SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	Raltegravir Tablets 400 mg To Treat HIV infection in adults and children
Manufacturer	**Hetero Labs Limited, Unit-III** **22-110, IDA,** Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

Section 2: Hazard(s) Identification	
Hazard Statement	Causes Skin Irritation Causes eye irritation May cause respiratory irritation
Precautionary Statement	Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection If on skin: Wash with plenty of soap and water
Other Hazards	None

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS No.**
Raltegravir Potassium	871038-72-1
Microcrystalline Cellulose	9004-34-6
Lactose Monohydrate	64044-51-5
Sodium Stearyl Fumarate	4070-80-8
Polyethylene Oxide	25322-68-3
Magnesium Stearate	557-04-0
Opadry II White	NA

Section 4: First-Aid Measures	
Description of first aid measures	
Eye contact	Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.
Skin contact	Rinse skin thoroughly with large amounts of water. Remove

	contaminated clothing and shoes and call a physician.
Inhalation	Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation
Ingestion	Wash out mouth with water; Do NOT induce vomiting; call a physician
Most important symptoms and effects, both acute and delayed	The most important known symptoms and effects are described in the labelling
Indication of any immediate medical attention and special treatment needed	Treat symptomatically.

Section 5: Fire-Fighting Measures

Extinguishing media	
Suitable extinguishing media	Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher
Special hazards arising from the substance or mixture	During combustion, may emit irritant fumes.
Advice for firefighters	Wear self-contained breathing apparatus and protective clothing

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.
Environmental precautions	Try to prevent further leakage or spillage. Keep the product away from drains or water courses
Methods and materials for containment and cleaning up	Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol

Section 7: Handling and Storage

Precautions for safe handling	Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation
Conditions for safe storage, including any incompatibilities	Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.
Storage	Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). See USP Controlled Room Temperature.

Section 8: Exposure Controls/Personal Protection	
Control parameters	
Components with workplace control parameters	This product contains no substances with occupational exposure limit values.
Exposure controls	
Engineering controls	Ensure adequate ventilation. Provide accessible safety shower and eye wash station.
Personal protective equipment	
Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Description	Raltegravir Tablets 400 mg are white to off white, oval biconvex film coated tablets debossed with "H l" on one side and '4' on other side of the tablet. They are supplied as follows Bottle of 60 Tablets NDC 31722-584-60
Section 10: Stability and Reactivity	
Reactivity	No data available.
Chemical stability	Stable under recommended storage conditions
Possibility of hazardous reactions	No data available
Conditions to avoid	No data available.
Incompatible materials	Strong acids/alkalis, strong oxidising/reducing agents
Hazardous decomposition products	Under fire conditions, may decompose and emit toxic fumes Other decomposition products - no data available
Section 11: Toxicological Information	
Information on toxicological effects	
Acute toxicity	Not classified based on available information **Components:** **Raltegravir:** Acute oral toxicity: LD50 (Mouse, male and female): > 2,000 mg/kg
Section 12: Ecological Information	
Toxicity **Toxicity to fish:**	Components: Raltegravir LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:	Method: OECD Test Guideline 203 LC50 (Cyprinodon variegatus (sheepshead minnow)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to microorganisms:	EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 NOEC : 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Persistence and degradability **Biodegradability:**	Components: Raltegravir Result: rapidly degradable Biodegradation: 50 % Exposure time: 9 d Method: OECD Test Guideline 302B
Stability in water:	Hydrolysis: < 10 % (5 d) Method: OECD Test Guideline 111
Bioaccumlative potential	Components: Raltegravir Partition coefficient: n-octanol/water: log Pow: -0.328
Mobility in soil	No data available
Results of PBT and vPvB assessment	**Product** Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Endocrine disrupting properties	**Product** Assessment: The substance/mixture does not contain components consid-ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Other adverse effects	No data available.

Section 13: Disposal Considerations

Waste treatment methods	
Product	Dispose substance in accordance with prevailing country, federal, state and local regulations
Contaminated packaging	Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

Section 14: Transport Information

DOT (US): - Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture	
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	Not applicable
Regulation (EU) No 2024/590 on substances that de-plete the ozone layer	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu-tants (recast)	Not applicable
Regulation (EU) No 649/2012 of the European Parlia-ment and the Council concerning the export and import of dangerous chemicals	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	Not applicable

Section 16: Other Information

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Version: 00

Further information

Revision date: 00

Revision note: 00.

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