



# Lamivudine(Form-I)

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision date: 18/05/2015

Version: 2.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Lamivudine(Form-I)
Chemical name	: 2(1H)-pyrimidinone,4-amino-1[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-,(2R-cis)-.
CAS No.	: 134678-17-4
Product code	: LF
Formula	: C8H11N3O3S
Product group	: Pharmaceutical product

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Main use category	: Industrial use,Professional use
Industrial/Professional use spec.	: Isolated intermediate
Function or use category	: Anti-hepatitis agent

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

Hetero Labs Ltd  
7-2-A2, Hetero corporate,  
500082 Hyderabad - INDIA  
T 04023774009  
[www.heterodrugs.com](http://www.heterodrugs.com)

#### 1.4. Emergency telephone number

No additional information available

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Classification according to Directive 67/548/EEC or 1999/45/EC

Carc.Cat.3; R40


Full text of R-phrases: see section 16.

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)	: 
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CLP Signal word	: Warning
Hazard statements (CLP)	: H302 - Harmful if swallowed H332 - Harmful if inhaled
Precautionary statements (CLP)	: P102 - Keep out of reach of children P103 - Read label before use P201 - Obtain special instructions before use P232 - Protect from moisture P233 - Keep container tightly closed P234 - Keep only in original container P235 - Keep cool P235+P410 - Keep cool. Protect from sunlight
EUH phrases	: EUH210 - Safety data sheet available on request

#### 2.3. Other hazards

No additional information available

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Name : Lamivudine(Form-I)  
CAS No. : 134678-17-4  
EC no :  
EC index no :

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		F; R11 Xi; R36 R66 R67
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		F; R11
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		F; R11 T; R23/24/25-39/23/24/25
Triethylamine	(CAS No.)121-44-8 (EC no)204-469-4 (EC index no)612-004-00-5		F; R11 Xn; R20/21/22 C; R35
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		F; R11 Repr.Cat.3; R63 Xn; R48/20-65 Xi; R38 R67
(2RS,5SR)-5-(4-amino-2-oxypyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylic acid			Not classified
4-amino-1[(2S,5R)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]pyrimidin-2(1H)-one			Not classified
Tetrahydrofuran	(CAS No.)109-99-9 (EC no)203-726-8 (EC index no)603-025-00-0		F; R11-19 Xi; R36/37
Methylene chloride	(CAS No.)75-09-2		Not classified
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		F; R11 Xi; R36 R66 R67
Pyridine	(CAS No.)110-86-1 (EC no)203-809-9 (EC index no)613-002-00-7		F; R11 Xn; R20/21/22

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl acetate	(CAS No.)141-78-6 (EC no)205-500-4 (EC index no)607-022-00-5		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Ethanol	(CAS No.)64-17-5 (EC no)200-578-6 (EC index no)603-002-00-5		Flam. Liq. 2, H225
Methanol	(CAS No.)67-56-1 (EC no)200-659-6 (EC index no)603-001-00-X		Flam. Liq. 2, H225 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Oral), H301 STOT SE 1, H370
Triethylamine	(CAS No.)121-44-8 (EC no)204-469-4 (EC index no)612-004-00-5		Flam. Liq. 2, H225 Skin Corr. 1A, H314 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302
Toluene	(CAS No.)108-88-3 (EC no)203-625-9 (EC index no)601-021-00-3		Flam. Liq. 2, H225 Asp. Tox. 1, H304 Repr. 2, H361d Skin Irrit. 2, H315 STOT RE 2, H373 STOT SE 3, H336
(2RS,5SR)-5-(4-amino-2-oxypyrimidin-1(2H)-yl)-1,3-oxathiolane-2-carboxylic acid			Not classified
4-amino-1[(2S,5R)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]pyrimidin-2(1H)-one			Not classified

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according to Regulation (EC) No. 453/2010

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Tetrahydrofuran	(CAS No.)109-99-9 (EC no)203-726-8 (EC index no)603-025-00-0		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H335
Methylene chloride	(CAS No.)75-09-2		Not classified
Acetone	(CAS No.)67-64-1 (EC no)200-662-2 (EC index no)606-001-00-8		Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Pyridine	(CAS No.)110-86-1 (EC no)203-809-9 (EC index no)613-002-00-7		Flam. Liq. 2, H225 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302

Full text of R-, H- and EUH-phrases: see section 16.

