

# Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 07/05/2014 : Version: 1.0

# SECTION1: Identification of the substance/mixture and of the company/undertaking

#### I.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 substance 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 safety data sheet

Hetero drugs Ltd

7-2-A2, Hetero Corporate, Industrial Estate

500082 Hyderabad - INDIA

T 04023774009

DRRama@heterodrugs.com - www.heterodrugs.com

#### 1.4. Emergency telephone number

No additional information available

### SECTION 2: Hazards identification

# 2.1. Classification of the substance or mixture

# Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

# Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40

Full text of R-phrases: see section 16.

# Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

# Labelling according to Regulation (EC) No. 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) : P102 - Keep out of reach of children

P103 - Read label before use

P201 - Obtain special instructions before use P234 - Keep only in original container

P235 - Keep cool

P235+P410 - Keep cool. Protect from sunlight

EUH phrases : EUH210 - Safety data sheet available on request

### 2.3. Other hazards

No additional information available

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# SECTION 3: Composition/information on ingredients

Substances

Name

: Abacavir Sulfate Name : 188062-50-2 CAS No.

EC no EC index no

Tetrahydrofuran	(CAS No.)109-99-9 (EC no)203-726-8		F; R11-19 Xi; R36/37
Propan-2-ol	(EC index no)603-025-00-0 (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		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H335
	(EC index no)603-025-00-0		3101 32 3, 11333
Propan-2-ol	(EC index no)603-025-00-0 (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
Propan-2-ol Acetone	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0 (CAS No.)67-64-1 (EC no)200-662-2		Flam. Liq. 2, H225 Eye Irrit. 2, H319
·	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0 (CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8 (CAS No.)64-17-5 (EC no)200-578-6		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 Flam. Liq. 2, H225 Eye Irrit. 2, H319
Acetone	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0 (CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8 (CAS No.)64-17-5		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Acetone	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0 (CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8 (CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5 (CAS No.)64-19-7 (EC no)200-580-7		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 Flam. Liq. 2, H225
Acetone  Ethanol  Acetic acid	(CAS No.)67-63-0 (EC no)200-661-7 (EC index no)603-117-00-0 (CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8 (CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5 (CAS No.)64-19-7 (EC no)200-580-7 (EC index no)607-002-00-6 (CAS No.)67-56-1 (EC no)200-659-6		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336  Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336  Flam. Liq. 2, H225  Skin Corr. 1A, H314 Flam. Liq. 3, H226  Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301

Product identifier

Classification according to Directive 67/548/EEC

%

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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-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

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

#### 3.2. Mixtures

Not applicable

# SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general

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

: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.

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

# SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment 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. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

No additional information available

#### 6.3. Methods and material for containment and cleaning up

For containment : Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous

solutions.

Other information : Wash clothing and equipment after handling.

#### 6.4. Reference to other sections

No additional information available

# SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Gloves. Handling temperature :  $25 \, ^{\circ}\mathrm{C}$ 

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#### 7.2. Conditions for safe storage, including 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/personal 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 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 No data available рΗ Melting point No data available : No data available Solidification point Boiling point : No data available No data available Flash point Relative evaporation rate (butylacetate=1) No data available Flammability (solid, gas) : No data available Explosive limits : No data available : No data available Vapour pressure Relative vapour density at 20 °C No data available : No data available Relative density

Solubility : Sparingly Soluble in Water.

Log Pow No data available No data available Log Kow Self ignition temperature : No data available Decomposition temperature : No data available : No data available Viscosity, kinematic Viscosity, dynamic No data available Explosive properties : No data available : No data available Oxidising properties

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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 strong oxidizers.

#### 10.6. Hazardous decomposition products

No additional information available

# SECTION 11: Toxicological information

#### 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 : Not classified : Not classified Carcinogenicity Reproductive toxicity : Not classified Specific target organ toxicity (single exposure) : Not classified Specific target organ toxicity (repeated : Not classified

exposure)

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).

soil.

### 12.2. Persistence and degradability

Abacavir Sulfate(188062-50-2)

Abdouvii Guilato(100002 00 2)	
Persistence and degradability	% biodegradation.
Acetic acid (64-19-7)	

Persistence and degradability	% biodegradation.
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# 12.3. Bioaccumulative potential Abacavir Sulfate(188062-50-2)

Acetic acid (64-19-7)	
Bioaccumulative potential	The substance has low potential for bioaccumulation.

The substance has low potential for bioaccumulation.

#### 12.4. Mobility in soil

Ecology - soil

Bioaccumulative potential

bacavir 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)	

The substance has moderate mobility in groundwater. The substance has moderate mobility in

Results of PBT and vPvB assessment

No additional information available

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#### 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 considerations**

#### 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 information

No dangerous good in sense of transport regulations.

# SECTION 15: Regulatory information

#### Safety, health and environmental 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

#### **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.

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xt of R-, H- and EUH-phrases:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Asp. Tox. 1	Aspiration hazard Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	skin corrosion/irritation Category 1A
Skin Irrit. 2	skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H226	Flammable liquid and vapour
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H335	May cause respiratory irritation
H336	May cause respiratory initiation  May cause drowsiness or dizziness
H361d	Suspected of damaging the unborn child.
	, , ,
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
R10	Flammable.
R11	Highly flammable.
R19	May form explosive peroxides.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R35	Causes severe burns.
R36	Irritating to eyes.
R36/37	Irritating to eyes and respiratory system.
R38	Irritating to skin.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R48/20	Harmful: danger of serious damage to health by prolonged exposure
R63	through inhalation.  Possible risk of harm to the unborn child.
R65	Harmful: may cause lung damage if swallowed.
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.
C	Corrosive
F	Highly flammable
T	Toxic
Xi	Irritant
Xn	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.

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