



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	
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Material	Entecavir Tablets, 0.5 mg and 1.0 mg
Manufacturer	Hetero Labs Limited, Unit V, Polepally, Jadcherla Mahaboob Nagar-509 301, India.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s) identification	
Classification	Suspected of causing cancer. May damage fertility (male reproductive toxicity) . May damage the unborn child (developmental toxicity) . May cause harm to breast-fed children. May cause respiratory irritation (liver, spleen, thymus, lymph nodes, bone marrow, testes, gastrointestinal tract)
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Section 3, Composition/information on ingredients	
Ingredients	CAS
Entecavir Monohydrate	209216-23-9
Section 4: First-Aid Measures	
Section 4, First-aid measures	
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical attention/advice.
Inhalation	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
Eye Contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.



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NOTES TO HEALTH PROFESSIONALS

Notes to Physician

Refer to Section 11. Employees with Hepatitis B and/or HIV may develop viral resistance to anti-viral drugs of this class depending on the nature and duration of exposure to this material. Based on the opportunity for exposure to this material, employees with Hepatitis B and/or HIV should consult with an occupational health physician to address any potential concerns.

Medical Surveillance

The need for a pre-placement physical examination and history for employees with potential exposure to this compound is to be evaluated by a physician that is thoroughly knowledgeable about both the toxicity of this compound and the extent of work place exposure. Baseline testing would include: a complete blood count with differential, a blood test for liver function, a blood test for kidney function, lung function test. Based on opportunity for exposure and duration of exposure a periodic follow-up examination may be considered. For employees with Hepatitis B and/or HIV handling this material, Medical Surveillance may include testing and/or counseling regarding use of additional personal protective equipment, additional engineering controls, and/or alternative work methods. Employees who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health. Pregnant or nursing women should avoid exposure.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Not available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Not available Protective equipment: Use personal protective equipment. In the event of fire, wear self- contained breathing apparatus. Hazardous Combustion Products: carbon oxides (COx), nitrogen oxides (NOx)
Other information	Decontaminate protective clothing and equipment before reuse.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Wear respiratory protection. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental Precautions	Prevent release to drains and waterways. Prevent release to the environment.
Clean-up Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste



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	materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials. Spill prevention procedures and a spill response procedure should be implemented.
Section 7: Handling and Storage	
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Handling	Avoid exposure - obtain special instructions before use. Avoid formation of dust and aerosols. When handling broken or crushed tablets or capsules, ensure worker exposure is below the recommended exposure limit. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage	Store Entecavir Tablets Store at 20 to 25°C (68 to 77° F) [see USP Controlled Room Temperature].
Section 8: Exposure Controls/Personal Protection	
Section 8, Exposure controls/personal protection	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.	
Section 9: Physical and Chemical Properties	
Section 9, Physical and chemical properties	
Physical Form	Entecavir Tablets 0.5mg White to off white, triangle shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '110' on the other side. Bottle of 30 Tablets (NDC 31722-833-30) Bottle of 90 Tablets (NDC 31722-833-90) Entecavir Tablets 1.0 mg Pink, triangle shaped, biconvex, film-coated tablets, debossed with 'J' on one side and '111' on the other side. Bottle of 60 Tablets (NDC 31722-834-30) Bottle of 500 Tablets (NDC 31722-834-90)
Section 10: Stability and Reactivity	
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Stable under recommended storage conditions.	
Section 11: Toxicological Information	
Carcinogenesis	Entecavir 2 Years oral (daily) mouse study : Tumor NOAEL = 0.004 mg/kg (males and females).



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[tumor organs: lungs, cardiovascular, liver] Effects include: increase in food consumption, death, decreased weight gain, decreased body weight. Effects considered species specific and may not be relevant for humans include: lung toxicity, The relevance for human risk assessment is unknown.

2 Years oral (daily) rat study : Tumor NOAEL = 0.2 mg/kg (males and females). [tumor organs: liver, brain, skin, uterus/cervix] Effects include: decreased body weight.

Microscopic changes were observed in the following organs: pancreas, kidney, testes.

Carcinogenicity Assessment

This material has limited evidence of carcinogenic potential. Several studies were conducted.

It is carcinogenic in rodents after long term chronic exposure. The relevance to humans is unknown.

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Advice On Disposal And Packaging: Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A



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DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other information

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.