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
- First-aid measures after inhalation : When symptoms occur: go into open air and ventilate suspected area.
- First-aid measures after skin contact : Remove contaminated clothing. Flush area with large amount of water. USE SOAP. seek medical attention.
- First-aid measures after eye contact : Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use carbon dioxide, dry chemical.

### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : Flammable with air within explosion limits Indirect fire hazard may be ignited by sparks  
Gas/vapour spreads at floor level: ignition hazard.
- Explosion hazard : Not expected for the product, although the packaging is combustible.
- Reactivity : Product is not explosive.

### 5.3. Advice for firefighters

No additional information available

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent premiss.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

### 6.3. Methods and material for containment and cleaning up

- For containment : Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
- Other information : Wash clothing and equipment after handling.

### 6.4. Reference to other sections

No additional information available

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Gloves.  
Handling temperature : 25 °C

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Packed in double polythene bags inner transparent, outer black, kept in HDPE drums at 5±3°C.  
Storage temperature : 2-8 °C  
Storage area : Room.  
Special rules on packaging : Triple laminated aluminium package.

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

Personal protective equipment : Gas mask with filter type A. Gloves. Protective clothing. Safety glasses.



Materials for protective clothing : Chloroprene rubber nitrile rubber.

Hand protection : Gloves.

Eye protection : Safety glasses.

Skin and body protection : Protective clothing.

Respiratory protection : Gas mask with filter type A.

Other information : The present safety data sheet is consistent with the specific conditions relied on to justify the registration of the substance as isolated intermediate.

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according to Regulation (EC) No. 453/2010

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: A white to off-white powder.
Molecular mass	: 229.26 g/mol
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Melting point	: No data available
Solidification point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosive limits	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Log Kow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Product is not explosive.

#### 10.2. Chemical stability

Stable under normal conditions of use.

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

As a precautionary measure. Keep away from strong oxidizers.

#### 10.6. Hazardous decomposition products

No additional information available

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified

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Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Soluble in water.

Ecology - air : Not dangerous for the ozone layer(1999/45/EC).

#### 12.2. Persistence and degradability

##### Lamivudine(Form-I)(134678-17-4)

Persistence and degradability	% biodegradation.
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##### Triethylamine (121-44-8)

Persistence and degradability	% biodegradation.
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#### 12.3. Bioaccumulative potential

##### Lamivudine(Form-I)(134678-17-4)

Bioaccumulative potential	The substance has low potential for bioaccumulation.
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##### Triethylamine (121-44-8)

Bioaccumulative potential	The substance has low potential for bioaccumulation.
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#### 12.4. Mobility in soil

##### Lamivudine(Form-I)(134678-17-4)

Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
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##### Triethylamine (121-44-8)

Ecology - soil	The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.
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#### 12.5. Results of PBT and vPvB assessment

No additional information available

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Additional information : Wash clothing and equipment after handling.

Ecology - waste materials : Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

### SECTION 14: Transport information

No dangerous good in sense of transport regulations.

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

No Annex XVII restrictions

Contains no REACH candidate substance

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No additional information available

### SECTION 16: Other information

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

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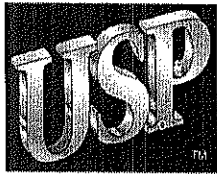
according to Regulation (EC) No. 453/2010

