

## SAFETY DATA SHEET



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

<b>Material</b>	<b>TRIZIVIR TABLETS</b>
<b>Synonyms</b>	TRIZIVIR 300 MG /150 MG/300 MG TABLETS * TRIZIVIR APVALKOTAS TABLETES * TRIZIVIR COMPRESSE * TRIZIVIR COMPRIMES * TRIZIVIR COMPRIMES PELLICULES * TRIZIVIR COMPRIMIDOS * TRIZIVIR COMPRIMIDOS RECUBIERTOS * TRIZIVIR COMPRIMIDOS REVESTIDOS * TRIZIVIR POTAHOVANE TABLETY * TRIZIVIR TABLETAS * TRIZIVIR TABLETTEN * TRIZIVIR TABLETTER * NDC NO 0173-0691-00 * NDC NO 0173-0691-01 * NDC NO 0173-0691-20 * ABACAVIR SULFATE/LAMIVUDINE/ZIDOVUDINE, FORMULATED PRODUCT
<b>Company Name</b>	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK 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  GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ABACAVIR HEMISULPHATE	188062-50-2	22.9
LAMIVUDINE	134678-17-4	9.7
ZIDOVUDINE	30516-87-1	19.5
NON-HAZARDOUS INGREDIENTS	Unassigned	47.9

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
---------------------------	---------------------------------

<b>Health</b>	Caution - Pharmaceutical agent. Exposure might occur via eyes; skin; ingestion. Severe eye irritant. May produce allergic skin reactions. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). Health effects information is based on hazards of components.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

#### 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	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. Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Antidotes</b>	No specific antidotes are recommended.

#### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
-----------------------------	--

<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	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.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

<b>INGREDIENT</b>	ABACAVIR HEMISULPHATE	
<b>GSK Occupational Hazard Category</b>	2	
<b>GSK Occupational Exposure Limit</b>	600 mcg/m <sup>3</sup> (8 HR TWA)	SKIN SENSITISER

<b>INGREDIENT</b>	ZIDOVUDINE	
<b>GSK Occupational Hazard Category</b>	2	
<b>GSK Occupational Exposure Limit</b>	350 mcg/m <sup>3</sup> (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** Blue/green.

**Physical Form** Tablet.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Inhalation Toxicity</b>	No studies have been conducted.
<b>Skin Effects</b>	Irritation is not expected following direct contact.
<b>Eye Effects</b>	Severe irritation might occur following direct contact with eyes.
<b>Target Organ Effects</b>	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells.
<b>Sensitisation</b>	Allergic skin reactions might occur following dermal exposure.
<b>Genetic Toxicity</b>	Possible human mutagen.
<b>Carcinogenicity</b>	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.
<b>Reproductive Effects</b>	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.
<b>Pharmacological Effects</b>	This preparation contains ingredient(s) with the following activity: a nucleoside inhibitor of viral reverse transcriptase
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>* Summary</b>	This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient is provided below. Appropriate precautions should be taken to limit release of this mixture to the environment. Local regulations and procedures should be consulted prior to environmental release.
------------------	---

### ECOTOXICITY

#### Aquatic

<b>* Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 71.4 mg/l, 3 Hours, Activated sludge
<b>* Algal</b>	This material contains an active pharmaceutical ingredient that is harmful to algae. IC50: 57.4 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test NOEL: 30 mg/l, 72 Hours, Selenastrum capricornutum, green algae, Static test
<b>* Daphnid</b>	This material contains an active pharmaceutical ingredient that is not toxic to daphids. EC50: 139 mg/l, 48 Hours, Daphnia magna, Static test NOEL: 70.9 mg/l, 48 Hours, Daphnia magna, Static test

- \* **Fish** This material contains an active pharmaceutical ingredient that is not toxic to fish.  
Adult Oncorhynchus mykiss, rainbow trout  
EC50: > 120 mg/l, 96 Hours, Static test  
Adult Oncorhynchus mykiss, rainbow trout  
NOEL: 120 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.  
Henry's Law Constant 8.50E-12 atm m<sup>3</sup>/mol, Measured 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 2.17 to 2.97, Measured (log Koc):  
Sludge Biomass Distribution Coefficient 1.89 to 2.7 Estimated (log Kd):
- \* **Partitioning** This mixture 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: 285 nm at pH 7
- \* **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 - Inherent  
Percent Degradation: 96 %, 2 days, Modified Zahn-Wellens, 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

ECOLOGICAL INFORMATION

#### Subsections

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

**SDS Sections Updated****Sections**

ECOLOGICAL INFORMATION

**Subsections**

Solubility

Summary

Volatility

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.