

**SAFETY DATA SHEET**

**Product Name** : VALGANCICLOVIR TABLETS USP 450mg  
**Date of Issue** : 17.12.2018 **Revision No.** : 04

**1 IDENTIFICATION**

**Product Name** : VALGANCICLOVIR TABLETS USP 450mg  
**Company** : *Head Office* - Cipla House, Peninsula Business Park, Ganpataro Kadam Marg,  
Lower Parel, Mumbai, Maharashtra, India ( Pin Code - 400 013)  
*Manufacturing division* – Cipla Limited, M.I.D.C. Patalganga, District – Raigad,  
Maharashtra, India ( Pin Code - 410 220 )  
**Telephone** : +91 2192 660900 / 660400 **Fax** : +91 2192 250819  
**E-mail** : safetyptg@cipla.com **Web site** : [www.cipla.com](http://www.cipla.com)  
**Emergency Contact** : +91 2192 660900

**2 HAZARD(S) IDENTIFICATION**

**Classification as per GHS -**  
**Physical** : Data not available  
**Health** : Carcinogenicity Category 2,  
Acute Toxicity (Oral) Category 5  
**Environmental** : Data not available

**Label in accordance with GHS -**



**Signal Word** - Warning

**Hazard Statement** - **H351** Suspected of causing cancer. **H303** May be harmful if swallowed.

**Precautionary Statements** - **P201** Obtain special instructions before use.  
**P280** Wear protective gloves/ protective clothing/eye protection/face protection.

**Note** : This is a pharmaceutical product. For further details regarding health hazards, Properties of please refer the related product label and leaflet.

**3 COMPOSITION / INFORMATION ON INGREDIENTS**

**Chemical name** : VALGANCICLOVIR TABLETS USP 450mg  
**Molecular Formula** : Not applicable  
**Molecular Weight** : Not applicable

Name of Active ingredients	Composition	
	CAS No.	Standard Quantity / tablet (%)
Valganciclovir Hydrochloride	175865-59-5	76.354

**CAS No.** : 175865-59-5 **UN No.** : Not applicable

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**4 FIRST AID MEASURES**

**Symptoms Observed:** Remove victim immediately from source of exposure. Receive immediate medical attention.

**General advice**

**Inhalation** : Physical form suggests that risk of inhalation exposure is negligible. Remove victim to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Receive immediate medical attention.

**Skin Contact** : May cause irritation. Remove contaminated clothing. Flush with copious quantities of water. Receive immediate medical attention.

**Eye Contact** : May cause irritation. Flush eyes with copious quantities of water for at least 15 minutes. Receive immediate medical attention.

**Ingestion** : May cause irritation. 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. Receive immediate medical attention.

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment** : Medical treatment in cases of overexposure should be treated as an overdose of the product. Treat according to locally approved protocols.

**Medical conditions caused or Aggravated by exposure** : No specific data available

**Antidote** : No specific data available

**5 FIRE FIGHTING MEASURES**

**Fire and Explosion hazard** : Product is expected to be not highly flammable. Packing may be combustible.

**Extinguishing media / equipment** : Water spray, Foam, Carbon dioxide, Dry Chemical Powder as appropriate for surrounding fire and material.

**Special fire fighting procedure and Protective Measures** : As with all fires, evacuate persons to safe area. Use of self – contained breathing apparatus and protective clothing is advisable. Contain and collect used fire fighting water for later disposal. Refer applicable laws.

**Hazardous Combustion Products** : Under fire conditions - May emit toxic fumes, carbon monoxide. Toxic, corrosive or flammable thermal decomposition products may expected under fire condition.

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**6 ACCIDENTAL RELEASE MEASURES**

Remove ignition sources. Suggested to be handling by trained persons. Avoid unwanted exposure. If required, evacuate area.

**Personal Precautions** : Personal clothing referred in section 8 should be wear.

**Environmental Precaution** : Take precautions to prevent discharge into water-courses and ground

**Clean - up Procedure** : Vacuum or Sweep up the material and place in a appropriate bag /

labelled container and hold for waste disposal. Avoid raising dust. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Flush contaminated are with water. Dispose off waste in accordance with applicable regulations / law.

**Decontamination Procedure** : No specific decontamination procedure has been identified.

**7 HANDLING AND STORAGE**

**Handling** : Handle material with care. Avoid exposure to moisture, humid conditions and direct sunlight. This material should be handled as per instructions to ensure product integrity. Avoid contact with skin, eyes and clothing. Avoid breathing dust or mist. Avoid breaking or crushing tablet.

*Information & Training – Prior to use of this material, Impart proper information & training to all concerns.*

**Storage :**

**1. Bulk Storage** : Store below 25°C. Avoid exposure to moisture, humid conditions and direct sunlight. Keep away from all heat sources, ignition sources including sparks and incompatible material. This material should be handled and stored as per instructions to ensure product integrity and to maintain efficacy.

