SAFETY DATA SHEET

1. Identification

Product identifier **ZIAGEN TABLETS**

Other means of identification

Synonyms 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 * ABACAVIR HEMISULPHATE, FORMULATED PRODUCT

Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

ViiV Healthcare
Five Moore Drive
Research Triangle Park
North Carolina, USA
27709-3398
US General Information (normal business hours): +1-877-844-8872 (+1 877 ViiVUSA)
Email Address: msds@gsk.com
Website: www.viivhealthcare.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES:
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE * ALPHA-CELLULOSE * AVICEL PH101 * AVICEL PH102 * AVICEL PH103 * AVICEL PH105 * AVICEL PH112 * AVICEL PH200 * CELLULOSE (8CI9CI) * CELLULOSE CRYSTALLINE * CELLULOSE, FOOD GRADE * CRYSTALLINE CELLULOSE	9004-34-6	45.87

Chemical name	Common name and synonyms	CAS number	%
ABACAVIR HEMISULPHATE	(1S,4R)-CIS-4-(2-AMINO-6-(CYCLOPROPY LAMINO)-9H-PURIN-9-YL)-2-CYCLOPENTENE-1 -METHANOL HEMISULFATE SALT * 1592U89 HEMISULPHATE * GI265235F * ABACAVIR HEMISULFATE * ABACAVIR SULPHATE * ABACAVIR SULFATE	188062-50-2	< 40
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT * MAGNESIUM DISTEARATE * DIBASIC MAGNESIUM STEARATE * MAGNESIUM DISTEARATE, PURE	557-04-0	0.89
SILICON DIOXIDE	SILICA * SILICA GEL * AMORPHOUS SILICA * DIATOMACEOUS EARTH * INFUSORIAL EARTH * CAB-O-SIL M-5	7631-86-9	0.27
Other components below reportable levels			14.16

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation
Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact
Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion
If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed
None known.
The following adverse effects have been noted with therapeutic use of this material: nausea; headache; malaise; fatigue; vomiting; symptoms of hypersensitivity (such as skin rash, hives, itching).

Indication of immediate medical attention and special treatment needed
No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media
Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

7. Handling and storage

Precautions for safe handling Avoid breaking or crushing tablets. Do not handle until all safety precautions have been read and understood. Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
ABACAVIR HEMISULPHATE (CAS 188062-50-2)	8 HR TWA	600 mcg/m3	SKIN SENSITISER, CARCINOGEN
	OHC	2	SKIN SENSITISER, CARCINOGEN

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers might be at greater risk from overexposure. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Tablet.
Color	Yellow
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use. May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
Symptoms related to the physical, chemical and toxicological characteristics	None known. The following adverse effects have been noted with therapeutic use of this material: nausea; headache; malaise; fatigue; vomiting; symptoms of hypersensitivity (such as skin rash, hives, itching).

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use. May be harmful if swallowed.

Components	Species	Test Results
ABACAVIR HEMISULPHATE (CAS 188062-50-2)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use. Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

ABACAVIR HEMISULPHATE	Acute dermal irritation; OECD 404, Primary irritation index = 0.0 Result: Negative Species: Rabbit

Irritation Corrosion - Skin: P.I.I. value

MAGNESIUM STEARATE	0

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.

Eye

ABACAVIR HEMISULPHATE	Acute ocular irritation; OECD 405, Overall mean score following 0.1 mL (weight equivalent) = 77; mean score following 10 mg = 12 Result: Severe Irritant Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE	4 Recovery Period: 2 days

Respiratory or skin sensitization

Respiratory sensitization	Not available.
Skin sensitization	Health injuries are not known or expected under normal use. Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.

Sensitization

ABACAVIR HEMISULPHATE	Clinical Use and Occupational Exposure Result: Sensitisation may occur in susceptible individuals Species: Human Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig

Germ cell mutagenicity Health injuries are not known or expected under normal use. The ingredient abacavir has caused genetic toxicity in laboratory studies.

Mutagenicity

ABACAVIR HEMISULPHATE	Ames Assay, GLP assay Result: Negative Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Positive Micronucleus Assay, Positive response only in male at maximum dose of 1000 mg/kg; negative at lower doses and in females Result: Positive Species: Mouse Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive SOS/umu Assay Result: Negative

Carcinogenicity Health injuries are not known or expected under normal use. Contains a material (abacavir) classified as a carcinogen by external agencies.

ABACAVIR HEMISULPHATE	2 year bioassay Result: Positive Species: Mouse 2 year bioassay Result: Positive Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Health injuries are not known or expected under normal use. The ingredient abacavir has caused adverse effects on the development of unborn offspring in animal studies.

Fertility effects - Males and females

ABACAVIR HEMISULPHATE	Result: Negative Species: Rat

Reproductivity

ABACAVIR HEMISULPHATE	Embryo-foetal development - Oral Result: NOAEL = 160 mg/kg/day; with a dose of 500 mg/kg/day evidence of maternal adverse effects; decreased foetal weight and length, increased incidence of skelatal efects and foetal oedema Species: Rat Embryo-foetal development - Oral Result: NOAEL = 700 mg/kg/day (maximum dose); no evidence of foetal malformation or teratogenicity Species: Rabbit

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Not available.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
ABACAVIR HEMISULPHATE (CAS 188062-50-2)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 71.4 mg/l, 3 hours
Algae	EC50	Green algae (Selenastrum capricornutum)	57.4 mg/l, 72 hours Static test, OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	30 mg/l, 72 hours Static test
Crustacea	EC50	Water flea (Daphnia magna)	139 mg/l, 48 hours Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	70.9 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 120 mg/l, 96 hours Static test, OECD 203
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	120 mg/l, 96 hours Static test
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days 7 day static renewal, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	5.6 mg/l, 7 days 7 day static renewal
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE	17 Hours Estimated

UV/visible spectrum wavelength

ABACAVIR HEMISULPHATE	285 nm, pH 7
MAGNESIUM STEARATE	210 nm

Hydrolysis

Half-life (Hydrolysis-acidic)

ABACAVIR HEMISULPHATE	> 1 Years Measured, pH 4 buffer solution

Half-life (Hydrolysis-basic)

ABACAVIR HEMISULPHATE	> 1 Years Measured, pH 9 buffer solution

Half-life (Hydrolysis-neutral)

ABACAVIR HEMISULPHATE	> 1 Years Measured, pH 7 Buffer Solution

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ABACAVIR HEMISULPHATE	96 %, 2 days Modified Zahn-Wellens, Activated sludge
MAGNESIUM STEARATE	77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE	50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ABACAVIR HEMISULPHATE	1.08

Bioconcentration factor (BCF)

MAGNESIUM STEARATE	> 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ABACAVIR HEMISULPHATE	1.89 - 2.7 Estimated

Soil/sediment sorption - log Koc

ABACAVIR HEMISULPHATE	2.17 - 2.97 Measured
MAGNESIUM STEARATE	5.86 Estimated

Mobility in general

Volatility

Henry's law

ABACAVIR HEMISULPHATE	0 atm m^3/mol Measured, 25 C

Distribution

Octanol/water distribution coefficient log DOW

ABACAVIR HEMISULPHATE	0.9, pH 5 1.2, pH 7 1.2, pH 9

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

US. New Jersey Worker and Community Right-to-Know Act

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

US. Pennsylvania Worker and Community Right-to-Know Law

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)
SILICON DIOXIDE (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	04-01-2015
Revision date	04-01-2015
Version #	12
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	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.
Revision Information	Handling and storage: Precautions for safe handling Handling and storage: Conditions for safe storage, including any incompatibilities Other information, including date of preparation or last revision: Further information