

1. Identification

Product identifier Lamivudine Resolution Mixture A

Other means of identification

Catalog number 1356847

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

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

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 Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement Not available.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

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

Other hazards which do not result in classification None known.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Lamivudine	3TC	134678-17-4	98.9

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Lamivudine Related Compound D	ent-Lamivudine	134680-32-3	1.1

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. 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 with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
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	Water. Foam. Dry chemical or CO ₂ . 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	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.
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. 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	For waste disposal, see section 13 of the SDS. 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.

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 Components	Type	Value
Lamivudine (CAS 134678-17-4)	TWA	600 micrograms/m ³

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).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Fine white powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	None known.
Chemical stability	Stable at 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. NO _x , SO _x .

11. Toxicological information

Information on likely routes of exposure

Ingestion	Classification not possible.
Inhalation	Classification not possible.
Skin contact	Classification not possible.

Eye contact	Classification not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Component: Gastrointestinal disturbances. Numbness, pain, tingling, or weakness in hands or feet. Cough. Wheezing. Nasal congestion. Dizziness. Fatigue. Headache. Insomnia.
Delayed and immediate effects of exposure	Component: Bone marrow suppression. Peripheral neuropathy.
Medical conditions aggravated by exposure	Human immunodeficiency virus (HIV) and hepatitis B co-infection. Pancreatitis (history of or risk factors for developing). Antiretroviral therapy (history of or current use of). Organ transplant. Impaired liver function. Impaired kidney function.

Acute toxicity

Components	Species	Test Results
Lamivudine (CAS 134678-17-4)		
Oral		
LD50	Rat	> 2000 mg/kg
Skin corrosion/irritation	Classification not possible.	
Serious eye damage/eye irritation	Classification not possible.	
Respiratory or skin sensitization		
Respiratory sensitization	Classification not possible.	
Skin sensitization	Classification not possible.	
Skin sensitization		
Lamivudine		Sensitization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin.
Germ cell mutagenicity	Classification not possible. Data from germ cell mutagenicity tests were not found.	
Mutagenicity		
Lamivudine		In vitro Ames test and bacterial fluctuation test Result: Negative. In vitro human whole blood lymphocyte assay Result: Positive. In vitro mouse embryo cell culture assay Result: Negative. In vitro mouse lymphoma cell test Result: Positive. In vivo rat micronucleus test Result: Negative. In vivo unscheduled DNA synthesis assay in rat livers Result: Negative.
Carcinogenicity	Classification not possible. A component of this mixture has not caused cancer in animal studies.	
Lamivudine		Carcinogenicity study Result: No evidence of carcinogenicity in rats or mice.
Reproductive toxicity	Classification not possible. Antiretrovirals are used during pregnancy to prevent maternal HIV transmission. Therapy does not appear to significantly increase the risk of birth defects. Anemia and mitochondrial dysfunction have been observed in newborns. It is not known if this material causes the same effects.	
Reproductivity		
Lamivudine		1000 mg/kg/day Reproductivity study Result: No evidence of fetal malformations. Species: Rabbit 4000 mg/kg/day Reproductivity study Result: No effect on offspring. Species: Rat
Specific target organ toxicity - single exposure	Classification not possible.	
Specific target organ toxicity - repeated exposure	Classification not possible.	
Aspiration hazard	Not classified.	
12. Ecological information		
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).	

Persistence and degradability	Not available.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

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	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	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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	Not available.
General information	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 not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.	
Superfund Amendments and Reauthorization Act of 1986 (SARA)		
Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No	
SARA 302 Extremely hazardous substance	Not listed.	
SARA 311/312 Hazardous chemical	No	
SARA 313 (TRI reporting)	Not regulated.	
Other federal regulations		
Safe Drinking Water Act (SDWA)	Not regulated.	
Food and Drug Administration (FDA)	Not regulated.	
US state regulations		
US. 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.		

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

Country(s) or region	Inventory name	On inventory (yes/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)
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	06-06-2006
Revision date	04-22-2016
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.