

MATERIAL SAFETY DATA SHEET

Cipla
Corporate

Product : VALACYCLOVIR HYDROCHLORIDE DIHYDRATE
Date of Issue : 19.09.2014 **Revision No.** : 06

1 IDENTIFICATION OF SUBSTANCE

Trade Name : VALACYCLOVIR HYDROCHLORIDE DIHYDRATE

Company : Cipla Limited

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Lower Parel, Mumbai - 400013 India.

Manufacturing division - Cipla Ltd. MIDC, Patalganga, M.S. 410 220 India.

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Note : THIS PRODUCT IS SOLD AS PHARMACEUTICAL PRODUCT

2 HAZARD IDENTIFICATION

Classification as per EC - Physical Hazard : Not Classified

Health Hazard : Acute Toxicity - Category 4

Environmental Hazard : Not Classified

Label in accordance with EC -



Signal Word - Warning

Contains - Not Classified

Hazard Statement - H302 : Harmful if swallowed.

Precautionary Statements - P264 : Wash hands thoroughly after handling.

P270 : Do not eat, drink or smoke when using this product.

Supplementary Precautionary Statement - Not Classified

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name : Valacyclovir Hydrochloride Dihydrate is L-valine, 2-[(2-amino-1, 6-dihydro-6-oxo-9H-purin-9-yl)methoxy]ethyl ester hydrochloride dihydrate.

Molecular Formula : $C_{13}H_{20}N_6O_4 \cdot HCl \cdot 2H_2O$.

Molecular Weight : 396.5

CAS No. : 124832-27-5

UN No. : 3077

EC No. : Data not available

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4 FIRST AID MEASURES

This is a pharmaceutical product. Health effects information is described in the leaflet attach with the product packaging. Exposure might occur via ingestion, skin absorption and eyes. Material may be harmful by ingestion, skin absorption and eyes.

General advice

Remove victim immediately from source of exposure. Receive immediate medical attention.

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 & Explosion hazard : Product is expected to be not highly flammable. Packing may be combustible.

Extinguishing media : 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 / labeled 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 :

- Bulk Storage** – Store in well closed containers. Store material in cool dry place protected from light. 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.

- Department Storage** - As mentioned above

Pictograms -



Keep Away
From Water



Keep Away From Sunlight,
radioactive and Heat



Store between
15 °C to 30 °C

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8 EXPOSURE CONTROLS / PERSONAL PROTECTION

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

This product is medicine and hence precautions and control specified in this section should be adopted only during spill control. For regular intended use, follow instructions and hygiene practices as suggested by the physician.

Personal protective equipment



Ensure before use - Personal Protective Equipment selected are consistent and compatible with degree of 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.

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 Ventilation : Adequate ventilation including local exhaust is required.

Hygiene Measure : Wash hands and contaminated parts after handling. Promptly remove contaminated clothing. Wash contaminated clothing before reuse. Handle material in accordance with applicable good industrial hygiene and safety procedures.

9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance and odour : A White to off - white crystalline powder.

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 : Freely soluble in water.

10 STABILITY AND REACTIVITY

Stability : The product is stable

Incompatibilities / Conditions to avoid : Data not available

Hazardous decomposition products : When heated to decomposition, may emit toxic fumes.

Hazardous reactions : Not applicable

Hazardous polymerization : Not applicable

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11 TOXICOLOGICAL INFORMATION

Oral Toxicity	: Data Not available	Sensitization	: Data Not available
Inhalation Toxicity	: Data Not available	Genetic Toxicity	: Data Not available
Skin Effects	: Data Not available	Carcinogenicity	: Data Not available
Eye Effects	: Data Not available	Reproductive Effects	: Data Not available
Target Organ Effects	: Data Not available		
Toxicity data			
ORL - RAT LD 50	: 903.5 mg/kg	SCU - RAT LD 50	: Data not available.
ORL - MICE LD 50	: Data not available.	SCU - MUS LD 50	: Data not available.

12 ENVIRONMENTAL / ECOLOGICAL INFORMATION

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 : May be harmful to aquatic organisms.

Degradability : Data Not available

13 DISPOSAL CONSIDERATION

Disposal Recommendations : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

Regulatory Requirements : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

14 TRANSPORT INFORMATION (UN Classification & Labeling)

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

Additional Pictogram -

▪ **ADR Packing Group – III**

▪ **ADR Class – 9**

▪ **UN No - 3077**

GHS Pictogram -



Other Information : - **Proper Shipping Name** – Environmentally hazardous substance, solid, N.O.S.

Trade Name – Valacyclovir Hydrochloride Dihydrate

Chemical / Technical Name – Valacyclovir Hydrochloride Dihydrate is L-valine, 2-[(2-amino-1, 6-dihydro-6-oxo-9H-purin-9-yl)methoxy]ethyl ester hydrochloride dihydrate.

Transportation of this product is not particularly restricted but packaging, labeling or transportation of product / consignment for air, maritime or ground transport purpose should be in adherence to transport regulations. Refer pictogram, Class / packing group.

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15 REGULATORY INFORMATION

Labeling according to EEC directives : As mentioned in section 14 of this document

National legislation / regulations

Any other regulatory information : -----

16 OTHER INFORMATION

Therapeutic category of Material : Antiviral

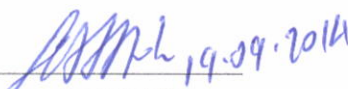
Reference :

1. Active Pharmaceutical Ingredient specification No. ACV0034 of Cipla, Patalganga Version No. 01, dated 29.04.2009
2. Material Safety Data Sheet of the Product Valacyclovir Hydrochloride by Sigma-Aldrich. Revised edition No. 4.0, dated 01.03.2010.
3. Globally Harmonized System Of Classification And Labelling Of Chemicals (GHS), Third revised Edition
4. Dangerous Goods Regulations.
5. Regulation on Classification, Labeling & Packaging of Substance & Mixtures.

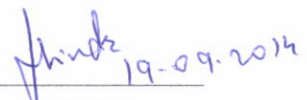
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