**Product Name:** **Lamivudine**
**Issued:** **Jul-15-2013**

# SAFETY DATA SHEET

## Section 1. Identification of the substance/mixture and of the company/undertaking

### 1.1 Product Identifier

**Product Name:** Lamivudine

**Chemical Name:** 2',3'-Dideoxy-3'-thiacytidine

**Synonyms:** Epivir; 4-Amino-1-[2-(hydroxymethyl)-1,3-oxathiolab-5-yl]-1H-pyrimidine-2-one

**Drug Code Number:** 14109

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

**Recommended use:** Pharmaceuticals
Scientific research and development
Industrial use

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

**Supplier:** Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA

**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)
+1-847-937-7433

**E-mail Address:** AbbVie.SDS@abbvie.com

### 1.4 Emergency telephone number

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

## Section 2. Hazards identification

### 2.1 Classification of the substance or mixture

**Regulation (EC) No 1272/2008**
**Reproductive toxicity** Category 2

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**
**Risk Phrases:** R63 - Possible risk of harm to the unborn child

### 2.2 Label elements

## Section 2. Hazards identification

**Signal Word:** Warning

**Hazard Statements:** H361 - Suspected of damaging fertility or the unborn child

P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

| Chemical Name | Percent | EINECS/ELINCS Number | EEC Classification | EU - GHS Substance Classification | REACH No. |
|---|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | 100 | NA | Repr. Cat 3; R63 | Repr. 2 (H361) | No data available |

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**
**For the full text of the H-Statements mentioned in this Section, see Section 16**

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

**4.2 Most important symptoms and effects, both acute and delayed**

**Signs and Symptoms:** None known from occupational exposure.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

**4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Treat symptomatically

## Section 5. Firefighting measures

**5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

**5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** Not determined

**5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

## Section 6. Accidental release measures

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

**Personal Precautions:** For personal protection see section 8

**6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

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

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

**6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

## Section 7. Handling and storage

**7.1. Precautions for safe handling**

Handle in accordance with good industrial hygiene and safety practice

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

Store according to label instructions

### 7.3. Specific end use(s)

**Recommended use:** Pharmaceuticals
Scientific research and development
Industrial use

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

**Exposure limits:**

| Chemical Name | Employee Exposure Limit | Skin Notation |
|---|---|---|
| Lamivudine<br>134678-17-4 | 250 mcg/$m^3$ | None |

### 8.2. Exposure controls

**Engineering Controls:** Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

## Section 9. Physical and chemical properties

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

**Appearance:** White to off-white Powder
**Odor:** Not determined.
**Odor Threshold:** Not determined
**pH:** 6-8as an aqueous solution.
**Boiling Pt. @ 760 mm Hg (°C):** Not determined.
**Melting/Freezing Point (°C):** 177-179.5
**Flash Point (°C):** Not determined.
**Evaporation Rate at 20°C:** Not determined.
**Flammability (Solid):** Not determined.
**Lower Explosive Limit:** Not determined.
**Upper Explosive Limit:** Not determined.
**Vapor Pressure (mm Hg):** Not determined.
**Vapor Density (Air = 1):** Not determined.
**Specific Gravity:** Not determined.

**Solubility(ies):** Soluble in: water.
**Partition coefficient: n-octanol/water** Not determined.
**Log Po/w** -0.7
**Autoignition Temp. (°C):** Not determined.
**Decomposition temperature (°C):** Not determined.
**Viscosity (centipoise):** Not determined.
**Explosion Severity:** Not determined.
**Oxidizer Properties:** Not determined.

### 9.2. Other information

Not determined

## Section 10. Stability and reactivity

### 10.1. Reactivity

Not determined

### 10.2. Chemical stability

Stable under normal conditions

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Not determined.

### 10.4. Conditions to avoid

Not determined.

### 10.5 Incompatible materials

Not determined

### 10.6 Hazardous decompostion products

Carbon oxides, Nitrogen oxides (NOx), Sulfur oxides

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

**Routes of Exposure:**
**Oral:** Yes
**Dermal:** Yes
**Inhalation:** Yes

**Acute Toxicity - Oral:** Data for component (s) given below.

| Chemical Name | Acute Test | Value | Units | Species |
|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | LD50 > | 2000 | mg/kg | Mice<br>Rats |

**Acute Toxicity - Dermal:** Not determined.

**Acute Toxicity - Inhalation:** Not determined.

**Corrosivity:** Not determined.

**Dermal Irritation:** Not an irritant.

**Eye Irritation:** Not irritant.

**Sensitization:** Presumed not to be a skin sensitizer.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Pregnancy Category C : Risk cannot be Ruled Out

| Chemical Name | Species | Dosage | Units | Route | Duration |
|---|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | Rabbits | 1000 | mg/kg | Oral | During Gestation |

**Carcinogenicity:** Not carcinogenic in animal study.

**Mutagenicity:** Data for component (s) given below.

| Chemical Name | Micronucleus Assay | Ames Test: | Mouse Lymphoma Assay | Chromosomal Abbr. Assay |
|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | Negative | Negative | Positive | Positive |

**Aspiration hazard:** Not determined

**Notes:**
**1. ALD: Approximate lethal dosage**
**2. LC50: Concentration in air that produces 50% mortality**
**3. LD50: Oral or dermal dosage that produces 50% mortality**

## Section 12. Ecological information

### 12.1. Toxicity

Not considered hazardous to the aquatic environment.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**
1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## Section 14. Transport information

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

**14.1. UN Number:** Not applicable
**14.2. Proper shipping name:** Not applicable
**14.3. Hazard class:** Not applicable
**14.4. Packing group:** Not applicable
**14.5. Environmental hazard:** Not applicable
**14.6. Special Provisions:** Not applicable
**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable

## Section 15. Regulatory Information

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

### International Inventories

| Chemical Name | EINECS/ ELINCS | TSCA | DSL | NDSL | PICCS |
|---|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | - | - | - | Not listed. | - |

| Chemical Name | ENCS | ISHL | IECSC | AICS | KECL | New Zealand |
|---|---|---|---|---|---|---|
| Lamivudine<br>134678-17-4 | - | - | - | - | - | |

### Legend

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**ENCS** - Japan Existing and New Chemical Substances
**ISHL** - Japan Industrial Safety and Health Law
**IECSC** - China Inventory of Existing Chemical Substances

**AICS** - Australian Inventory of Chemical Substances
**KECL** - Korean Existing and Evaluated Chemical Substances

**Carcinogenicity Rating:**

| Chemical Name | Percent | NTP: | IARC: | ACGIH: |
|---|---|---|---|---|
| Lamivudine | 100 | Not Listed | Not Listed | Not Listed |

**SARA 313 Information**

| Chemical Name | Percent | SARA 313 Chemical: | CERCLA RQ/SARA EHS RQ (lbs): | SARA EHS TPQ (lbs): |
|---|---|---|---|---|
| Lamivudine | 100 | No | Not Applicable | Not applicable |

**Immediate Health:** Yes
**Delayed Health:** No
**Fire:** No
**Sudden Pressure:** No
**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**
Health: 1
Fire: 1
Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

### 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

## Section 16. Other information

**Risk Phrases:** R63 - Possible risk of harm to the unborn child

**Full text of H-Statements referred to under sections 2 and 3**
H361d - Suspected of damaging the unborn child

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**Product Name:** **Lamivudine**
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