



GILEAD

Material Safety Data Sheet

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VISTIDE (CIDOFOVIR INJECTION)

1. Identification of the Substance

Material: Cidofovir, Vistide®
Synonyms: GS-0504, HPMPC, (S)-1-[3-hydroxy-2-(phosphonomethoxy)-propyl]cytosine
Chemical Formula: C₈H₁₄N₃O₆ P-2H₂O
Chemical Family: Nucleotide Analog
Molecular Weight: 315.22
Ingredients: 75 mg/ml cidofovir in water, pH 7

2. Composition/Information on Ingredients - % by Weight

Ingredient	CAS RN	EINECS/ELINCS No.	Percentage	EU Risk Phrases
Cidofovir	149394-66-1	Not identified		

3. Hazards Identification

Emergency Overview: Wear gloves and protective clothing when handling material. Avoid direct contact with the solution. In case of broken vials, promptly remove material on skin, eyes or clothing by rinsing thoroughly with water.

Fire & Explosion: This product is not expected to be combustible.

Health: Renal impairment is the major toxicity of cidofovir after intravenous injection. Neutropenia (reduced neutrophil counts and uveitis/iritis) has been observed in patients. In animal studies, cidofovir was carcinogenic, teratogenic and caused hypospermia.

Environment: Unknown.

4. First Aid Measures

If adverse systems develop, seek medical attention. Provide medical professional with a copy of the Material Safety Data Sheet for reference.

Skin Contact: Immediately wash skin with soap and water

Eye Contact: Flush thoroughly with running water for at least 15 minutes.

Ingestion: Avoid ingestion.

Inhalation: No data available. Avoid inhalation

Notes to Health Professionals

Medical Treatment: No medical conditions aggravated by occupational exposure are known. Treat symptomatically.

5. Fire Fighting Measures

Fire and Explosion Hazard: Not a fire hazard. Not an explosion hazard.

Extinguishing Media: Use appropriate means for extinguishing surrounding fire.

Special Firefighting Procedures: None.

Hazardous Combustion Products: Not determined.

6. Accidental Release Measures

Spills

Personal Precautions: In the event of a spill, wear gloves and other suitable protective equipment to avoid skin exposure.

Environmental Precautions: Collect material and dispose of in accordance with local, state and federal regulations.

Clean-up Methods: Place all material exposed to Vistide in a leak-proof, puncture-proof container for disposal.

Decontamination Procedures: Not available.

7. Handling and Storage

Observe all federal, state and local regulations. Use prudent laboratory practices and good chemical hygiene for handling and storage of chemical substances of unknown toxicity.

Handling: Avoid contact with skin, eyes or clothing. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below OEL.

Storage: Material is supplied in vials containing 5 ml of liquid, with 75 mg Cidofovir per ml. The vials are stoppered and crimp sealed. Store Vistide at room temperature – between 15 – 30 degrees Celsius. Health hazards can only arise in case of vial damage allowing contents to leak or spill.

8. Exposure Controls/Personal Protection

Ingredient Vistide, Cidofovir

Gilead Occupational Hazard Category (HC) 3—Potent (1—Low Toxicity; 4—Highly Potent)

Occupational Exposure Limits (OELs) Not established.

Control levels are established for operations involving this material upon the OEL/Hazard Category (HC) and the outcome of a site- or operation-specific risk assessment. Exposure controls should be verified to ensure that the OEL for the compound can be met. Contact Gilead Sciences, Inc. for more information about the OEL and Hazard Categorization regarding this compound.

Engineering Controls and Ventilation:

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below the OEL. If user operations generate dust, fumes or mists, use appropriate ventilation equipment to keep exposure to airborne contaminants below the exposure limit.

Quantities up to 2 kilograms (kg) must be handled in powder weighing hoods such as ventilated balance enclosures (VBE) or unventilated glove boxes, or equivalent containment systems.

Quantities exceeding 2 kg should be handled as appropriate to the operation, either using specific containment, appropriate ventilation equipment or specific local exhaust, and appropriate personal protective equipment (PPE). HEPA filtered exhaust is considered necessary.

Barrier/containment technology (enclosed processes that create a barrier between the equipment and the worker) with the use of glove bags, isolator/box systems, direct connections, coupling/transfer systems and closed systems should be used in manufacturing. Selective use of directionalized, specially designed airflow booths may be employed if effectiveness has been verified through industrial hygiene monitoring.

Respiratory Projection:

When engineering controls are not sufficient to control exposure when handling API, wear an approved respirator with a NIOSH Class 100 or high efficiency particulate (HEPA) filter or cartridges for quantities of 300 mg or less. A half-face negative pressure, full-face negative pressure, or powered air purifying respirator (PAPR) is required when handling 300 milligrams to 1 kilogram, and a full-face negative pressure, helmet-type PAPR, or supplied air respirator is required when handling >2 kg.

