

Safety Data Sheet according to Regulation (EC) No. 453/2010

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Revision date: 07/05/2014

	ion date: 07/05/2014 . Version: 1.
SECTION1: Identification of the su	ubstance/mixture and of the company/undertaking
1.1. Product identifier	
Product form	: Substance
Substance name	: Abacavir Sulfate
Chemical name	: (1S,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt)(2:1)
CAS No.	: 188062-50-2
Product code	: ACS
Formula	: (C14H18N6O)2.H2SO4
Product group	: Pharmaceutical product
1.2. Relevant identified uses of the s	ubstance or mixture and uses advised against
1.2.1. Relevant identified uses	
Main use category	: Industrial use, Professional use
Industrial/Professional use spec.	: Isolated intermediate
Function or use category	: Antiritroviral
1.2.2. Uses advised against	
No additional information available	
1.3. Details of the supplier of the safe	ety data sheet
Hetero drugs Ltd 7-2-A2, Hetero Corporate, Industrial Estate 500082 Hyderabad - INDIA T 04023774009 DRRama@heterodrugs.com - www.heterodru	
1.4. Emergency telephone number	
No additional information available	
SECTION 2: Hazards identification	n
2.1. Classification of the substance of	or mixture
Classification according to Regulation (EC Not classified	C) No. 1272/2008 [CLP]
Classification according to Directive 67/54 Carc.Cat.3; R40 Full text of R-phrases: see section 16.	48/EEC or 1999/45/EC
Adverse physicochemical, human health a No additional information available	and environmental effects
2.2. Label elements	
Labelling according to Regulation (EC) No	0. 1272/2008 [CLP]
Hazard pictograms (CLP)	· · · · · · · · · · · · · · · · · · ·
	None
CLP Signal word	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed H332 - Harmful if inhaled
Precautionary statements (CLP)	<ul> <li>P102 - Keep out of reach of children</li> <li>P103 - Read label before use</li> <li>P201 - Obtain special instructions before use</li> <li>P234 - Keep only in original container</li> <li>P235 - Keep cool</li> <li>P235+P410 - Keep cool. Protect from sunlight</li> </ul>
EUH phrases	: EUH210 - Safety data sheet available on request
2.3. Other hazards	
No additional information available	

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1. Substances			
	cavir Sulfate		
AS No. : 188	062-50-2		
C no :			
C index no			
Name	Product identifier	%	Classification according to
		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Directive 67/548/EEC
Tetrahydrofuran	(CAS No.)109-99-9 (EC no)203-726-8 (EC index no)603-025-00-0		F; R11-19 Xi; R36/37
Propan-2-ol	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0		F; R11 Xi; R36 R67
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		F; R11 Xi; R36 R66 R67
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		F; R11
Acetic acid	(CAS No.)64-19-7 (EC no)200-580-7 (EC index no)607-002-00-6		R10 C; R35
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		F; R11 Repr.Cat.3; R63 Xn; R48/20-65 Xi; R38 R67
[(1S,4R)-4-(2,6-Diamino-9H-purin-9-yl)cyclopent-2- enyl]methanol.			Not classified
{(1R,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9yl]- cyclopent-2-enyl}methanol			Not classified
N6-Cyclopropyl-9-{(1R,4S)-4-[(2,5-diamino-6-chloropyrimidin-4 yl-oxy)methyl]cyclopent-2-enyl}-9H-purine-2,6-diamine.	-		Not classified
9-[(1R,4S)-4-(tert-Butoxymethyl)cyclopent-2-enyl]-N6- cyclopropyl-9H-purine-2,6-diamine.			Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tetrahydrofuran	(CAS No.)109-99-9 (EC no)203-726-8 (EC index no)603-025-00-0		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H335
Propan-2-ol	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		Flam. Liq. 2, H225
Acetic acid	(CAS No.)64-19-7 (EC no)200-580-7 (EC index no)607-002-00-6		Skin Corr. 1A, H314 Flam. Liq. 3, H226
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Repr. 2, H361d Skin Irrit. 2, H315 STOT RE 2, H373 STOT SE 3, H336
			Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
{(1R,4R)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9yl]- cyclopent-2-enyl}methanol			Not classified
N6-CyclopropyI-9-{(1R,4S)-4-[(2,5-diamino-6-chloropyrimidin-4- yl-oxy)methyl]cyclopent-2-enyl}-9H-purine-2,6-diamine.			Not classified
9-[(1R,4S)-4-(tert-Butoxymethyl)cyclopent-2-enyl]-N6- cyclopropyl-9H-purine-2,6-diamine.			Not classified

