SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	**Lenalidomide Capsules 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg and 25 mg** Pharmaceutical product
Manufacturer	**Hetero Labs Limited Unit V,** Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 INDIA
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification: Classification of the substance or mixture	Drugs in the finished state and intended for the final user are not subject to labeling in the US. Please refer the prescribing/packaging information.
GHS Classification	STOT-R1: H372; RT1B: H360D; Carc2: H351

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Lenalidomide	191732-72-6
Anhydrous Lactose	63-42-3
Croscarmellose Sodium	74811-65-7
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6

Section 4: First-Aid Measures	
Ingestion	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Unsuitable Extinguishing Media	None known.
Specific hazards arising from the the substance or mixture	No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/ Explosivity	Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
Protective equipment and precautions for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.
Section 6: Accidental Release Measures	
Personal precautions	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust.
Environmental Precautions	Do not empty into drains. Avoid release to the environment.
Methods and materials for containment and cleaning up	If capsules are broken or crushed, DO NOT RAISE DUST. Surround spill or powder with absorbents and

	place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.

Section 7: Handling and Storage

Storage	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

Engineering Controls	None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.
Personal protection equipment	
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent,

	wear gloves that provide protection against the solvent.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

Section 9: Physical and Chemical Properties

Physical Form	Capsule
Description	Lenalidomide Capsules 2.5 mg: Pink opaque cap and white opaque body, size '4' hard gelatin capsules imprinted with 'H' on cap and 'L1' on body, filled with off white to pale yellow color powder. Bottles of 28 NDC 31722-0257-28 Bottles of 100 NDC 31722-0257-01 Lenalidomide Capsules 5 mg: White opaque cap and white opaque body, size '2' hard gelatin capsules imprinted with 'H' on cap and 'L2' on body, filled with off white to pale yellow color powder. Bottles of 28 NDC 31722-0258-28 Bottles of 100 NDC 31722-0258-01 Lenalidomide Capsules 10 mg: Orange opaque cap and white opaque body, size '0' hard gelatin capsules imprinted with 'H' on cap and 'L4' on body, filled with

	off white to pale yellow color powder. Bottles of 28 NDC 31722-0259-28 Bottles of 100 NDC 31722-0259-01 Lenalidomide Capsules 15 mg: Red opaque cap and white opaque body, size '0' hard gelatin capsules imprinted with 'H' on cap and 'L5' on body, filled with off white to pale yellow color powder. Bottles of 21 NDC 31722-0260-21 Bottles of 100 NDC 31722-0260-01 Lenalidomide Capsules 20 mg: Brown opaque cap and white opaque body, size '0' hard gelatin capsules imprinted with 'H' on cap and 'L6' on body, filled with off white to pale yellow color powder. Bottles of 21 NDC 31722-0261-21 Bottles of 100 NDC 31722-0261-01 Lenalidomide Capsules 25 mg: White opaque cap and white opaque body, size '0' hard gelatin capsules imprinted with 'H' on cap and 'L7' on body, filled with off white to pale yellow color powder. Bottles of 21 NDC 31722-0262-21 Bottles of 100 NDC 31722-0262-01

Section 10: Stability and Reactivity

Reactivity	No information identified.
Chemical stability	Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on

	package.
Possibility of Hazardous Reactions	Not expected to occur.
Conditions to Avoid	Avoid extreme temperatures.
Incompatible materials	Strong oxidizers.
Hazardous Decomposition products	No information identified.

Section 11: Toxicological Information

Information on toxicological effects

Route of entry: May be absorbed by inhalation, skin or eye contact and ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Cellulose	LC50	Inhalation	Rat	>5800 mg/m³/4h
	LD50	Oral	Rat	>5000 mg/kg
	LD50	Dermal	Rabbit	>2000 mg/kg
Lenalidomide	Minimum Lethal Dose	Oral	Rat/Mouse	>2000 mg/kg
	Minimum Lethal Dose	Intravenous	Rat/Mouse	>40 mg/kg
Magnesium Stearate	LC50	Inhalation	Rat	>2000 mg/m³

Irritation/Corrosion	No data available.
Sensitization	No data available.
STOT-single exposure	No data available.

Section 12: Ecological Information

Toxicity	Avoid release into the environment.
Persistence and Degradability	No data available.
Bioaccumulative Potential	No data available.
Mobility in Soil	No data available.
Results of PBT and vPvB assessment:	Not performed.
Other adverse effects	No data available.

Section 13: Disposal Considerations	
Waste treatment methods	Dispose of wastes by appropriately permitted chemical waste incinerator in accordance to prescribed federal, state, and local guidelines. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or onsite wastewater treatment facility.
Section 14: Transport Information	
Transport:	This product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Due to lack of data, avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
Section 15: Regulatory Information	
This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.	

Section 16: Other Information

Issue Date : 15-03-2023

Version : 01

Further information

Revision date: 15-03-2023

Revision note: 01 – Excipient details included in section 3.

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.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.