



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** TRIUMEQ TABLETS

**Other means of identification**

**Synonyms**

DOLUTEGRAVIR, ABACAVIR, LAMIVUDINE FIXED DOSE COMBINATION TABLETS \*  
DOLUTEGRAVIR, ABACAVIR, LAMIVUDINE FDC TABLETS \* DOLUTEGRAVIR 50MG,  
ABACAVIR 600MG, LAMIVUDINE 300MG FIXED DOSE COMBINATION TABLETS \*  
DOLUTEGRAVIR, ABACAVIR, 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**

**COMPANY NAME** GlaxoSmithKline US  
**Address:** 5 Moore Drive  
Research Triangle Park, NC 27709 USA  
**Telephone:** +1-888-825-5249 (General Inquiries)  
**Email:** msds@gsk.com  
**Website:** www.gsk.com

## EMERGENCY CONTACTS

**Telephone:** CHEMTREC EMERGENCY NUMBERS  
+(1) 703 527 3887 (International)  
24/7; multi-language response  
**Contract Number:** CCN9484

**Telephone:** VERISK 3E GLOBAL INCIDENT RESPONSE  
+(1) 760 476 3971 (In country)  
+(1) 760 476 3962 or +(1) 866 519 4752 (International)  
24/7; multi-language response  
**Contract Number:** 334878

## 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	ABACAVIR HEMISULFATE ABACAVIR SULPHATE ABACAVIR SULFATE 1592U89 HEMISULPHATE GI265235F (1S,4R)-CIS-4-(2-AMINO-6-(CYCLOPROPYLAMINO)-9H-PURIN-9-YL)-2-CYCLOPENTENE-1-METHANOL HEMISULFATE SALT	188062-50-2	42.0 - 43.0
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	18
LAMIVUDINE	GR109714X (-)-CIS-5-(4-AMINO-1,2-DIHYDRO-2-OXO-1-PYRIMIDINYL) (2R,CIS)-4-AMINO-1-(2-HYDROXYMETHYL-1,3-OXATHIOLAN-5-YL) (1H)-PYRIMIDIN-2-ONE	134678-17-4	17.0 - 18.0
MANNITOL	D-MANNITOL 1,2,3,4,5,6-HEXANEHEXOL MANNA SUGAR MANNITE OSMITROL BP-686 MANNITOL, D- DIOSMOL MANITON-S MANNIDEX MANNIGEN MANNISTOL OSMOSOL D-MANNITE CORDYCEPIC ACID D-(-)-MANNITOL MANNITOLUM OSMOSAL ISOTOL C6H14O6 OHS13660 RTECS OP2060000	69-65-8	8
SODIUM STARCH GLYCOLATE	STARCH, CARBOXYMETHYL ETHER, SODIUM SALT CARBOXYMETHYL STARCH SODIUM SALT EXPLOTAB SODIUM CARBOXYMETHYL STARCH SODIUM CM-STARCH 738 (GW ACN) CARBOXYMETHYLSTÄRKE, NATRIUMSALZ SODIUM STARCH GLYCOLATE	9063-38-1	8
DOLUTEGRAVIR	DOLUTEGRAVIR SODIUM S-349572B GSK1349572A	1051375-19-9	3.0 - 4.0

Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	2
POVIDONE 30	Poly(1-ethenylpyrrolid-2-one) CROSPVIDONE POLY(1-VINYL-2-PYRROLIDINONE) 2-PYRROLIDINONE, 1-VINYL-, POLYMERS	9003-39-8	1

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

#### 4. First-aid measures

<b>Inhalation</b>	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
<b>Skin contact</b>	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on unaffected skin.
<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
<b>Ingestion</b>	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes. May cause temporary blindness and severe eye damage. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause allergic skin reaction. Prolonged exposure may cause chronic effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use water spray to cool unopened containers. Water runoff can cause environmental damage.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. 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.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. Dike far ahead of spill for later disposal. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground. Contact local authorities in case of spillage to drain/aquatic environment.

