



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	
GHS Product identifier	Abacavir Sulfate Oral Solution, 20 mg/mL
Trade Name	Not applicable
Other means of identification Synonyms	Abacavir Sulfate Oral solution, Finished product
Recommended use	Abacavir Sulfate Oral Solution in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus (HIV-I) infection.
Manufacturer	Hetero Labs Limited, 22-110, IDA, Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Section 2, Hazard(s)identification	This product is classified as non-flammable.
Classified hazards	
Label elements	
Hazard statement	No information is available about the potential of this product to produce adverse environmental effects.
Environment	
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Abacavir sulfate	188062-50-2
Noncrystallizing sorbitol solution	50-70-4
Sodium citrate	6132-04-3
Methylparaben	99-76-3
Propylparaben	94-13-3
Propylene glycol	57-55-6
Anhydrous citric acid	77-92-9
Saccharin sodium	6155-57-3



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Ingredients	CAS
Strawberry FL N&A WILD TYPE # 958 K	---
Banana Flavor ART # 11090 K	---
Section 4: First-Aid Measures	
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.
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.
Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.



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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	No special requirements needed.
Special Firefighting 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 firefighters. If leakage of this material occurs, contain and collect 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	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
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	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.
Conditions for safe storage, including any incompatibilities	Store at 20 to 25°C (68° to 77°F) [see USP Controlled Room Temperature].



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Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Components	Type	
	ACGIH TLV	OSHA PEL
Abacavir sulfate	8 HR TWA 600 mcg/m ³	Not applicable
Noncrystallizing sorbitol solution	Not available	Not available
Sodium citrate	Not available	Not available
Methylparaben	Not available	Not available
Propylparaben	Not available	Not available
Propylene glycol	TWA 10(mg/m ³) from AIHA	Not available
Anhydrous citric acid	10 mg/m ³ TWA	15 mg/m ³ TWA
Saccharin sodium	Not available	Not available
Strawberry FL N&A WILD TYPE # 958 K	Not available	Not available
Banana Flavor ART # 11090 K	Not available	Not available
Individual protection measures, such as personal protective equipment		
Eye protection	Wear approved safety glasses with side shields if eye contact is possible.	
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. Eye wash and shower stations should be available.	
Section 9: Physical and Chemical Properties		
Section 9, Physical and chemical properties		
Physical State	Liquid	
Form	Oral solution	
Colour	Clear to opalescent, yellowish	
Odor	Not available	



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Description	Abacavir sulfate Oral solution 20mg/ml Clear to opalescent, yellowish, strawberry banana flavored liquid filled in 250cc HDPE opaque bottles. 240ml FSE Wad (NDC 31722-562-24)
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Section 10: Stability and Reactivity

Section 10, Stability and reactivity	
Reactivity	Not available
Chemical stability	This product is expected to be stable.
Reactions	Not available
Conditions to avoid	None for normal handling of this product.
Incompatible materials	Not available
Hazardous decomposition	Not available

Section 11: Toxicological Information

Information on likely routes of exposure	
Inhalation	No studies have been conducted.
Skin contact	Irritation is not expected following direct contact.
Eye contact	Severe irritation might occur following direct contact with eyes. Permanent damage occurred after direct application. Assessment based upon effects of individual components.
Ingestion	No data available

Acute toxicity :

Components	LD50 oral	LD50 dermal	LD50 inhalation
Noncrystallizing sorbitol solution	17,800 mg/kg-mouse 7100 mg/kg -Rat	Not available	Not available
Sodium citrate	Not available	Not available	Not available
Methylparaben	>8000 mg/kg-mouse	Not available	Not available
Propylparaben	7500 mg/kg-mouse	Not available	Not available
Propylene glycol	18500 mg/kg -Rabbit	20800 mg/kg -Rabbit	Not available
Anhydrous citric acid	3000 mg/kg -Rat 7000mg/kg-Rabbit	Not available	Not available
Saccharin sodium	Not available	Not available	Not available



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Components	LD50 oral	LD50 dermal	LD50 inhalation
Strawberry FL N&A WILD TYPE # 958 K	Not available	Not available	Not available
Banana Flavor ART # 11090 K	Not available	Not available	Not available
Skin corrosion/irritation		Allergic skin reactions might occur following dermal exposure.	
Respiratory or skin sensitization		No data available	
Germ cell mutagenicity		No data available	
Carcinogenicity		Abacavir, the active substance in this product, produced carcinogenic effects in a lifetime study in mice; a lifetime study in rats. High concentrations or doses administered over an extended period of time were required to produce adverse effects	
Reproductive toxicity		Not expected to produce adverse effects on fertility or development under occupational exposure conditions.	
Effects on Fertility:		No specific target organ effects have been identified.	
Specific target organ toxicity - single exposure (GHS)		No data available	
Specific target organ toxicity - repeated exposure (GHS)		No data available	
Aspiration hazard		No data available	

Section 12: Ecological Information

Toxicity : Contains a substance which causes risk of hazardous effects to the environment.

Components	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Daphnia Magna(Water flea)
Noncrystallizing sorbitol solution	Not available	Not available	Not available	Not available
Sodium citrate	Not available	Not available	Not available	Not available
Methylparaben	Not available	Not available	Not available	Not available
Propylparaben	Not available	Not available	Not available	Not available
Propylene glycol	Not available	>5000 mg/l 24 hours	Not available	>1000mg/l 48 hours



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Components	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Daphnia Magna(Water flea)
Anhydrous citric acid	Not available	Not available	Not available	Not available
Saccharin sodium	Not available	Not available	Not available	Not available
Strawberry FL N&A WILD TYPE # 958 K	Not available	Not available	Not available	Not available
Banana Flavor ART # 11090 K	Not available	Not available	Not available	Not available

Section 13: Disposal Considerations

Waste treatment methods	
Disposal instructions	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.
Local disposal regulations	No data available
Hazardous waste code	No data available
Waste from residues I unused	No data available
Contaminated packaging	No data available

Section 14: Transport Information

DOT	
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number	Not applicable
IATA	
UN-Number Proper shipping name Hazard class Description	Not applicable
IMDG	
UN-Number Proper shipping name Hazard class Reportable quantity Description Emergency response guide Number	Not applicable



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Section 15: Regulatory Information

U.S State regulations	
California Proposition 65: This product does not content any proposition 65 chemicals	

Section 16: Other Information

Section 16, Other information

Issue Date : 13-09-2017

Version : 01

Further information

Revision date: New issue

Revision note: New issue

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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