SAFETY DATA SHEET

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

Material: ZIAGEN TABLETS

Synonym(s): ZIAGEN TABLETS 300 MG * ZIAGEN COMPRESSE * ZIAGEN COMPRIMES PELLICULES * ZIAGEN COMPRIMIDOS RECUBIERTOS * ZIAGEN COMPRIMIDOS REVESTIDOS * ZIAGEN APVALKOTAS TABLETES * ZIAGEN FILMOMHULDE TABLETTEN * ZIAGEN TABLETTEN * ZIAGEN TABLETER * ZIAGENVIR TABLETS * NDC NO 0173-0661-00 * NDC NO 0173-0661-01 * ABACAVIR HEMISULPHATE, FORMULATED PRODUCT

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Transport Emergency (non EU) +1-703-527-3887
US number, available 24 hours
Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Percent</th>
<th>EC-No.</th>
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<tbody>
<tr>
<td>ABACAVIR HEMISULPHATE</td>
<td>188062-50-2</td>
<td>38.8</td>
<td></td>
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<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>61.2</td>
<td></td>
</tr>
</tbody>
</table>

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.
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.
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.

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.

**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

ENGINEERING 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.

Gloves
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.

Other Equipment or Procedures
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Colour
Yellow.

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
Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects
None known for occupational exposure.
12. ECOLOGICAL INFORMATION

Summary
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.

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
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.

Henry's 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 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 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.

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**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.

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**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.


**Classification**

This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status**

Exempt

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**16. OTHER INFORMATION**

**References**

GSK Hazard Determination

**SDS Version Number**

9

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**SDS Sections Updated**

**Sections**

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.