SAFETY DATA SHEET

GlaxoSmithKline

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

Material **COMBIVIR TABLET**

Synonyms COMBIVIR TABLET 150/300MG * COMBIVIR COMPRESSE * COMBIVIR COMPRIMES * COMBIVIR COMPRIMIDOS * COMBIVIR COMPRIMIDOS RECUBIERTOS * COMBIVIR COMPRIMIDOS REVESTIDOS * COMBIVIR FILMOM OBALENE TABLETY * COMBIVIR FILMTABLETTEN * COMBIVIR POTAHOVANE TABLETY * COMBIVIR TABLETAS * COMBIVIR TABLETE * COMBIVIR TABLETES * COMBIVIR TABLETKI POWLEKANE * COMBIVIR TABLETTA * COMBIVIR TABLETTEN * COMBIVIR TABLETTER * COMBIVIR TABLETTI * NDC NO 0173-0595-00 * NDC NO 0173-0595-02 * LAMIVUDINE/ZIDOVUDINE, FORMULATED PRODUCT

Company Name

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
LAMIVUDINE	134678-17-4	17.6
ZIDOVUDINE	30516-87-1	35.2
NON-HAZARDOUS INGREDIENTS	Unassigned	47.2

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health	Caution - Pharmaceutical agent. Eye irritant. May produce mutagenic effects in human cells. Exposure might occur via eyes; skin; ingestion. Health effects information is based on hazards of components.
*** 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.
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 current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Avoid breaking or crushing capsules.
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/m3 (8 HR TWA)	REPRODUCTIVE HAZARD
INGREDIENT	ZIDOVUDINE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	350 mcg/m3 (8 HR TWA)	CARCINOGEN

ENGINEERING CONTROLS

Exposure Controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.
Containment	Open handling may result in overexposure.
Ventilation	Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields or cover goggles if eye contact is possible.
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	White.
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. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation might occur following direct contact with eyes.

Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Possible human mutagen.
Carcinogenicity	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. Positive results occurred in some studies that are not considered to be relevant to occupational exposure conditions. Not expected to produce cancer in humans under occupational exposure conditions based upon negative results in laboratory assays.
Reproductive Effects	Contains components which have been classified as: Possible risk of toxicity in developing human offspring. Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a nucleoside inhibitor of viral reverse transcriptase
*** Other Adverse Effects**	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary**

No information is available about the potential of this product to produce adverse environmental effects. This material contains two or more active pharmaceutical ingredients that have been tested, and no environmental effects have been identified. Consult the MSDS of each ingredient for specific information about potential environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient which is the majority component is provided below.

ECOTOXICITY

Aquatic

*** Activated Sludge Respiration**

This material is not toxic to activated sludge microorganisms. This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge

*** Microbial Growth Inhibition**

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

Minimum Inhibition Concentration:	250 mg/l, , Aspergillus flavus
	> 1000 mg/l, , Azotobacter chroococcum
	> 1000 mg/l, , Chaetomium globosum
	> 1000 mg/l, , Nostoc sp.
	> 1000 mg/l, , Pseudomonas fluorescens

*** Daphnid**

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

EC50:	> 100 mg/l, 48 Hours, Daphnia magna, Static test
Chronic LOEC:	40 mg/l, 21 Days, Daphnia magna, Static renewal test
Chronic NOEC:	16 mg/l, 21 Days, Daphnia magna, Static renewal 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 the air from hard surfaces or from a container of the pure substance.

Henry's Law Constant 3.50E-15 atm m^3/mol, Estimated at 25 C

*** Adsorption**

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

Soil Sediment Sorption (log Koc): 1.1, Estimated at pH 7

Sludge Biomass Distribution Coefficient (log Kd): 1.34 Measured Measured at pH 7

*** 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 has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.

Half-Life, Aqueous: 9.04 Hours, Measured, pH 7 Buffer Solution

UV/Visible Spectrum: 266 nm

*** Biodegradation**

This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

Aerobic - Ready

Percent Degradation: 0.23 %, 28 days, Modified Sturm test., Activated sludge

Percent Degradation: 50 %, 3 days, , Activated sludge

Aerobic - Inherent

Percent Degradation: 50 %, 3 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

*** 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

Date Approved/Revised 18-Nov-2004 **SDS Version Number** 6

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation
	Daphnid
	Distribution
	Earthworm
	Ecotoxicity
	Fish
	Hydrolysis
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Volatility
HAZARDS IDENTIFICATION	Environment

SDS Sections Updated

Sections	Subsections
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Other Adverse Effects

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.