



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

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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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 explosin 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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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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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.