SAFETY DATA SHEET

1. Identification

Product identifier **Stavudine**

Other means of identification

Catalog number 1620209

Chemical name Thymidine, 2',3'-didehydro-3'-deoxy-

Synonym(s) d4T

Recommended use Specified quality tests and assay use only.

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

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 4
Serious eye damage/eye irritation	Category 2B
Specific target organ toxicity, repeated exposure	Category 1 (blood, liver, peripheral nervous system)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Harmful if swallowed. Causes eye irritation. Causes damage to organs (blood, liver, peripheral nervous system) through prolonged or repeated exposure.

Precautionary statement

Prevention Wash thoroughly after handling.

Response If swallowed: Call a poison center/doctor// if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Get medical advice/attention if you feel unwell.

Storage Not available.

Disposal Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Stavudine	d4T	3056-17-5	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

Most important symptoms/effects, acute and delayed Irritation of eyes and mucous membranes. Liver enlargement. Jaundice.

Indication of immediate medical attention and special treatment needed Treatment of antiviral nucleoside overdose should be symptomatic and supportive and may include the following: Administer activated charcoal as a slurry. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For bone marrow suppression, transfusions and protective measures for granulocytopenia may be needed. For severe metabolic acidosis, correct with intravenous sodium biocarbonate. Riboflavin (oral or intravenous) and L-carnitine have also been used to treat patients with severe lactic acidosis associated with nucleoside analogs. (Meditext)

General information 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.

5. Fire-fighting measures

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

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

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

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

7. Handling and storage

Precautions for safe 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. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Stavudine (CAS 3056-17-5)	TWA	0.02 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white, crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	332.6 - 345.2 °F (167 - 174 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Partition coefficient (n-octanol/water)	0.1
Auto-ignition temperature	914 °F (490 °C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Thymidine analog.
Molecular formula	C10-H12-N2-O4

Molecular weight	224.21
Solubility (other)	Soluble in dimethylacetamide and in dimethyl sulfoxide; slightly soluble in dichloromethane; sparingly soluble in methanol, in ethanol, in acetonitrile, and in propylene glycol; insoluble in hexane.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Causes eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	Numbness, pain, tingling, or weakness in hands or feet. Burning or tingling sensations. Muscle pain. Joint pain. Nausea. Vomiting. Diarrhea. Stomach pain. Yellow eyes and/or skin. Dark urine. Clay-colored stools. Fatigue. Shortness of breath. Weakness. Rapid breathing. Chills. Fever. Headache. Unsteadiness. Rash. Trouble sleeping.
Delayed and immediate effects of exposure	Liver damage. Jaundice.
Chronic effects	Peripheral polyneuropathy. Liver damage.
Medical conditions aggravated by exposure	Lactic acidosis. Pancreatitis. Impaired liver function. Impaired kidney function. History of peripheral neuropathy.
Acute toxicity	Harmful if swallowed.

Product	Species	Test Results
Stavudine (CAS 3056-17-5)		
Oral		
LD50	Mouse	1000 - 2000 mg/kg
	Rat	> 4055 mg/kg, (female rats only)
		882 - 2000 mg/kg, (male rats only)

Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Causes eye irritation.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Data from germ cell mutagenicity tests were not found. Due to inconclusive data the classification criteria are not met.

Mutagenicity

600 - 2000 mg/kg/day In vivo micronucleus test (3 days)
Result: Clastogenic in bone marrow cells.
Species: Mouse
Test Duration: 3 days
Ames test
Result: Negative.
Cell transformation assay
Result: Positive.
Chromosome aberration test (human lymphocytes)
Result: Positive, without activation.
In vitro genotoxicity assay (mouse fibroblasts)
Result: Positive.
In vivo micronucleus test (1 month)
Result: Negative.
Species: Mouse

Mutagenicity

In vivo micronucleus test (7 days)
Result: Negative.
Species: Rat
Mammalian cell forward gene mutation assay (Chinese hamster ovary/HGPRT)
Result: Negative, with and without metabolic activation.

Carcinogenicity Due to lack of data the classification is not possible.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Two-year dietary study
Result: Benign and malignant liver tumors and malignant urinary bladder tumors in male rats occurred at doses 732x the human level.
Species: Rat
Two-year dietary study
Result: Benign and malignant tumors developed in the liver at doses 250x the human level.
Species: Mouse

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductivity

1000 mg/kg/day Developmental study (oral doses 399x human dose)
Result: Changes in fetal skeletal development and increased mortality.
Species: Rat
600 mg/kg/day Developmental study (oral doses 183x human dose)
Result: No significant adverse effects observed.
Species: Rabbit
600 mg/kg/day Developmental study (oral doses 216x human dose)
Result: Maternal toxicity, postimplantation loss, and decreased pup body weight.
Species: Rat

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Causes damage to organs (blood, liver, peripheral nervous system) through prolonged or repeated exposure.

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

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

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

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. 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 Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

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.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
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
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)

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

Issue date	02-25-2009
Revision date	01-07-2014
Version #	02
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.