

## SAFETY DATA SHEET



GlaxoSmithKline

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

<b>Material</b>	<b>ZIAGEN TABLETS</b>
<b>Synonym(s)</b>	ZIAGEN TABLETS 300 MG * ZIAGEN COMPRESSE * ZIAGEN COMPRIMES PELLICULES * ZIAGEN COMPRIMIDOS RECUBIERTOS * ZIAGEN COMPRIMIDOS REVESTIDOS * ZIAGEN APVALKOTAS TABLETES * ZIAGEN FILMOMHULDE TABLETTEN * ZIAGEN POTAHOVANE TABLETY * ZIAGEN TABLETAS * ZIAGEN TABLETE * ZIAGEN TABLETTEN * ZIAGEN TABLETTER * ZIAGEN TABLETY * ZIAGENAVIR TABLETS * NDC NO 0173-0661-00 * NDC NO 0173-0661-01 * ABACAVIR HEMISULPHATE, FORMULATED PRODUCT
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; 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 &amp; 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.
ABACAVIR HEMISULPHATE	188062-50-2	38.8	
NON-HAZARDOUS INGREDIENTS	Unassigned	61.2	

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	<p>Caution - Pharmaceutical agent. Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components. Severe eye irritant. May produce mutagenic effects in human cells. Limited evidence of carcinogenic effect. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: symptoms of hypersensitivity (such as skin rash, hives, itching); gastrointestinal distress; headache; fatigue. Exposure might occur via ingestion; skin; eyes.</p>

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**Environment** No information is available about the potential of this product to produce adverse environmental effects.

#### 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. Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.

**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.

**Antidotes** For the latest information, refer to the local poison control information centres.

#### 5. FIRE-FIGHTING MEASURES

**Fire and Explosion Hazards** Not expected for the product, although the packaging is combustible.

**Extinguishing Media** Water or foam extinguishers are recommended. Carbon dioxide or dry powder 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.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>INGREDIENT</b>	ABACAVIR HEMISULPHATE	
<b>GSK Occupational Hazard Category</b>	2	
<b>GSK Occupational Exposure Limit</b>	600 mcg/m3 (8 HR TWA)	CARCINOGEN, SKIN SENSITISER

**ENGINEERING CONTROLS**

<b>Exposure Controls</b>	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.
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**PERSONAL PROTECTIVE EQUIPMENT**

<b>Eye Protection</b>	Wear approved safety glasses with side shields if eye contact is possible.
<b>Gloves</b>	The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department.
<b>Other Equipment or Procedures</b>	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

<b>Colour</b>	Yellow.
<b>Physical Form</b>	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. TOXICOLOGY INFORMATION

<b>Pharmacological Effects</b>	This preparation contains ingredient(s) with the following activity: a nucleoside analogue. Adverse effects of overexposure might include: symptoms of hypersensitivity (such as skin rash, hives, itching); gastrointestinal distress; headache; fatigue.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Routes of Exposure</b>	
<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. Permanent damage occurred after direct application. Assessment based upon effects of individual components.
<b>Sensitisation</b>	Allergic skin reactions might occur following dermal exposure.
<b>Genetic Toxicity</b>	Contains a component that produced mutagenicity in laboratory tests.
<b>Carcinogenicity</b>	Abacavir, the active substance in this product, produced carcinogenic effects in a lifetime study in mice; a lifetime study in rats. High concentrations or doses administered over an extended period of time were required to produce adverse effects.
<b>Reproductive Effects</b>	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.
<b>ECOTOXICITY</b>	
<b>Aquatic</b>	
<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 NOEC: 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 daphnids. EC50: 139 mg/l, 48 Hours, Daphnia magna, Static test NOEC: 70.9 mg/l, 48 Hours, Daphnia magna, Static test
<b>Fish</b>	This material contains an active pharmaceutical ingredient that is not toxic to fish. Adult Oncorhyncus mykiss, rainbow trout EC50: > 120 mg/l, 96 Hours, Static test Adult Oncorhyncus mykiss, rainbow trout NOEC: 120 mg/l, 96 Hours, Static test
<b>MOBILITY</b>	
<b>Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
<b>Volatility</b>	This material contains an active pharmaceutical ingredient that will not readily enter into air from water. Henrys Law Constant 8.50E-12 atm m <sup>3</sup> /mol, Measured at 25 C
<b>Adsorption</b>	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): 2.17 to 2.97, Measured Sludge Biomass Distribution Coefficient (log Kd): 1.89 to 2.7 Estimated
<b>Partitioning</b>	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.
<b>PERSISTENCE/DEGRADATION</b>	
<b>Hydrolysis</b>	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
<b>Photolysis</b>	This material contains an active pharmaceutical ingredient that is unlikely to undergo photodegradation. UV/Visible Spectrum: 285 nm at pH 7

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**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

**SDS Version Number** 9

#### 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.