**Department Storage** - As mentioned above

**Any Specific Storage Requirements** :

**Pictograms -**



Keep Away from  
Water



Keep Away from Sunlight,  
radioactive and Heat



Store below 25°C

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**8 EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Hazard category and Exposure Limits** : Refer section 9, 10, 11 and 12

**Appropriate Engineering Controls** : Not applicable

**Personal protective equipment**



**Ensure before use -** Personal Protective Equipment selected are consistent and hazard. Ensure that Personal protective equipment which are to be use are tested and approved under appropriate government standards such as NIOSH ( US ) or CEN ( EU ) etc. compatible with degree of

**Respiratory protection** : 3M / NIOSH approved Respirator or Pressure suit. Use Self Contained Breathing apparatus in an emergency.

**Hand protection** : Chemically compatible hand gloves

**Eye protection** : Safety Goggle or Face Shield

**Skin protection** : Protective clothing including apron / suit, shoes

**Exposure control** : Adequate ventilation including local exhaust is required.

**Ventilation**

**Hygiene Measure** : Wash hands and contaminated parts after handling. Promptly remove

**9 PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance and odour** : Pink coloured, capsule shaped, biconvex film coated tablet plain on both sides.

**Vapour pressure** : Not applicable

**Vapour density** : Not applicable

**Flash point** : Not applicable

**Viscosity** : Not applicable

**Melting range** : Not applicable

**Boiling point** : Not applicable

**Specific gravity** : Not applicable

**Auto-ignition** : Not applicable

**Relative density** : Data not available.

**Flammability** : Data not available.

**Solubility** : Not applicable

**10 STABILITY AND REACTIVITY**

**Stability** : This product is expected to be stable till expiry period under prescribed conditions.

**Incompatibility /Conditions to avoid** : Data not available

**Hazardous decomposition products** : Data not available

**Hazardous reactions** : Not applicable

**Hazardous polymerization** : Not applicable

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**11 TOXICOLOGICAL INFORMATION**

This is a pharmaceutical product. Adverse effect might occur on certain organs, for detail information refer the related product label and leaflet.

<b>Oral Toxicity</b>	: Data Not available	<b>Sensitization</b>	: Data Not available
<b>Inhalation Toxicity</b>	: Data Not available	<b>Genetic Toxicity</b>	: Data Not available
<b>Skin Effects</b>	: Data Not available	<b>Carcinogenicity</b>	: Data Not available
<b>Eye Effects</b>	: Data Not available	<b>Reproductive Effects</b>	: Data Not available
<b>Target Organ Effects</b>	: Data Not available		:
<b>Toxicity data</b>			
<b>ORL - RAT LD 50</b>	: >2000 mg/kg	<b>SCU - RAT LD 50</b>	: Data Not available
<b>ORL -MICE LD 50</b>	: Data Not available	<b>SCU - MUS LD 50</b>	: Data Not available

**12 ECOLOGICAL INFORMATION (NON MANDATORY)**

**Summary** : This product is having active ingredients which may be harmful if releases directly to the environment. No detail information is available about the potential of this product to produce adverse environmental effects. Appropriate precautions should be taken to limit release of this material in the environment. Local regulations and procedures should be consulted prior to environmental release.

**Ecotoxicity** : Data Not available

**Degradability** : Data Not available

**13 DISPOSAL CONSIDERATIONS (NON MANDATORY)**

**Disposal Recommendations** : Data Not available

**Regulatory Requirements** : Data Not available

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**14 TRANSPORT INFORMATION (NON MANDATORY)**

Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release.

**UN Proper Shipping Name** – Not dangerous goods

**ADR Packing Group** – Not Classified

**ADR Class** – Not Classified

**Additional Pictogram -**

**UN No -** Not classified

**ADR**

**IATA**

**GHS Pictogram - :**

Data not available



**Other Information** : Packaging, labelling or transportation of product / consignment for air, maritime or ground transport purpose should be in adherence to applicable Local, State, National, International transport regulations. Refer pictogram, Class / packing group.

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**15 REGULATORY INFORMATION (NON MANDATORY)**

**National legislation / regulations** : As mentioned in section 14 of this document

**Any other regulatory information** : Not Classified

**16 OTHER INFORMATION**

**Therapeutic category of Material** : Antivirals

**Reference** :

1. Finished product specification document No. 1035-32016407, Version No. 2.0, Current of Cipla Corporate, date of issue 24-Aug-2016.
2. Master manufacturing formula BFG code 31007441, Version No. 0001, of Cipla, Patalganga dated 16.09.2016.
3. Material safety data sheet Valcyte(R) F. C. Tablets (450 mg) published by Roche, USA Date 24.07.2009.
4. Material safety data sheet Valganciclovir (Valganciclovir Hydrochloride) published by Chemwatch Version No. 2.1.1.1, Issue date 04.12.2017.
5. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Sixth revised Edition.
6. Dangerous Goods Regulations.
7. Regulation on Classification, Labelling & Packaging of Substance & Mixtures.

*The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendations given 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. Recipients of material must take responsibility for observing existing laws, regulations and suitability of material for handling, transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with*

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*the handling, storage, use and disposal of the product. Information mentioned in this document relates only to the specific material designated and may not be valid for such material used in combination with other material or in any process.*

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