SAFETY DATA SHEET

Section 1: Identification	
Material	**Pomalidomide Capsules, 1 mg, 2 mg, 3 mg and 4 mg**
Recommended use	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	
Hazard Statements	H360D - May damage the unborn child. H373 - May cause damage to hematological, neurological and gastrointestinal system through prolonged or repeated exposure. H351 - Suspected of causing cancer.
Precautionary Statements	P201 - Obtain special instructions before use. P260 - Do not breathe dust. P281 – Use personal protective equipment are required. P308+ P31 – If exposed or concerned: get medical advice/attention. P405 - Store locked up. P501 – Dispose of contents/container to location in accordance with local/regional/national/international regulations.
Other hazards	The most commonly reported effects in clinical trials with pomalidomide include potentially severe hematological toxicity. (e.g., neutropenia, thrombocytopenia, anaemia), rash, constipation, fatigue, muscle pain, paresthesia, peripheral edema, fever, dizziness and headache. It may also be associated with an increased risk of thrombotic events. No human studies of pregnancy outcomes after exposure to pomalidomide were identified. However, because it is an analogue of thalidomide (a known human teratogen), causes embryo/fetotoxicity in rats, and is teratogenic to both rats and rabbits, pomalidomide is considered a probable human developmental toxicant. An increased incidence of second primary malignancies (SPMs) was seen in certain cancer patients treated with pomalidomide in combination with a corticosteroid in comparison to the corticosteroid alone. Although SPM rates were low overall, the

	data suggest that a potential for pomalidomide to increase neoplasms cannot be excluded if accidental exposure occurs.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Pregelatinized starch	9005-25-8
Mannitol	69-65-8
Microcrystalline Cellulose	9004-34-6
Sodium Stearyl Fumarate	4070-80-8

Section 4: First-Aid Measures	
Description of first aid measures	
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.
Skin contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, 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.
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.
Indication of immediate medical attention and special treatment needed, if necessary	Treat symptomatically and supportively. Exposure may increase the risk of infections as this substance is an immune modulator. Substance may cause birth defects.

Section 5: Fire-Fighting Measures	
Extinguishing Media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Special hazards arising from the substance or mixture	No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Flammability/Explosivity	No information identified. High concentrations of finely divided organic particles can explode if ignited.
Advice 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, protective equipment and emergency procedures	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment area should be adequately ventilated. Do not breathe dust. Consider the use of appropriate respiratory protection.
Environmental Precautions	Do not empty into drains. Avoid release to the environment.
Methods and material 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	Storage: Store at 20°C to 25°C (68°F to77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
Section 8: Exposure Controls/Personal Protection	
Exposure/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 of the active ingredient (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 substance, 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.
Respiratory protection	None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly won powered air purifying respiratory equipped with HEPA filters or combination filters, should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air supplied respiratory if there

	is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
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.
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.
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.
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	Pomalidomide Capsules, 1 mg are opaque, white cap and opaque white body, hard gelatin capsules imprinted with 'H' on cap and 'P1' on body, filled with pale yellow to yellowish color powder. They are supplied as follows:

Bottles of 21 Capsules	NDC 31722-770-21
Bottles of 100 Capsules	NDC 31722-770-01
Carton of 60 capsules (6 x 10 unit-dose)	NDC 31722-770-32

Pomalidomide Capsules, 2 mg are opaque, white cap and opaque brown body, hard gelatin capsules imprinted with 'H' on cap and

<table>
<tr><td></td><td>‘P2’ on body, filled with pale yellow to yellowish color powder. They are supplied as follows:
<table>
<tr><td>Bottles of 21 Capsules</td><td>NDC 31722-771-21</td></tr>
<tr><td>Bottles of 100 Capsules</td><td>NDC 31722-771-01</td></tr>
<tr><td>Carton of 60 capsules (6 x 10 unit-dose)</td><td>NDC 31722-771-32</td></tr>
</table>
Pomalidomide Capsules, 3 mg are opaque, white cap and opaque pink body, hard gelatin capsules imprinted with ‘H’ on cap and ‘P3’ on body, filled with pale yellow to yellowish color powder. They are supplied as follows:
<table>
<tr><td>Bottles of 21 Capsules</td><td>NDC 31722-772-21</td></tr>
<tr><td>Bottles of 100 Capsules</td><td>NDC 31722-772-01</td></tr>
<tr><td>Carton of 60 capsules (6 x 10 unit-dose)</td><td>NDC 31722-772-32</td></tr>
</table>
Pomalidomide Capsules, 4 mg are opaque, white cap and opaque white body, hard gelatin capsules imprinted with ‘H’ on cap and ‘P4’ on body, filled with pale yellow to yellowish color powder. They are supplied as follows:
<table>
<tr><td>Bottles of 21 Capsules</td><td>NDC 31722-773-21</td></tr>
<tr><td>Bottles of 100 Capsules</td><td>NDC 31722-773-01</td></tr>
<tr><td>Carton of 60 capsules (6 x 10 unit-dose)</td><td>NDC 31722-773-32</td></tr>
</table>
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].</td></tr>
<tr><th colspan="2">Section 10: Stability and Reactivity</th></tr>
<tr><td>Reactivity</td><td>No information identified.</td></tr>
<tr><td>Chemical stability</td><td>Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.</td></tr>
<tr><td>Possibility of hazardous reactions</td><td>Not expected to occur.</td></tr>
<tr><td>Conditions to avoid</td><td>Avoid extreme temperatures.</td></tr>
</table>

