



# Valganciclovir Hydrochloride

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 04/09/2014

Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Valganciclovir Hydrochloride
Chemical name	: 2-[(2-amino-6-oxo-6,9-dihydro-3H-purin-9-yl)methoxy]-3-hydroxypropyl (2S)-2-amino-3-methylbutanoate Hydrochloride
CAS No.	: 175865-59-5
Product code	: VG
Formula	: C <sub>14</sub> H <sub>22</sub> N <sub>6</sub> O <sub>5</sub> .HCl
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	: 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](mailto:DRRama@heterodrugs.com) - [www.heterodrugs.com](http://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
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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 P233 - Keep container tightly closed 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

#### 3.1. Substances

Name : Valganciclovir Hydrochloride  
CAS No. : 175865-59-5  
EC no :  
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		F; R11 Xi; R36 R66 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
Dimethyl formamide	(CAS No.)68-12-2		Not classified
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
Dichloromethane	(CAS No.)75-09-2 (EC no)200-838-9 (EC index no)602-004-00-3		Carc.Cat.3; R40
Isopropyl alcohol			Not classified
Ganciclovir			Not classified
Guanine			Not classified
Methoxy methyl guanine			Not classified
Iso valganciclovir			Not classified
Mono acetoxyl ganciclovir			Not classified
Bis valine ester of ganciclovir			Not classified
Ganciclovir monopropionate			Not classified
Valganciclovir dimer-A			Not classified
Valganciclovir dimer-B			Not classified
Valganciclovir Dimer-C			Not classified
Ganciclovir mono-N-methyl valinate			Not classified

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		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
Dimethyl formamide	(CAS No.)68-12-2		Not classified
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
Dichloromethane	(CAS No.)75-09-2 (EC no)200-838-9 (EC index no)602-004-00-3		Carc. 2, H351
Isopropyl alcohol			Not classified
Ganciclovir			Not classified

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Guanine			Not classified
Methoxy methyl guanine			Not classified
Iso valganciclovir			Not classified
Mono acetoxy ganciclovir			Not classified
Bis valine ester of ganciclovir			Not classified
Ganciclovir monopropionate			Not classified
Valganciclovir dimer-A			Not classified
Valganciclovir dimer-B			Not classified
Valganciclovir Dimer-C			Not classified
Ganciclovir mono-N-methyl valinate			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	: Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
First-aid measures after inhalation	: When symptoms occur: go into open air and ventilate suspected area.
First-aid measures after skin contact	: Remove any contaminated clothing. Wash exposed area thoroughly with soap and water. If irritation occurs or persists, 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

## 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-lying area-Close doors and windows of adjacent 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

Other information : Wash clothing and equipment after handling.

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### 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 °C

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Packing in tight light resistant containers. Store the material at temperature 25°C. Exclusions permitted between 15° - 30°C.

Storage temperature : 25 °C

Storage area : Room.

Special rules on packaging : Triple laminated aluminium package.

### 7.3. Specific end use(s)

No additional information available

## 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 used 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. 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.

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### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: White to off-white powder, slightly hygroscopic.
Molecular mass	: 390.82 g/mol
Colour	: White.
Odour	: None.
Odour threshold	: No data available
pH	: 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	: Freely soluble in water, sparingly soluble in methanol.
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

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

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Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Freely soluble in water.  
Ecology - air : Not dangerous for the ozone layer(1999/45/EC).

#### 12.2. Persistence and degradability

##### Valganciclovir Hydrochloride(175865-59-5)

Persistence and degradability	% biodegradation.
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##### Acetic acid (64-19-7)

Persistence and degradability	% biodegradation.
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#### 12.3. Bioaccumulative potential

##### Valganciclovir Hydrochloride(175865-59-5)

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

Bioaccumulative potential	The substance has low potential for bioaccumulation.
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#### 12.4. Mobility in soil

##### Valganciclovir Hydrochloride(175865-59-5)

Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
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##### Acetic acid (64-19-7)

Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
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#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

Other information : No other effects known.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.  
Ecology - waste materials : Take up liquid spill 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

#### 15.1. 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

##### 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.

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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
Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Flam. Liq. 3	Flammable liquids Category 3
Skin Corr. 1A	skin corrosion/irritation Category 1A
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
H226	Flammable liquid and vapour
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H336	May cause drowsiness or dizziness
H351	Suspected of causing cancer
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.
C	Corrosive
F	Highly flammable
T	Toxic
Xi	Irritant

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.*