SAFETY DATA SHEET



1. Identification

Product identifier Cidofovir Enantiomer

Other means of identification

Catalog number 1133864

Chemical name 1-[(R)-3-Hydroxy-2-(phosphonomethoxy) propyl] cytosine dihydrate

Recommended use For analytical laboratory use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790

20852-1790 United States

Telephone Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Skin corrosion/irritation Category 2

Germ cell mutagenicity

Category 2

Carcinogenicity

Category 2

Reproductive toxicity

Category 2

Specific target organ toxicity, single exposure Category 2 (kidney)

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statementCauses skin irritation. Suspected of causing genetic defects. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. May cause damage to organs (kidney).

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after

handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take

off contaminated clothing and wash it before reuse. If exposed or concerned: Call a poison

center/doctor.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Material name: Cidofovir Enantiomer

USP SDS US

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|----------------------|--------------------------|------------|-----|
| Cidofovir Enantiomer | | No Data | 100 |

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Inhalation

Call a physician if symptoms develop or persist.

Wash off with soap and water. Get medical attention if irritation develops and persists. Wash Skin contact

contaminated clothing before reuse.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

may cause physiological effects.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special

treatment needed **General information**

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

5. Fire-fighting measures

Suitable extinguishing media

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Material name: Cidofovir Enantiomer USP SDS US Conditions for safe storage. including any incompatibilities Store in tight container. This material should be handled and stored per label instructions to ensure

product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for

solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When **Hand protection**

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Train employees in proper gowning and degowning practices. Wear disposable lab coat, Other

> disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head Respiratory protection

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS

are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Solid. Physical state Powder. **Form**

White. Off-white. Color Odor Not available. **Odor threshold** Not available. Not available. Not available. Melting point/freezing point Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

Not available.

Explosive limit - lower (%) Not available. Explosive limit - upper (%) Not available.

Not available. Vapor pressure Vapor density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water)

Material name: Cidofovir Enantiomer

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Molecular formula C8H14N3O6P . 2H2O

Molecular weight 315.22

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. POx.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact Causes skin irritation.

Eye contact Knowledge about health hazard is incomplete. **Ingestion** Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics

Related material: Systemic effects following injection or infusion: Headache. Gastrointestinal

disturbances. Fever. Chills. It is not known if this material causes the same effects.

Information on toxicological effects

Acute toxicity Not known.

Skin corrosion/irritation Causes skin irritation.

In animal tests, a related material caused irritation.

Serious eye damage/eye

irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. **Skin sensitization** Knowledge about health hazard is incomplete.

Germ cell mutagenicity Suspected of causing genetic defects.

A related material was mutagenic in some, but not all, in vitro and/or in vivo assays.

Carcinogenicity Suspected of causing cancer.

A related material was carcinogenic in animal studies.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Suspected of damaging fertility or the unborn child. A related material has caused birth defects in

animals

Specific target organ toxicity -

single exposure

May cause damage to organs (kidney).

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmaceutical related compound of unknown potency. It is not known if occupational exposure

may cause physiological effects.

Material name: Cidofovir Enantiomer usp sps us

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this substance.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

General information

Not applicable.

It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

Germ cell mutagenicity

Skin corrosion or irritation

categories

Carcinogenicity Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Material name: Cidofovir Enantiomer USP SDS US

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

Inventory name

(SDWA)

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region

| Australia | Australian Inventory of Chemical Substances (AICS) | No |
|-----------------------------|--|----|
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

 Issue date
 03-24-2022

 Revision date
 03-24-2022

Version # 03

Disclaimer USP materials are sold for analytical laboratory use only, and NOT for human consumption. The

information contained herein is applicable solely to the chemical substance when used for analytical laboratory use and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP materials are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRIES OF MERCHANTABILITY AND FINESS FOR A

PARTICULAR PURPOSE is made with respect to the information contained herein.

Material name: Cidofovir Enantiomer usp sds us

On inventory (yes/no)*