



SAFETY DATA SHEET

1. Identification

Product identifier	EPZICOM TABLETS
Other means of identification	
Synonyms	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
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	%
ABACAVIR HEMISULPHATE	(1S,4R)-CIS-4-(2-AMINO-6-(CYCLOPROPYLAMINO)-9H-PURIN-9-YL)-2-CYCLOPENTENE-1 -METHANOL HEMISULFATE SALT 1592U89 HEMISULPHATE GI265235F ABACAVIR HEMISULFATE ABACAVIR SULPHATE ABACAVIR SULFATE	188062-50-2	< 50

Chemical name	Common name and synonyms	CAS number	%
LAMIVUDINE	GR109714X (-)-CIS-5-(4-AMINO-1,2-DIHYDRO-2-OXO-1-PYRIMIDINYL)-1,3-OXATHIOLANE-2-METHANOL (2R,CIS)-4-AMINO-1-(2-HYDROXYMETHYL-1,3-OXATHIOLAN-5-YL)-(1H)-PYRIMIDIN-2-ONE	134678-17-4	< 25
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	< 25
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	< 1
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	< 1

Other components below reportable levels

5 - < 10

*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

The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); gastrointestinal distress; headache; fatigue.

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. 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 Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. 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. Pregnant or breastfeeding women must not handle this product. Provide adequate ventilation. Wear appropriate personal protective equipment. 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
LAMIVUDINE (CAS 134678-17-4)	8 HR TWA	600 mcg/m3	REPRODUCTIVE HAZARD
	OHC	2	REPRODUCTIVE HAZARD

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.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

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
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total
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. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.		
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 environmental, 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	Not available.
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	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.
Eye contact	Health injuries are not known or expected under normal use. May be irritating to eyes.
Ingestion	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 The following adverse effects have been noted with therapeutic use of this material: symptoms of hypersensitivity (such as skin rash, hives, itching); gastrointestinal distress; headache; fatigue.

Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel. May cause an allergic skin reaction.

Components	Species	Test Results
ABACA VIR HEMISULPHATE (CAS 188062-50-2)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
LAMIVUDINE (CAS 134678-17-4)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
TITANIUM DIOXIDE (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
Subacute		
Inhalation		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

* 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.

Irritation Corrosion - Skin

TITANIUM DIOXIDE

0, Literature data
Result: Non-irritant
Species: Guinea pig

0, Literature data
Result: Non-irritant
Species: Human

Acute dermal irritation; OECD 404, Literature data

Result: Non-irritant

Species: Rabbit

ABACAVIR HEMISULPHATE

Acute dermal irritation; OECD 404, Primary irritation index = 0.0

Result: Negative

Species: Rabbit

LAMIVUDINE

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. May be irritating to eyes.

Eye

LAMIVUDINE

Acute ocular irritation; OECD 405, Overall mean score = 0.0

Result: Negative

Species: Rabbit

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

TITANIUM DIOXIDE

OECD 405, Literature data

Result: Mild irritant

Species: Rabbit

Eye / Kay and Calandra class - Intact

MAGNESIUM STEARATE

4

Recovery Period: 2 days

Respiratory or skin sensitization**Respiratory sensitization**

No studies have been conducted. Due to partial or complete lack of data the classification is not possible.

Skin sensitization

Health injuries are not known or expected under normal use. May cause an allergic skin reaction.

Sensitization

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum

Result: Negative

Species: Guinea pig

Test Duration: 48 hour exposure

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

TITANIUM DIOXIDE

Patch test, Literature data

Result: Negative

Species: Human

LAMIVUDINE

Split adjuvant assay, Maximum concentration applied to skin = 10%

Result: Negative

Species: Guinea pig

Germ cell mutagenicity

Health injuries are not known or expected under normal use. Contains a component that produced mutagenicity in laboratory tests. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

Mutagenicity

ABACAVIR HEMISULPHATE

Ames Assay, GLP assay

Result: Negative

LAMIVUDINE

Ames Assay, GLP assay

Result: Negative

TITANIUM DIOXIDE

Ames, Literature data

Result: Negative

ABACAVIR HEMISULPHATE

Chromosomal Aberration Assay In Vitro, human lymphocytes

Result: Positive

LAMIVUDINE

Chromosomal Aberration Assay In Vitro, human lymphocytes

Result: Positive

Chromosomal Aberration Assay In Vivo, bone marrow

Result: Negative

Species: Rat

High Throughput Bacterial Fluctuation Test

Result: Negative

TITANIUM DIOXIDE

Micronucleus Assay in vitro, CHO cells, Literature data

Result: Negative

Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data

Result: Positive

LAMIVUDINE

Micronucleus Assay, Maximum dose = 2000 mg/kg

Result: Negative

Species: Rat

ABACAVIR HEMISULPHATE

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

Mutagenicity

ABACAVIR HEMISULPHATE	Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive
LAMIVUDINE	Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay Result: Positive
ABACAVIR HEMISULPHATE	SOS/umu Assay Result: Negative
TITANIUM DIOXIDE	Syrian Hamster Embryo (SHE) cell transformation assay Result: Negative
LAMIVUDINE	Unscheduled DNA Synthesis in vivo, Maximum dose = 2000 mg/kg Result: Negative
TITANIUM DIOXIDE	Species: Rat WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data Result: Positive

Carcinogenicity

Carcinogenic effects are not expected as a result of occupational exposure. Positive results occurred in some studies that are not considered to be relevant to occupational exposure conditions. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.

