

SAFETY DATA SHEET



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

Material	COMBIVIR TABLETS
Synonym(s)	COMBIVIR TABLETS 150 MG/300 MG * 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 * 3TC COMPLEX COMPRIMIDOS * COMBID 300 TABLETS * NDC NO 0173-0595-00 * NDC NO 0173-0595-02 * LAMIVUDINE AND ZIDOVUDINE, 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	17.6	
NON-HAZARDOUS INGREDIENTS	Unassigned	47.2	
ZIDOVUDINE	30516-87-1	35.2	

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. May produce mutagenic effects in human cells. Limited evidence of carcinogenic effect. Exposure might occur via skin; eyes; ingestion. Health effects information is based on hazards of components.</p>

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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 Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of an anti-viral agent.

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 tablets.

STORAGE

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	ZIDOVUDINE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	350 mcg/m ³ (8 HR TWA)	CARCINOGEN

INGREDIENT	LAMIVUDINE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	600 mcg/m ³ (8 HR TWA)	REPRODUCTIVE HAZARD

Other Equipment or Procedures Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. 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. TOXICOLOGY INFORMATION

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

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.

Routes of Exposure

Oral Toxicity	Not expected to be toxic following ingestion. Assessment based upon effects of individual components.
Skin Effects	Irritation is not expected following direct contact. Assessment based upon effects of individual components.
Eye Effects	Irritation is not expected following direct contact with eyes. Assessment based upon effects of individual components.

Sensitisation Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.

Genetic Toxicity Possible human mutagen. Assessment based upon effects of individual components.

Carcinogenicity Possible human carcinogen. Assessment based upon effects of individual components. Not expected to produce cancer in humans under occupational exposure conditions.

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

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 daphnids.

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 m³/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 K_{oc}): 1.1, Estimated at pH 7

Sludge Biomass Distribution Coefficient (log K_d): 1.34 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

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Biodegradation	UV/Visible Spectrum:	266 nm
	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
Bioaccumulation	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.	
	Aerobic - Ready	
	Percent Degradation:	50 %, 3 days, , Activated sludge
	Aerobic - Inherent	
	Percent Degradation:	50 %, 3 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

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. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.
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.
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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.
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Other US Regulations

TSCA Status	Exempt
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16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 10

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
HANDLING AND STORAGE	General Requirements

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.