Full text of R-, H- and EUH-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Asp. Tox. 1	Aspiration hazard Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Flam. Liq. 2	Flammable liquids Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Corr. 1A	skin corrosion/irritation Category 1A
Skin Irrit. 2	skin corrosion/irritation Category 2
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
STOT SE 1	Specific target organ toxicity (single exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapour
H301	Toxic if swallowed
H302	Harmful if swallowed
H304	May be fatal if swallowed and enters airways
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H361d	Suspected of damaging the unborn child.
H370	Causes damage to organs
H373	May cause damage to organs through prolonged or repeated exposure
R11	Highly flammable.
R19	May form explosive peroxides.
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R35	Causes severe burns.
R36	Irritating to eyes.
R36/37	Irritating to eyes and respiratory system.
R38	Irritating to skin.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.
R40	Limited evidence of a carcinogenic effect
R48/20	Harmful: danger of serious damage to health by prolonged exposure through inhalation.
R63	Possible risk of harm to the unborn child.
R65	Harmful: may cause lung damage if swallowed.
R66	Repeated exposure may cause skin dryness or cracking.
R67	Vapours may cause drowsiness and dizziness.
C	Corrosive
F	Highly flammable
T	Toxic
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-816-8129  
8 a.m. to 5 p.m. EST Mon. - Fri.

## ATTENTION !

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard 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 Reference Standards 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 WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

## ZIDOVUDINE

Catalog Number: 1724500

Revision Date:

August 22, 2006

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Zidovudine

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

#### EMERGENCY OVERVIEW - Cancer Suspect Agent.

**Adverse Effects:** Adverse effects may include headache; muscle soreness, pain, or cramping; nausea; vomiting; general feeling of discomfort; rash; fever; chills; sore throat; changes in skin or nail color; eye problems; diarrhea; fast, shallow breathing or shortness of breath; unusual tiredness or weakness; loss of appetite; weight loss; constipation; and trouble sleeping. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Overdose effects may include pale skin, unusual tiredness or weakness, fever, chills, sore throat, increase in bleeding or bruising, severe nausea or vomiting, lack of coordination, involuntary eye movement, and convulsions.

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization, bone marrow suppression, myopathy or myositis, and cancer.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material, bone marrow depression, and impaired liver or kidney function.

**Cross Sensitivity:** n/f

**Target Organs:** Bone marrow and blood

For additional information on toxicity, see Section 11.

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Zidovudine



## ZIDOVUDINE

Catalog Number: 1724500

Revision Date:

August 22, 2006

Formula: C<sub>10</sub>H<sub>13</sub>N<sub>5</sub>O<sub>4</sub>

Synonym: Azidothymidine; AZT

Chemical Name: Thymidine, 3'-azido-3'-deoxy-

CAS: 30516-87-1

RTECS Number: XP2072000

Chemical Family: Organic azide (nucleoside compound)

Therapeutic Category: Antiviral

Composition: Pure Material

### SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** May cause irritation. Flush with copious quantities of water.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is rapidly absorbed from the gastrointestinal tract.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

#### Note to Physicians

**Overdose Treatment:** Overdose treatment should be symptomatic and supportive and may include the following:

1. Monitor closely for evidence of neurotoxicity or bone marrow suppression.
  2. Administer activated charcoal as a slurry.
  3. For bone marrow suppression, treat with transfusions and protective measures for granulocytopenia.
  4. For severe acidosis, administer intravenous sodium bicarbonate.
  5. Zidovudine is NOT effectively removed from blood by peritoneal dialysis or hemodialysis.
- [Meditext 2006 and USP DI 2006]

### SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

### SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.

### SECTION 7 - HANDLING AND STORAGE

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

### SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

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**ZIDOVUDINE****Catalog Number:** 1724500**Revision Date:**August 22, 2006

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**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.**Respiratory Protection:** Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.**Gloves:** Chemically compatible**Eye Protection:** Safety glasses or goggles**Protective Clothing:** Protect exposed skin.**Exposure Limits:** Industry: TWA 350 micrograms/m<sup>3</sup>

