

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 15/08/2013 : Version: 1.0

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

.1. Product identifier

Product form : Substance
Substance name : Acyclovir

Chemical name : 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin-6-one

CAS No. : 59277-89-3
Product code : AC

Formula : C18H11N5O3

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 Industrial/Professional use spec. : isolated intermediate

Function or use category : Antiviral

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) : P103 - Read label before use

P102 - Keep out of reach of children P201 - Obtain special instructions before use

P233 - Keep container tightly closed P403 - Store in a well-ventilated place

EUH phrases : EUH210 - Safety data sheet available on request

EUH401 - To avoid risks to human health and the environment, comply with the instructions for

use

2.3. Other hazards

No additional information available

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

SECTION 3: Composition/information on ingredients

Substances

: Acyclovir Name : 59277-89-3 CAS No.

EC no EC index no

Name	Product identifier	%	Classification according to Directive 67/548/EEC
2-[(2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl-N- methyl-L-valinate			Not classified
2-amino-1,7-dihydro-6H-purin-6-one.			Not classified
2-amino-7-[(2-hydroxyethoxy)methyl]-1,7-dihydro-6H-purin-6- one			Not classified
N-[9-[(2-hydroxyethoxy)methyl]-6-oxo-6,9-dihydro-1H-purin-2- yl]acetamide			Not classified
2-[[2-(acetylamino)-6-oxo-1,6-dihydro-9H-purin-9- yl]methoxy]ethyl acetate			Not classified
2-amino-7-[[2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9- yl)methoxy]ethoxy]methyl]1,7-dihydro-6H-purin-6-one.			Not classified
9,9'-[ethylenebis(oxymethylene)]bis(2-amino-1,9-dihydro-6H- purin-6-one)			Not classified
2,2'-[methylenediimino]bis[9-[(2-hydroxyethoxy)methyl]-1,9- dihydro-6H-purin-6-one]			Not classified
2-Amino-9-[(2-Hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6- one			Not classified
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		F; R11 Xi; R36 R66 R67
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
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-[(2-Amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl-N- methyl-L-valinate			Not classified
2-amino-1,7-dihydro-6H-purin-6-one.			Not classified
2-amino-7-[(2-hydroxyethoxy)methyl]-1,7-dihydro-6H-purin-6- one			Not classified
N-[9-[(2-hydroxyethoxy)methyl]-6-oxo-6,9-dihydro-1H-purin-2- yl]acetamide			Not classified
2-[[2-(acetylamino)-6-oxo-1,6-dihydro-9H-purin-9- /l]methoxy]ethyl acetate			Not classified
2-amino-7-[[2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9- yl)methoxy]ethoxy]methyl]1,7-dihydro-6H-purin-6-one.			Not classified
9,9'-[ethylenebis(oxymethylene)]bis(2-amino-1,9-dihydro-6H- purin-6-one)			Not classified
2,2'-[methylenediimino]bis[9-[(2-hydroxyethoxy)methyl]-1,9- dihydro-6H-purin-6-one]			Not classified
2-Amino-9-[(2-Hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6- one			Not classified
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
Acetic acid	(CAS No.)64-19-7 (EC no)200-580-7 (EC index no)607-002-00-6		Not classified
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

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

3.2. Mixtures

Not applicable

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

ininediate

First-aid measures after inhalation : Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.

First-aid measures after skin contact : When symptoms occur: rinse immediately with plenty of water. Rewmove contaminated clothing. Flush arera 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 : Rinse mouth with water-Immediately after ingestion:give lots of water to drink.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediatly.

Symptoms/injuries after inhalation : Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms/injuries after skin contact : Remove contaminated clothing. Flush area with large amounts of water. Use sope. Seek

medical attention.

Symptoms/injuries after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention

immediatly.

Symptoms/injuries after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water.Do not

induce vomting unless directed by medical personnel. Seek medical attention immediately.