## 7. Handling and storage

### Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get this material in contact with eyes. Avoid contact with skin. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

### Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. 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)

OHC

2

CARCINOGEN, SKIN  
SENSITISER

600 mcg/m3

CARCINOGEN, SKIN  
SENSITISER

DOLUTEGRAVIR (CAS  
1051375-19-9)

8 HR TWA

300 mcg/m3

LAMIVUDINE (CAS  
134678-17-4)

OHC

OHC

2

600 mcg/m3

REPRODUCTIVE  
HAZARD  
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.

#### 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

### Biological limit values

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

### Appropriate engineering controls

Not available.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

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

#### Skin protection

##### Hand protection

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. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Glove selection must take into account any solvents and other hazards present.

##### Other

Wear suitable protective clothing.

<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	None under normal conditions.
<b>Incompatible materials</b>	Not available.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Due to lack of data the classification is not possible.
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<b>Skin contact</b>	May cause an allergic skin reaction.
<b>Eye contact</b>	Risk of serious damage to eyes.
<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Irritating to eyes and respiratory system. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. symptoms of hypersensitivity (such as skin rash, hives, itching)

#### Information on toxicological effects

**Acute toxicity** Based on available data, the classification criteria are not met.

Components	Species	Test Results
ABACAVIR HEMISULPHATE (CAS 188062-50-2)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
DOLUTEGRAVIR (CAS 1051375-19-9)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD	Rat	> 1000 mg/kg
<b><u>Subacute</u></b>		
<b>Oral</b>		
NOAEL	Monkey	15 mg/kg, 38 weeks daily dosing
	Rat	50 mg/kg, 26 weeks daily dosing
LAMIVUDINE (CAS 134678-17-4)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
MANNITOL (CAS 69-65-8)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	13.5 g/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<b><u>Acute</u></b>		
<b>Dermal</b>		
LD50	Rabbit	> 2000 mg/kg
<b>Oral</b>		
LD50	Rat	> 2000 mg/kg
POVIDONE 30 (CAS 9003-39-8)		
<b><u>Acute</u></b>		
<b>Oral</b>		
LD50	Rat	> 5000 mg/kg

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

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

#### Irritation Corrosion - Skin

ABACAVIR HEMISULPHATE

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

<b>Irritation Corrosion - Skin</b>		
LAMIVUDINE		Acute dermal irritation; OECD 404, Primary irritation index = 0.0 Result: Negative Species: Rabbit
DOLUTEGRAVIR		Reconstituted Human Epidermis (RHE) Result: Negative
<b>Irritation Corrosion - Skin: P.I.I. value</b>		
MAGNESIUM STEARATE		0
<b>Skin / Primary irritation index - Abraded</b>		
DOLUTEGRAVIR		Acute Dermal Irritation, Primary irritation index = 0.17 Result: Mild irritant Species: Rabbit
<b>Skin / Primary irritation index - Intact</b>		
DOLUTEGRAVIR		Acute Dermal Irritation, Primary irritation index = 0 Result: Negative Species: Rabbit
<b>Serious eye damage/eye irritation</b>	Risk of serious damage to eyes.	
<b>Eye</b>		
DOLUTEGRAVIR		Acute ocular irritation, Overall mean score = 4; Draize assay Result: Mild irritant Species: Rabbit
LAMIVUDINE		Acute ocular irritation; OECD 405, Overall mean score = 0.0 Result: Negative Species: Rabbit
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
DOLUTEGRAVIR		Reconstituted Human Corneal Epithelium (HCE) Result: Negative
<b>Eye / Kay and Calandra class - Intact</b>		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitization</b>	May cause an allergic skin reaction.	
<b>Sensitization</b>		
ABACAVIR HEMISULPHATE		Clinical Use and Occupational Exposure Result: Sensitisation may occur in susceptible individuals Species: Human
DOLUTEGRAVIR		Local lymph node assay, Maximum concentration = 25%; vehicle = DMF Result: Negative Species: Mouse
ABACAVIR HEMISULPHATE		Maximisation assay (Magnusson and Kligman) Result: Negative Species: Guinea pig
LAMIVUDINE		Split adjuvant assay, Maximum concentration applied to skin = 10% Result: Negative Species: Guinea pig
<b>Germ cell mutagenicity</b>	Suspected of causing genetic defects.	
<b>Mutagenicity</b>		
DOLUTEGRAVIR		Ames Assay Result: Negative
ABACAVIR HEMISULPHATE		Ames Assay, GLP assay Result: Negative
LAMIVUDINE		Ames Assay, GLP assay Result: Negative
DOLUTEGRAVIR		Bacterial Fluctuation Test Result: Negative

