HETERO LABS LIMITED
"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http//www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification	
Material	**Valacyclovir Hydrochloride Tablets, 500 mg and 1000 mg**
Manufacturer	**Hetero Labs Limited** Unit V, APIIC Formulation SEZ, Survey. No 439, 440, 441 & 458, Polepally Village, Jadcherla (Mandal), MahaboobNagar (District). Pin-509301 Telangana, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification	
Fire and Explosion	Expected to be non-combustible.
Health	Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Caution - Pharmaceutical agent. Possible effects of overexposure in the workplace include: headache; nausea.
Environment	No environmental hazards have been identified for this material.

Section 3: Composition / Information on Ingredients

Section 3, Composition/information on ingredients	
Ingredients	Valacyclovir Hydrochloride Monohydrate
CAS	124832-27-5

Section 4: First-Aid Measures

Section 4, First-aid measures	
Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures	
Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water or foam extinguishers are recommended. Carbon dioxide or dry powder extinguishers may be ineffective.
Special Fire fighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging,

	self contained breathing apparatus and full protective equipment are recommended for fire-fighters. If possible, contain and collect fire fighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

Section 7: Handling and Storage

Section 7, Handling and storage

HANDLING	
General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
STORAGE	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in a well-closed container as defined in the USP.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

None required for normal handling. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties

Physical Form	**Valacyclovir Hydrochloride Tablets, 500 mg** Blue, film-coated, capsule shaped tablets, debossed with 'I' on one side and '86' on other side. Bottle of 30 Tablets (NDC 31722-704-30) Bottle of 60 Tablets (NDC 31722-704-60) Bottle of 90 Tablets (NDC 31722-704-90) Bottle of 100 Tablets (NDC 31722-704-01) Bottle of 500 Tablets (NDC 31722-704-05) Blister pack of 10x10's (Alu-PVC) (NDC 31722-704-32) Blister pack of 10x10's (Alu-PVC/PVdC) (NDC 31722-704-34) **Valacyclovir Hydrochloride Tablets, 1000 mg** White, film-coated, capsule shaped tablets, debossed with 'I' on one side and '87' on other side. Bottle of 30 Tablets (NDC 31722-705-30) Bottle of 60 Tablets (NDC 31722-705-60) Bottle of 90 Tablets (NDC 31722-705-90)

	Bottle of 100 Tablets (NDC 31722-705-01)
	Bottle of 500 Tablets (NDC 31722-705-05)

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Oral Toxicity	Not expected to be toxic following ingestion.
Skin Effects	No studies have been conducted.
Eye Effects	No studies have been conducted.
Target Organ Effects	Adverse effects might occur in the following organ(s) following Over exposure: kidney. Assessment based upon information from animal studies.
Sensitisation	Potential for inducing allergic reactions via the dermal or respiratory route is not known.
Genetic Toxicity	Genetic toxicity is not expected under occupational exposure conditions based upon negative results in laboratory assays. No evidence of DNA damage occurred in the following assay(s): bacterial mutation assay (Ames).
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions based upon negative results in laboratory assays.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a nucleoside analogue. This product is intended for the treatment of viral infection. Adverse effects of overexposure might include: headache; nausea.
Other Adverse Effects	None known for occupational exposure.

Section 12: Ecological Information

Section 12: Ecological Information	
Summary	This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release. Specific information on the active pharmaceutical ingredient is provided below.
ECOTOXICITY	
Aquatic	
*** Activated Sludge Respiration**	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 100 mg/l, 3 Hours, Activated sludge
*** Microbial Growth Inhibition**	This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

	Minimum Inhibition Concentration: > 1000 mg/l, Chaetomium globosum > 1000 mg/l, Aspergillus flavus > 1000 mg/l, Nostoc sp. > 1000 mg/l, Azotobacter chroococcum > 1000 mg/l, Pseudomonas fluorescens
*** Daphnid**	This material contains an active pharmaceutical ingredient that is not toxic to daphids. EC50:340 mg/l, 48 Hours, Daphnia magna, Static test NOEL:56 mg/l, 48 Hours, Daphnia magna, Static test
MOBILITY	
*** Solubility**	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
*** Volatility**	This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.
*** Partitioning**	This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
PERSISTENCE/DEGRADATION	
Hydrolysis	This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism. Half-Life, Neutral:55.92 Hours, Measured Half-Life, Basic:15.13 Hours, Measured Half-Life, Acidic:68.38 Days, Measured Hydrolysis Product(s) - By ACYCLOVIR Products
*** Photolysis**	This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation. UV/Visible Spectrum: 264
*** Biodegradation**	This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment. Aerobic - Ready Percent Degradation: 0.08 %, 28 days, Modified Sturm test. Aerobic - Inherent Percent Degradation: 100 %, 14 days, Modified Zahn Wellens, Activated sludge.
*** BIOACCUMULATION**	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

Section 13: Disposal Considerations

Section 13: Disposal Considerations	
Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

Section 14: Transport Information

Section 14: Transport Information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

Section 15: Regulatory Information

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The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status	Exempt

Section 16: Other Information

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The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.