Full text of R-, H- and EUH-phrases: see section 16.

#### 3.2. **Mixtures**

Not	applicable	
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SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures general	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
First-aid measures after inhalation	Remove the victim into fresh air-Respiratory problems:consult a doctor/medical service.
First-aid measures after skin contact	Remove contaminated clothing. Flush area with large amount of water.use soap. seek medical attention.
First-aid measures after eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid measures after ingestion	Never give anything by mouth to an unconscious person.Wash out mouth with water.Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
4.2. Most important symptoms and effects	, both acute and delayed

#### No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures	
5.1. Extinguishing media	
Suitable extinguishing media	: Use carbon dioxide, dry chemical.
5.2. Special hazards arising from the	substance or mixture
Fire hazard	: Flammable with air within explosin limits Indirect fire hazard may be ignited by sparks Gas/vapour spreads at floor level:ignition hazard.
Explosion hazard	: Not expected for the product, although the packaging is combustible.
Reactivity	: Product is not explosive.
5.3. Advice for firefighters	

No additional information available

Handling temperature

SECT	ION 6: Accidental release meas	ures
6.1.	Personal precautions, protective equ	lipment and emergency procedures
General	measures	: Keep upwind-Mark the danger area-Consider evacuation-Seal off low-liing area-Close doors and windows of adjecent premiss.
6.1.1. No addi	For non-emergency personnel tional information available	
6.1.2. No addi	For emergency responders tional information available	
6.2.	Environmental precautions	
No addi	tional information available	
6.3.	Methods and material for containme	nt and cleaning up
For cont	tainment	: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Other in	formation	: Wash clothing and equipment after handling.
6.4.	Reference to other sections	
No addi	tional information available	
SECT	ON 7: Handling and storage	
7.1.	Precautions for safe handling	
Precaut	ions for safe handling	: Gloves.

: 25 °C

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7.2. Conditions for safe storage, inc	luding any incompatibilities
Storage conditions	: Pack in air tight containers. Store the material at temparature 25°C.
Storage temperature	: 25 °C
Storage area	: Room.
Special rules on packaging	: Triple laminated aluminium package.
7.3. Specific end use(s)	
Fabric Refresher.	
SECTION 8: Exposure controls/p	ersonal protection
8.1. Control parameters	
No additional information available	
8.2. Exposure controls	
Appropriate engineering controls	: Engineering controls should be usd as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limites listed above in this section.
Personal protective equipment	: Gas mask with filter type A. Gloves. Protective clothing. Protective goggles. Safety glasses.
Materials for protective clothing	: Chloroprene rubber nitrile rubber.
Hand protection	: Gloves.
Eye protection	: Safety glasses.
Skin and body protection	: Protective clothing.
Respiratory protection	: Gas mask with filter type A.
Other information	: The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.

#### SECTION 9: Physical and chemical properties

9.1. Information on basic physical and	d chemical properties
Physical state	: Solid
Appearance	: White to off-white powder.
Molecular mass	: 670.74 g/mol
Colour	: White.
Odour	: None.
Odour threshold	: No data available
рН	: No data available
Melting point	: No data available
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Sparingly Soluble in Water.
Log Pow	: No data available
Log Kow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

