   |
|---|---|
| <b>Reactivity</b>                         | No additional information available                             |
| <b>Chemical stability</b>                 | The product is stable at normal handling and storage conditions |
| <b>Possibility of hazardous reactions</b> | Will not occur  |
| <b>Conditions to avoid</b>                | Air contact   |
| <b>Incompatible materials</b>             | None known  |
| <b>Hazardous decomposition products</b>   | None known  |

### Section 11: Toxicological Information

#### Information on toxicological effects

|                                      |                                |
|--------------------------------------|--------------------------------|
| <b>Acute toxicity</b>                | Not classified                 |
| <b>Decitabine for Injection</b>      |                                |
| ATE US (oral)                        | 1295.337 mg/kg body weight     |
| <b>Hydrochloric acid (7647-01-0)</b> |                                |
| LD50 oral rat                        | 238 – 277 mg/kg                |
| LD50 dermal rabbit                   | > 5010 mg/kg                   |
| LC50 Inhalation - Rat                | 1.68 mg/l (Exposure time: 1 h) |
| ATE US (oral)                        | 238 mg/kg body weight          |
| ATE US (vapors)                      | 1.68 mg/l/4h                   |



|   |  |
|---|--|
| ATE US (dust, mist)                               | 1.68 mg/l/4h   |
| <b>Sodium hydroxide (1310-73-2)</b>               |  |
| LD50 oral rat                                     | 140 – 340 mg/kg  |
| <b>Sodium hydroxide (1310-73-2)</b>               |  |
| LD50 dermal rabbit                                | 1350 mg/kg   |
| ATE US (dermal)                                   | 1350 mg/kg   |
| <b>Hydrochloric acid (7647-01-0)</b>              |  |
| <b>IARC group</b>                                 | 3 - Not classifiable   |
| <b>Reproductive toxicity</b>                      | May damage fertility or the unborn child   |
| <b>STOT - single exposure</b>                     | May cause respiratory irritation.  |
| <b>STOT - repeated exposure</b>                   | Not classified   |
| <b>Aspiration Hazard</b>                          | Not classified   |
| <b>Section 12: Ecological Information</b>         |  |
| <b>Toxicity</b>                                   |  |
| <b>Sodium hydroxide (1310-73-2)</b>               |  |
| LC50 - Fish [1]                                   | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])                            |
| <b>Persistence/Degradability</b>                  | No additional information available  |
| <b>Bioaccumulation potential</b>                  | No additional information available  |
| <b>Mobility in soil</b>                           | No additional information available  |
| <b>Other Adverse Effects</b>                      | No additional information available  |
| <b>Section 13: Disposal Considerations</b>        |  |
| <b>Waste treatment methods</b>                    |  |
| <b>Product/Packaging disposal recommendations</b> | Dispose of contents/container in accordance with local/regional/national/international regulations |



### Section 14: Transport Information

#### Department of Transportation (DOT)

In accordance with DOT – Not regulated

In accordance with IATA – Not regulated

In accordance with IMDG – Not regulated

### Section 15: Regulatory Information

#### US State regulations

|                                      |  |
|--------------------------------------|--|
| <b>Hydrochloric acid (7647-01-0)</b> | U.S. - Massachusetts - Right To Know List      |
|                                      | U.S. - Pennsylvania - RTK (Right to Know) List |
| <b>Sodium hydroxide (1310-73-2)</b>  | U.S. - Massachusetts - Right To Know List      |
|                                      | U.S. - Pennsylvania - RTK (Right to Know) List |

### Section 16: Other Information

**Issue Date : 06-09-2024**

**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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