

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	EPIVIR-HBV TABLETS
Synonym(s)	EPIVIR-HBV TABLETS 100 MG * ZEFFIX TABLETS 100 MG * ZEFIX TABLETS 100 MG * HEPTOVIR TABLETS 100 MG * HEPTODIN TABLETS 100 MG * HEPTODINE TABLETS 100 MG * HEPITEC TABLETS 100 MG * 3TC-HBV TABLETS 100 MG * LAMIVUDINE TABLETS 100 MG * NDC NO 0173-0662-00 * LAMIVUDINE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
LAMIVUDINE	134678-17-4	39.1	
NON-HAZARDOUS INGREDIENTS	Unassigned	60.9	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: abdominal pain; headache; nausea; vomiting; fatigue; rash. Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.</p>
Environment	No environmental hazards have been identified for this material.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
------------------	---

Material EPIVIR-HBV TABLETS

Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE

HANDLING

General Requirements Avoid breaking or crushing tablets.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	LAMIVUDINE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	600 mcg/m ³ (8 HR TWA) REPRODUCTIVE HAZARD
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

Material EPIVIR-HBV TABLETS

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Tablet.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This preparation contains ingredient(s) with the following activity: an anti-viral agent.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity Not expected to be genotoxic, based on effects of individual components.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Contains components which have been classified as: Possible risk of toxicity in developing human offspring.

Other Adverse Effects The following adverse effects have been noted with therapeutic use of this material: abdominal pain; headache; nausea; vomiting; fatigue; rash.

12. ECOLOGICAL INFORMATION

Summary This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Microbial Growth Inhibition This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

Minimum Inhibition Concentration:

- > 1000 mg/l, , Azotobacter beijerinckii
- > 1000 mg/l, , Pseudomonas aeruginosa
- > 1000 mg/l, , Trichoderma harzianum
- > 1000 mg/l, , Aspergillus niger
- > 1000 mg/l, , Nostoc commune

Algal This material contains an active pharmaceutical ingredient that is not toxic to algae.

IC50: > 96.9 mg/l, 72 Hours, Selenastrum capricornutum, green algae

NOEC: > 96.9 mg/l, 72 Hours, Selenastrum capricornutum, green algae

Daphnid This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

NOEC: > 1000 mg/l, 48 Hours, Daphnia magna, Static test

Fish This material contains an active pharmaceutical ingredient that is not toxic to fish.

Material EPIVIR-HBV TABLETS

Juvenile Oncorhynchus mykiss, rainbow trout

EC50: > 97.7 mg/l, 96 Hours, Static test

MOBILITY**Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

AdsorptionHenry's Law Constant 1.00E-13 atm m³/mol, Estimated

This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.

Soil Sediment Sorption 1.5 to 2.03, Measured (log K_{oc}):**Partitioning**

This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION**Hydrolysis**

This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured

Photolysis

This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation.

UV/Visible Spectrum: 271 nm at pH 7

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

Aerobic - Ready

Percent Degradation: < 1 %, 28 days, Modified Sturm test.

Aerobic - Inherent

Percent Degradation: 4 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

Aerobic - Inherent

Percent Degradation: 0 %, 28 days, Modified Zahn-Wellens, DOC removal., Activated sludge

Aerobic - Soil

Percent Degradation: 15 to 24 %, 64 days

Bioaccumulation

This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

13. DISPOSAL CONSIDERATIONS**Disposal Recommendations**

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling**Transport Information**

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 11

SDS Sections Updated

Sections

COMPOSITION / INFORMATION ON INGREDIENTS

Subsections

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.