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9.2. Other information	
No additional information available	
SECTION 10: Stability and reactivity	
10.1.         Reactivity           Product is not explosive.	
10.2. Chemical stability	
Stable under normal conditions of use.	
10.3. Possibility of hazardous reactions	
No additional information available	
10.4. Conditions to avoid	
No additional information available	
10.5. Incompatible materials	
As a precautionary measure. Keep away from stro	ng oxidizers.
10.6. Hazardous decomposition products	
No additional information available	
SECTION 11: Toxicological information	n
11.1. Information on toxicological effects	
Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity : Carcinogenicity :	Not classified
Reproductive toxicity : Specific target organ toxicity (single exposure) :	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified
SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general	Sparingly soluble in water.
Ecology - air	Not dangerous for the ozone layer(1999/45/EC).
12.2. Persistence and degradability	
Abacavir Sulfate(188062-50-2)	
Persistence and degradability	% biodegradation.
Acetic acid (64-19-7)	
Persistence and degradability	% biodegradation.
12.3. Bioaccumulative potential	
Abacavir Sulfate(188062-50-2)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.
Acetic acid (64-19-7)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.
12.4. Mobility in soil	
Abacavir Sulfate(188062-50-2)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
Acetic acid (64-19-7)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
12.5. Results of PBT and vPvB assessment	
No additional information available	
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12.6. Other adverse effects	
Other adverse effects	: Overexposure in the workplace might have the following effects: headache, nausea, vomiting, abdominal pain, and soft stools.
Other information	: No other effects known.
SECTION 13: Disposal consider	ations
13.1. Waste treatment methods	
Waste disposal recommendations	: However Hetero recommends disposal of waste Material via high-temperature incineration.
Ecology - waste materials	: Take up liquid spil into absorbent material-Scoop absorbed substance into closing containers.
SECTION 14: Transport informa	tion
No dangerous good in sense of transport r	egulations.
SECTION 15: Regulatory inform	ation
15.1. Safety, health and environmer	tal regulations/legislation specific for the substance or mixture
15.1.1. EU-Regulations	
No Annex XVII restrictions	
Contains no REACH candidate substance	
EURAL code	: 20 01 32
CESIO recommendations	: This surfactant complies with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.
15.1.2. National regulations	
No additional information available	
15.2. Chemical safety assessment	
No additional information available	
SECTION 16: Other information	
Training advice	· Normal use of this product shall imply use in accordance with the instructions on the packaging

Training advice

: Normal use of this product shall imply use in accordance with the instructions on the packaging.

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Full text of R-, H- and EUH-phrases:

Acute toxicity (dermal) Category 3
Acute toxicity (inhalation) Category 3
Acute toxicity (oral) Category 3
Aspiration hazard Category 1
Serious eye damage/eye irritation Category 2
Flammable liquids Category 2
Flammable liquids Category 3
Reproductive toxicity Category 2
skin corrosion/irritation Category 1A
skin corrosion/irritation Category 2
Specific target organ toxicity (repeated exposure) Category 2
Specific target organ toxicity (single exposure) Category 1
Specific target organ toxicity (single exposure) Category 3
Specific target organ toxicity (single exposure) Category 3
Highly flammable liquid and vapour
Flammable liquid and vapour
Toxic if swallowed
May be fatal if swallowed and enters airways
Toxic in contact with skin
Causes severe skin burns and eye damage
Causes skin irritation
Causes serious eye irritation
Toxic if inhaled
May cause respiratory irritation
May cause drowsiness or dizziness
Suspected of damaging the unborn child.
Causes damage to organs
May cause damage to organs through prolonged or repeated
exposure
Flammable.
Highly flammable.
May form explosive peroxides.
Toxic by inhalation, in contact with skin and if swallowed.
Causes severe burns.
Irritating to eyes.
Irritating to eyes and respiratory system.
Irritating to skin.
Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
Limited evidence of a carcinogenic effect
Harmful: danger of serious damage to health by prolonged exposur through inhalation.
Possible risk of harm to the unborn child.
Harmful: may cause lung damage if swallowed.
Repeated exposure may cause skin dryness or cracking.
Vapours may cause drowsiness and dizziness.
Corrosive
Highly flammable
Harmful

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.