For information on potential signs and symptoms of exposure. See section 2-Hazards

Symptoms/injuries upon intravenous administration

identification and/or section11-Toxicological information.

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 catrbon 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

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

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

6.3. Methods and material for containment and cleaning up

No additional information available

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 : Do not eat, drink or smoke when using this product.

Handling temperature : 25 °C

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Pack in air tight containers. Storevthe material at temparature below25°C.

Storage temperature : 25 °C Storage area : Room.

Special rules on packaging : Triple laminated alumminium packeag.

15/09/2011 EN (English) 3/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

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. Kepp airborne contamination levels below the exposure limites listed above in this section.

Personal protective equipment

: Wear gas mask with filter type A if conc. in air >. Safety glasses. Respiratory protection of the dependent type. Protective goggles. Protective clothing. On heating: heatproof clothing. Gloves.



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 or almost white, crystalline powder.

Molecular mass : 225 g/mol Colour : White. Odour : None.

Odour threshold No data available pΗ No data available Melting point No data available Solidification point : No data available 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 Relative density : No data available

Solubility : Slightly soluble in water, freely soluble in dimethyl sulfoxide and very slightly soluble in

No data available

: No data available

ethanol(96%). It dissolves in dilute solutions of mineral acids and alkali hydroxides.

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

9.2. Other information

Oxidising properties

Log Pow

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 10: Stability and reactivity

Reactivity

Product is not explosive.

Chemical stability

Stable under normal conditions of use.

Possibility of hazardous reactions

No additional information available

Conditions to avoid

No additional information available

Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

Information on toxicological effects

Acute toxicity : Not classified Skin corrosion/irritation : Not classified Not classified Serious eye damage/irritation Respiratory or skin sensitisation Not classified Germ cell mutagenicity Not classified Carcinogenicity : Not classified : Not classified Reproductive toxicity Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated

exposure)

: Not classified

Aspiration hazard : Not classified

Other information : Information on Effects: refer to section 4.

SECTION 12: Ecological information

Toxicity

: Slightly soluble in water, freely soluble in dimethyl sulfoxide and very slightly soluble in Ecology - general

ethanol(96%). It dissolves in dilute solutions of mineral acids and alkali hydroxides.

Ecology - air : Not dangerous for the ozone layer(1999/45/EC).

12.2. Persistence and degradability

Acyclovir(59277-89-3)	
Persistence and degradability	% biodegradation.

12.3. **Bioaccumulative potential**

Acyclovir(59277-89-3)		
Bioaccumulative potential	The substance has low potential for bioaccumulation.	

Mobility in soil

Acyclovir(59277-89-3)	
Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

Results of PBT and vPvB assessment 12.5.

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

Waste treatment methods 13.1.

Additional information : Wash clothiong and equipment after handling.

: Take up liquid spil into absorbent material-Scoop absorbed substance into closing containers. Ecology - waste materials

15/09/2011 EN (English) 5/6

Safety Data Sheet

according to Regulation (EC) No. 453/2010

SECTION 14: Transport information

No dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

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.

Full text 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	
Eye Irrit. 2	Serious eye damage/eye irritation Category 2	
Flam. Liq. 2	Flammable liquids Category 2	
STOT SE 1	Specific target organ toxicity (single exposure) Category 1	
STOT SE 3	Specific target organ toxicity (single exposure) Category 3	
H225	Highly flammable liquid and vapour	
H301	Toxic if swallowed	
H311	Toxic in contact with skin	
H319	Causes serious eye irritation	
H331	Toxic if inhaled	
H336	May cause drowsiness or dizziness	
H370	Causes damage to organs	
R10	Flammable.	
R11	Highly flammable.	
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.	
R35	Causes severe burns.	
R36	Irritating to eyes.	
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	
R66	Repeated exposure may cause skin dryness or cracking.	
R67	Vapours may cause drowsiness and dizziness.	

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.

15/09/2011 EN (English) 6/6