CIDOFOVIR INJECTION

MATERIAL SAFETY DATA SHEET

1 CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cidofovir Injection

Trade Name(s): Vistide®

Product Use: Cidofovir is indicated for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

Manufacturer Information:
Mylan Institutional LLC
4901 Hiawatha Drive
Rockford, IL 61103
1-888-258-4199

Emergency Telephone:
1-888-875-1671

2 HAZARD IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Emergency Overview

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Potential Health Effects – Finished Pharmaceutical Product

Contraindications: In patients with a serum creatinine > 1.5 mg/dL, a calculated creatinine clearance ≤ 55 mL/min, or a urine protein ≥ 100 mg/dL. Cidofovir is also contraindicated in patients with nephrotoxic potential or those with known hypersensitivity to cidofovir, probenecid, or other sulfa-containing medications.

Precautions: Dose-dependent nephrotoxicity is the dose-limiting toxicity related to cidofovir injection administration. Neutropenia, decreased intraocular pressure, or decreased serum bicarbonate may occur during cidofovir injection therapy.

Adverse Reactions: During clinical trials, nephrotoxicity, neutropenia, decreased intraocular pressure/ocular hypotony, anterior uveitis/iritis, and metabolic acidosis were reported.

Overdosage: Two cases of overdose have been reported. Patients received single doses of cidofovir injection at 16.3 mg/kg and 17.4 mg/kg, respectively, with concomitant oral probenecid and intravenous hydration. In both cases, the patients were hospitalized and received oral probenecid and vigorous intravenous hydration with normal saline for 3-5 days. Significant changes in renal function were not observed in either patient.

3 COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS No.
Cidofovir	149394-66-1
Water for injection	7732-18-5

Sodium hydroxide and/or hydrochloric acid are used for pH adjustment

4 FIRST AID MEASURES

Finished Pharmaceutical Product

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Contact may cause irritation. Effects may include stinging, watering, and/or redness to the eyes. Get medical attention if symptoms persist.

Skin Contact: The risk of skin contact is negligible when product is in its final packaged form. If skin contact occurs, wash skin with soap and water for at least 15 minutes. Contact may cause irritation. Should skin irritation, allergic reaction, itching/burning, or rash occur, remove contaminated clothing if required, and flush exposed area with large amounts of water. Seek medical attention if skin reaction occurs.

Ingestion: Ingestion is not an anticipated route of exposure. Do not induce vomiting unless directed by medical personnel. Flush mouth out with water and get medical attention.

5 FIRE-FIGHTING MEASURES

Extinguishing Media: Product is non-flammable. Use appropriate extinguishing media for fire in surrounding area.

Special Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Unusual Fire & Explosion Hazards: None are expected.

Hazardous Combustion Products: Thermal decomposition or combustion may generate toxic and hazardous fumes.

6 ACCIDENTAL RELEASE MEASURES

Steps To Be Taken When Handling Damaged Packages or if Significant Quantities of Product is Spilled: Use appropriate personal protective equipment (safety glasses, protective clothing and gloves) to minimize exposure. Collect spill with absorbent material and place in a suitable, properly labeled container for recovery or disposal. Dispose according to applicable regulations.

7 HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling. Normal room ventilation is expected to be adequate for routine handling of the product.

Storage: No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain product efficacy.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Not generally required when handling product in its final packaged form. In an occupational setting, site-specific risk assessments should be conducted to determine the appropriate exposure control measures.

Personal Protective Equipment: Not generally required when handling product in its final packaged form.

Respiratory Protection: Not generally required when handling product in its final packaged form. In an occupational setting, site-specific risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

Eye Protection: Not generally required when handling product in its final packaged form. In laboratory, medical, or industrial settings, safety glasses with side shields are recommended if eye contact is possible.

Hand/Skin Protection: Not generally required when handling product in its final packaged form. In laboratory, medical or industrial settings, nitrile or neoprene gloves, and lab coats are recommended for product contact.

Hygiene Measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Keep product away from foodstuffs, beverages, and food.

9 PHYSICAL AND CHEMICAL PROPERTIES

Finished Pharmaceutical Product

Physical State and Color: Cidofovir injection is a sterile, hypertonic aqueous solution. The solution is clear and colorless and is supplied in single-use clear glass vials. The formulation is pH-adjusted to 7.4.

10 STABILITY AND REACTIVITY

Stability: Stable at recommended storage conditions.

Conditions to Avoid: Excess heat, cold or moisture. Store according to Physician's Desk Reference.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Polymerization: Will not occur.

11 TOXICOLOGICAL INFORMATION

Active Ingredient (Cidofovir)

Acute Toxicity: Minimum Lethal IV Dose: >800mg/kg (rodents); >100mg/kg (rabbits); 40mg/kg (monkeys)

Carcinogenicity: The substance is not listed as a carcinogen by IARC, NTP or OSHA.

Mutagenicity: No mutagenic response was observed in microbial mutagenicity assays involving *Salmonella typhimurium* (Ames) and *Escherichia coli* in the presence and absence of metabolic activation; however, cidofovir induced chromosomal aberrations in human peripheral blood lymphocytes *in vitro* (without metabolic activation) and was positive in an *in vivo* micronucleus assay.

Developmental and Reproductive Effects: Developmental toxicity occurred in rats and rabbits at maternally toxic intravenous doses. Cidofovir caused inhibition of spermatogenesis in rats and monkeys; however, no adverse effects on fertility or reproduction were observed in male rats administered weekly intravenous injections of cidofovir at 15 mg/kg/week for 13 consecutive weeks. Female rats dosed intravenously once per week at 1.2 mg/kg/week for up to 6 weeks prior to, and for 2 weeks post-mating, had decreased litter sizes and live births per litter, and increased early resorptions. No adverse effects on reproduction were noted in peri- and post-natal studies in female rats.

12 ECOLOGICAL INFORMATION

Ecological properties have not been investigated. Local regulations should be consulted in the event of an environmental release.

13 DISPOSAL CONSIDERATIONS

Occupational Disposal Information: Disposal must be in accordance with applicable federal, state/provincial and/or local regulations.

14 TRANSPORT INFORMATION

U.S. DOT: Not Regulated
IATA: Not Regulated
TDG: Not Regulated
IMDG: Not Regulated

15 REGULATORY INFORMATION

US Regulations:

Drug Enforcement Act: Not regulated
Inventory - United States TSCA: Exempt
CERCLA Status: Not regulated
SARA Status: Not regulated
RCRA Status: Not regulated
FDA: Cidofovir Injection is an FDA approved prescription drug product.

Component Analysis:

Cidofovir

California Proposition 65:	Listed as a carcinogen, developmental toxicant, and reproductive toxicant

Water for injection

Inventory - United States TSCA - Sect. 8(b):	Present
Australia (AICS):	Present
EU EINECS List:	231-791-2

16 OTHER INFORMATION

Revision Information: New
Issue Date: 18-June-12

Disclaimer: This MSDS has been prepared for occupational exposure. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.