Incompatible materials	Strong oxidizer (pomalidomide).
Hazardous decomposition products	No information identified.

Section 11: Toxicological Information	
Irritation/Corrosion	No data available.
Sensitization	No data available.
STOT-single exposure	Clinical signs of acute toxicity in rodents treated with pomalidomide included increased breathing rate, lethargy, piloerection and eyelid closure.
STOT-repeated exposure/Repeat-dose toxicity	No significant effects were observed in rats orally treated with pomalidomide. The following data were identified in rats: NOAEL (28-days; oral) = 2000 mg/kg/day. NOAEL (13-week; oral) = 1500 mg/kg/day. NOAEL (6-months; oral) = 1000 mg/kg/day. Monkeys were significantly more sensitive to the effects of pomalidomide in comparison to rats. Overall, the principal adverse effects were on the hematopoietic and lymphoid systems. NOAEL (28 days; oral) = 0.2 mg/kg/day. Decreased white blood cell count was observed (day 14-21) at the 2 mg/kg/day dose. NOAEL (13 week; oral) = 0.2 mg/kg/day. Hematological and acute immunological toxicity (systemic inflammation) were observed at ≥ 2 mg/kg/day. Target organs included the bone marrow, spleen and thymus. NOAEL (9- month; oral) = 0.1 mg/kg/day. Immunosuppressive effects (decreased peripheral blood lymphocytes, lymphoid depletion, and hypocellularity of bone marrow) and infection were noted at 1 mg/kg/day.
Reproductive toxicity	In a fertility and early embryonic development study in rats, drug-treated males were mated with untreated or treated females. Pomalidomide was administered to males and females at doses of 25 to 1000 mg/kg/day. When treated males were mated with treated females, there was an increase in post-implantation loss and a

	decrease in mean number of viable embryos at all dose levels. There were no other effects on reproductive functions or the number of pregnancies. The lowest dose tested in animals resulted in an exposure (AUC) approximately 100-fold of the exposure in patients at the recommended dose of 4 mg/day. When treated males on this study were mated with untreated females, all uterine parameters were comparable to the controls. Based on these results, the observed effects were attributed to the treatment of females.
Developmental toxicity	Pomalidomide was teratogenic in both rats and rabbits in the embryofetal developmental studies, when administered during the period of organogenesis. In rats, pomalidomide was administered orally to pregnant animals at doses of 25 to 1000 mg per kg per day. Fetal malformations were observed at all dose levels. There was no maternal toxicity observed in this study. The lowest dose in rats resulted in an exposure (AUC) approximately 85-fold of the human exposure at the recommended dose of 4 mg per day. Other embryofetal toxicities included increased resorptions leading to decreased number of viable fetuses. In rabbits, pomalidomide was administered orally to pregnant animals at doses of 10 to 250 mg per kg per day. Fetal malformations were seen at all doses. No maternal toxicity was observed at the low dose (10 mg per kg per day) that resulted in cardiac anomalies in fetuses; this dose resulted in an exposure (AUC) approximately equal to that reported in humans at the recommended dose of 4 mg per day. Additional embryofetal toxicity included increased resorption.
Genotoxicity	Pomalidomide was not mutagenic or clastogenic in a battery of tests, including the bacteria reverse mutation assay (Ames test), an in vitro chromosomal aberration assay using human peripheral blood lymphocytes and an in vivo micronucleus test in orally treated rats administered doses up to 2000 mg/kg/day.
Carcinogenicity	No carcinogenicity studies with pomalidomide have been conducted. One of twelve monkeys dosed with 1 mg/kg of pomalidomide (an exposure comparable to about 15 times the exposure at the RHD) developed acute myeloid leukemia in a 9 month repeat-dose toxicology study. No other components of the product present at

	levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data available.
Section 12: Ecological Information	
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.
Note	The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.
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	Based on the available data, 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

Safety, health and environmental regulations/legislation specific for the substance or mixture	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.
Chemical safety assessment	Not conducted.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

Section 16: Other Information

Issue Date: 27-01-2026

Version: 00

Further information

Revision date: NA

Revision notes: NA

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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