Eye Protection:

Wear safety glasses (ANSI Z87.1). Note: choice of eye protection may be influenced by the type of respirator selected.

Hand/Arm Protection;

Wear impervious (nitrile or low protein, powder-free latex) gloves whenever the potential for skin contact exists. If material is handled in solution, the solvent used must be considered in selecting the glove material. Employees who are allergic to natural rubber latex should use nitrile gloves. Use particular care when removing gloves to minimize exposure.

Skin Protection:

Wear protective laboratory coat or coverall when handling quantities less than 1 kilogram. For quantities greater than 1 kilogram and where mist generation can occur, wear coverall and shoe covers. If material is handled in solution, the solvent should be considered when selecting the protective clothing material.

Hygiene:

Wash hands after handling components and before eating, smoking, using the restroom and at the end of the workday.

9. Physical and Chemical Properties

Appearance:	Clear liquid.
Odor:	None
Chemical Formula:	C ₈ H ₁₄ N ₃ O ₆ P-2H ₂ O
Molecular Weight:	315.22
Physical Form:	Liquid, 75 mg/ml cidofovir in water
Solubility:	N/A
Melting Point:	N/A
Boiling Point:	Not known
Density:	1.044 g/ml
pH:	7
Vapor Pressure:	Not Known.
Evaporation Point:	Not known.

10. Stability and Reactivity

Stability:	Stable under normal ambient conditions.
Incompatibility:	None known.
Hazardous Decomposition:	None.
Hazardous Polymerization:	Will not occur

11. Toxicological Information

The toxicological properties of this molecule have not been fully characterized. Because of this, it is suggested that conservative handling practices be employed at all times.

Inhalation:	No information available.
Eye Contact:	Minimal effects; may cause irritation.
Skin Contact:	Minimal effects; may cause irritation.
Ingestion:	May be harmful if swallowed.
Reproductive Effects:	Teratogenic in rabbits, embryotoxic in rats and rabbits. The no-observable-effect (NOEL) doses for embryotoxicity was 0.5 mg/kg/day (rats) and 0.25 mg/kg/day (rabbits) after intravenous administration.
Mutagenic Effects:	Negative in Ames test. Positive for chromosomal aberrations in human peripheral blood lymphocytes, and in a mouse micronucleus assay.
Carcinogenic Effects:	Mammary and Zymbal gland tumors were induced in rats when treated subcutaneously or intravenously. Therefore, cidofovir should be considered a potential carcinogen for humans.
Acute Toxicity:	Minimum lethal IV dose is >800 mg/kg in CD-1 mice and in Sprague-Dawley rats. In the cynomolgus monkey, the lethal dose is greater than 40 mg/kg, but less than 75 mg/kg.
Chronic Toxicity:	The major toxicities target the kidney (renal tubular nephrosis) and testicles (reduced weight and reduced spermatogenesis)
Sensitization:	No data available.
Target Organ Effects:	Renal impairment is the major toxicity of cidofovir after intravenous injection. Neutropenia (reduced neutrophil counts and uveitis/iritis) has been observed in patients. In animal studies, cidofovir was carcinogenic, teratogenic and caused hypospermia

12. Ecological Information

Summary:	This research compound has not been tested. Therefore, the environmental effects are not known. Local regulations and procedures should be consulted prior to environmental release.
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13. Disposal Considerations

Disposal Recommendations:	Incineration at an approved facility is the preferred method of disposal.
Regulatory Requirements:	Dispose in accordance with all applicable federal, state and local regulations.

14. Transportation Information

This Material Safety Data Sheet should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification for Labeling
And Transport Information:**

No information available.

15. Regulatory Information

The information included below is an overview of major regulatory requirements. It should not be considered an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labeling
Classification:**

No information available

**US OSHA Standard
(29 CFR 1910.1200):**

This MSDS complies with the requirements of the Hazard Communication Standard (29CFR 1910.1200).

Other US Regulations

TSCA Status:

Exempt

16. Other

The aforementioned information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Gilead Sciences, Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.

Abbreviations

ACGIH:	American Conference of Governmental Industrial Hygienists
CAS#:	Chemical Abstract Services Number
CFR	Code of Federal Regulations
DOT:	Department of Transportation
EINECS:	European Inventory of New and Existing Chemical Substances
EU:	European Union
HEPA:	High Efficiency Particulate Air Filter)
HVAC:	Heating, Ventilation and Air Conditioning (system)
IARC:	International Agency for Research on Cancer
OSHA:	Occupational Safety and Health Administration
NTP:	National Toxicology Program
TSCA:	Toxic Substances Control Act