TITANIUM DIOXIDE	0.5 mg/m3, Literature data Result: Negative Species: Rat Test Duration: 24 months 0.72 - 14.8 mg/m3, Literature data Result: Negative Species: Mouse 10 - 250 mg/m3, Dietary study - Literature data. Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration. Species: Rat Test Duration: 24 months
LAMIVUDINE	2 year bioassay Result: Negative Species: Mouse 2 year bioassay Result: Negative Species: Rat
ABACAVIR HEMISULPHATE	2 year bioassay Result: Positive Species: Mouse 2 year bioassay Result: Positive Species: Rat
TITANIUM DIOXIDE	25000 - 50000 ppm, Dietary study Result: Negative Species: Mouse 25000 - 50000 ppm, Dietary study - Literature data. Result: Negative Species: Rat 7.2 - 14.8 mg/m3, Literature data Result: Lung tumour Species: Rat Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7) 2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Fertility effects - Males and females

LAMIVUDINE	Result: NOAEL = 2000 mg/kg/day (maximum dose) Species: Rat
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 skeletal effects and foetal oedema

Species: Rat

LAMIVUDINE

Embryo-foetal development - Oral

Result: NOAEL = 2000 mg/kg/day; no evidence of foetal malformation or teratogenicity

Species: Rat

Embryo-foetal development - Oral

Result: NOAEL = 500 mg/kg/day; no evidence of foetal malformation or teratogenicity

Species: Rabbit

Embryo-foetal development - Oral

Result: NOAEL = 7.5 mg/kg/day; LOAEL = 20 mg/kg/day / increase in pre-implantation loss

Species: Rabbit

ABACAVIR HEMISULPHATE

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 May cause damage to organs through prolonged or repeated exposure.

LAMIVUDINE

Repeat dose non-clinical studies

Species: Rat

Organ: Liver

Aspiration hazard Not likely, due to the form of the product.

Chronic effects Causes damage to organs through prolonged or repeated exposure.

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		
<i>Acute</i>		
Activated Sludge Respiration	IC50 Residential sludge	> 71.4 mg/l, 3 hours
Algae	EC50 Green algae (<i>Selenastrum capricornutum</i>)	57.4 mg/l, 72 hours Static test, OECD 201
	NOEC Green algae (<i>Selenastrum capricornutum</i>)	30 mg/l, 72 hours Static test
Crustacea	EC50 Water flea (<i>Daphnia magna</i>)	139 mg/l, 48 hours Static test, OECD 202
	NOEC Water flea (<i>Daphnia magna</i>)	70.9 mg/l, 48 hours Static test
Fish	EC50 Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	> 120 mg/l, 96 hours Static test, OECD 203
	NOEC Rainbow trout (Adult <i>Oncorhynchus mykiss</i>)	120 mg/l, 96 hours Static test
<i>Chronic</i>		
Crustacea	LOEC Water flea (<i>Ceriodaphnia dubia</i>)	10 mg/l, 7 days 7 day static renewal, EPA 1002
	NOEC Water flea (<i>Ceriodaphnia dubia</i>)	5.6 mg/l, 7 days 7 day static renewal

Components	Species	Test Results
LAMIVUDINE (CAS 134678-17-4)		
Aquatic		
<i>Acute</i>		
Algae	EC50	Green algae (Selenastrum capricornutum) > 96.9 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum) > 96.9 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Juvenile Oncorhynchus mykiss) > 97.7 mg/l, 96 hours Static test
Microtox	MIC	Azotobacter beijerinckii > 1000 mg/l
Other	MIC	Aspergillus niger > 1000 mg/l
		Nostoc commune > 1000 mg/l
		Pseudomonas aeruginosa > 1000 mg/l
		Trichoderma harzianum > 1000 mg/l
<i>Chronic</i>		
Crustacea	EC50	Water flea (Ceriodaphnia dubia) > 100 mg/l, 7 days 7 day static renewal
	LOEC	Water flea (Ceriodaphnia dubia) > 100 mg/l, 7 days
	NOEC	Water flea (Ceriodaphnia dubia) 100 mg/l, 7 days

MAGNESIUM STEARATE (CAS 557-04-0)

Aquatic

Acute

Fish EC50 Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours

TITANIUM DIOXIDE (CAS 13463-67-7)

Aquatic

Fish LC50 Mummichog (Fundulus heteroclitus) > 1000 mg/l, 96 hours

Acute

Crustacea EC50 Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test

* 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

LAMIVUDINE 271 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

LAMIVUDINE > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ABACAVIR HEMISULPHATE 96 %, 2 days Modified Zahn-Wellens, Activated sludge

LAMIVUDINE 0 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

LAMIVUDINE 4 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
MAGNESIUM STEARATE 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

LAMIVUDINE < 1 %, 28 days Modified Sturm test.
MAGNESIUM STEARATE 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

LAMIVUDINE 15 - 24 %, 64 days
MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ABACAVIR HEMISULPHATE 1.08
LAMIVUDINE -0.7

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
LAMIVUDINE 1.5 - 2.03 Measured
MAGNESIUM STEARATE 5.86 Estimated

Mobility in general

Volatility

Henry's law

ABACAVIR HEMISULPHATE 0 atm m³/mol Measured, 25 C
LAMIVUDINE 0 atm m³/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

ABACAVIR HEMISULPHATE 0.9, pH 5
1.2, pH 7
1.2, pH 9
LAMIVUDINE -1.17, pH 9
-1.44, pH 7
-1.86, pH 5

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

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. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

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

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

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
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	09-10-2015
Revision date	09-10-2015
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	Product and Company Identification: Business Units Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Ecological Information: Mobility Transport Information: Regulatory Information: United States GHS: Classification