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

**Appearance and Odor:** White to yellowish crystalline solid; odorless.**Odor Threshold:** n/f**pH:** n/f**Melting Range:** 122 - 124° C; also reported as 106 - 115° C**Boiling Point:** n/f**Flash Point:** n/f**Autoignition Temperature:** n/f**Evaporation Rate:** n/f**Upper Flammability Limit:** n/f**Lower Flammability Limit:** n/f**Vapor Pressure:** n/f**Vapor Density:** n/f**Specific Gravity:** n/f**Solubility in Water:** Sparingly soluble**Fat Solubility:** n/f**Other Solubility:** Soluble in alcohol**Partition Coefficient: n-octanol/water:** 0.05**Percent Volatile:** n/f**Reactivity in Water:** n/f**Explosive Properties:** n/f**Oxidizing Properties:** n/f**Formula:** C<sub>10</sub>H<sub>13</sub>N<sub>5</sub>O<sub>4</sub>**Molecular Weight:** 267.24

## ZIDOVUDINE

Catalog Number: 1724500

Revision Date:

August 22, 2006

### SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to light, heat and moisture.

**Incompatibilities:** Oxidizing agents.

**Decomposition Products:** When heated to decomposition material emits toxic fumes of NO<sub>x</sub>. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

### SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: 3084 mg/kg

**Oral Mouse:** LD50: 3062 mg/kg

**Other Toxicity Data:** n/f

**Irritancy Data:** n/f

**Corrosivity:** n/f

**Sensitization Data:** n/f

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** Yes      **OSHA:** No

**Other Carcinogenicity Data:** Malignant and benign vaginal squamous cell tumors occurred female mice given doses of up to 120 mg/kg/day for 19 months. In rats, vaginal squamous cell carcinomas were found when given doses of up to 600 mg/kg/day for 20 months.

One transplacental carcinogenicity study in pregnant mice showed an increase in the incidence of vaginal tumors in offspring after both the mother and offspring were administered doses of 20 mg/kg/day or 40 mg/kg/day. An increase in the incidence of tumors of the lung, liver, and female reproductive tract was seen in another transplacental study where zidovudine was given at doses of 25 mg/day from days 12 to 18 of gestation.

An increase in the incidence of alveolar/bronchiolar carcinoma, adenoma or carcinoma (combined), and histiocytic cellular infiltration of the lung occurred in the male offspring of pregnant mice administered zidovudine at a dose of 200 and 300 mg/kg/day.

**Mutagenicity Data:** Zidovudine was shown to be mutagenic in a 5178Y/TK +/- mouse lymphoma assay and positive in an in vitro cell transformation assay. It was also clastogenic in a cytogenic assay using cultured human lymphocytes. Zidovudine was negative in one cytogenic study in rats, but was positive in mouse and rat micronucleus test after repeated doses.

**Reproductive and Developmental Effects:** Zidovudine has been used throughout pregnancy in women with HIV infections without evidence of birth defects or harm to the fetus.  
No effects on male or female fertility was observed in studies of rats given oral zidovudine at doses up to 450 mg/kg/day. Studies in rats and rabbits given oral doses of up to 500 mg/kg/day have not shown zidovudine to cause birth defects. There was an increased incidence of fetal resorptions in rats given 150 or 450 mg/kg/day, rabbits given 500 mg/kg/day, and mice given 0.25 mg/ml in drinking water. In rats, 3000 mg/kg/day caused maternal toxicity and an increase in the incidence of fetal malformations, but birth defects were not seen at doses of 600 mg/kg/day or less.

### SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** This material is not toxic to daphnids, is not readily nor inherently biodegradable, and may persist in the environment.

### SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.

ZIDOVUDINE

Catalog Number: 1724500

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**SECTION 14 - TRANSPORT INFORMATION**

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

**SECTION 15 - REGULATORY INFORMATION**

U.S. Regulatory Information: n/f

International Regulatory Information: Hazard Code: Xn  
Risk Phrases: R40, R68  
Safety Phrases: S36/37/39, S53

**SECTION 16 - OTHER INFORMATION**

Revision: 22-Aug-06

Previous Revision Date: 30-Apr-04