SAFETY DATA SHEET

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

Material **EPZICOM TABLETS**

Synonym(s) EPZICOM 600 MG/300 MG TABLETS * KIVEXA 600 MG/300 MG TABLETS * ABC/3TC COMBINATION TABLETS * NDC NO. 0173-0742-00 * ABACAVIR SULFATE AND LAMIVUDINE, FORMULATED PRODUCT

Company Name

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* 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
ABACAVIR HEMISULPHATE	188062-50-2	49.6	
LAMIVUDINE	134678-17-4	21.2	
NON-HAZARDOUS INGREDIENTS	Unassigned	29.2	

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health

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.
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); gastrointestinal distress; headache; fatigue.
Exposure might occur via ingestion; skin; eyes.

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 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	ABACAVIR HEMISULPHATE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	600 mcg/m3 (8 HR TWA)	CARCINOGEN, SKIN SENSITISER
INGREDIENT	LAMIVUDINE	
GSK Occupational Hazard Category	2	
GSK Occupational Exposure Limit	600 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD

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.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields if eye contact is possible.

Other Equipment or Procedures An eye wash station should be available. Wear appropriate clothing to avoid skin contact.

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: a nucleoside analogue. Adverse effects of overexposure might include: symptoms of hypersensitivity (such as skin rash, hives, itching); gastrointestinal distress; headache; fatigue.

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

Routes of Exposure

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 Severe irritation might occur following direct contact with eyes. Permanent damage occurred after direct application. Assessment based upon effects of individual components.

Sensitisation Allergic skin reactions might occur following dermal exposure.

Genetic Toxicity Contains a component that produced mutagenicity in laboratory tests.

Carcinogenicity 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.

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 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

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

IC50:	> 71.4 mg/l, 3 Hours, Activated sludge

Algal 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

Daphnid 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

Fish 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

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.

Henrys Law Constant	8.50E-12 atm m3/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 (log Koc):	2.17 to 2.97, Measured
Sludge Biomass Distribution Coefficient (log Kd):	1.89 to 2.7 Estimated

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

SDS Version Number 10

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	

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.