**Mutagenicity**

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

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

DOLUTEGRAVIR

Mouse Lymphoma Cell (L5178Y) Assay

Result: Negative

ABACAVIR HEMISULPHATE

Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay

Result: Positive

LAMIVUDINE

Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay

Result: Positive

DOLUTEGRAVIR

Rat Micronucleus Test

Result: Negative

SAR

Result: Negative

ABACAVIR HEMISULPHATE

SOS/umu Assay

Result: Negative

LAMIVUDINE

Unscheduled DNA Synthesis in vivo, Maximum dose = 2000 mg/kg

Result: Negative

Species: Rat

**Carcinogenicity**

Suspect cancer hazard.

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

DOLUTEGRAVIR

ICH S1B

Result: Negative

Species: Mouse

Test Duration: 104 weeks

ICH S1B

Result: Negative

Species: Rat

Test Duration: 104 weeks

SAR

Result: Negative

**IARC Monographs. Overall Evaluation of Carcinogenicity**

POVIDONE 30 (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Suspected of damaging the unborn child.



**Fertility effects - Males and females**

ABACAVIR HEMISULPHATE

Result: Negative

Species: Rat

DOLUTEGRAVIR

Result: NOAEL = 1000 mg/kg/day (maximum dose)

Species: Rat

LAMIVUDINE

Result: NOAEL = 2000 mg/kg/day (maximum dose)

Species: Rat

**Reproductivity**

DOLUTEGRAVIR

1000 mg/kg/day Embryo-foetal development - Oral

Result: NOAEL

Species: Rabbit

1000 mg/kg/day Embryo-foetal development - Oral

Result: NOAEL

Species: Rat

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**

Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**

LAMIVUDINE

Repeat dose non-clinical studies

Species: Rat

Organ: Liver

**Aspiration hazard**

Not available.

**Chronic effects**

Prolonged inhalation may be harmful. Possible risks of irreversible effects. Causes damage to organs through prolonged or repeated exposure.

**12. Ecological information****Ecotoxicity**

Toxic to aquatic life with long lasting effects. Accumulation in aquatic organisms is expected.

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

Components		Species	Test Results
Fish	EC50	Rainbow trout (Adult Oncorhynchus mykiss)	> 120 mg/l, 96 hours Static test, OECD 203
	NOEC	Rainbow trout (Adult Oncorhynchus mykiss)	120 mg/l, 96 hours Static test
<i>Chronic</i>			
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
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	> 10 mg/l, 32 days Semi-static, OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	10 mg/l, 32 days
Other	EC50	Chironomid (Chironomus riparius)	> 180 mg/kg, 28 days , OECD 218
	LOEC	Chironomid (Chironomus riparius)	180 mg/kg, 28 days
	NOEC	Chironomid (Chironomus riparius)	100 mg/kg, 28 days
DOLUTEGRAVIR (CAS 1051375-19-9)			
<b>Aquatic</b>			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	684 mg/l, 3 hours OECD 209
	NOEC	Residential sludge	24 mg/l, 3 hours
Algae	EC50	Green algae (Pseudokirchneriella subcapitata)	0.245 mg/l, 72 hours Nominal, OECD 201
	NOEC	Algae	0.1 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 6.77 mg/l, 48 hours semi-static test conditions, OECD 202
	NOEC	Water flea (Daphnia magna)	0.78 mg/l, 48 hours
<i>Chronic</i>			
Crustacea	LOEC	Water flea (Daphnia magna)	2.83 mg/l, 21 days semi-static test conditions, OECD 211
	NOEC	Water flea (Daphnia magna)	0.88 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	> 0.292 mg/l, 28 days Flow-through test, OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.23 mg/l, 28 days
Other	EC50	Chironomid (Chironomus riparius)	> 903 mg/kg, 28 days OECD 218
	LOEC	Chironomid (Chironomus riparius)	> 903 mg/kg, 28 days
	NOEC	Chironomid (Chironomus riparius)	903 mg/kg, 28 days
<b>Terrestrial</b>			
<i>Acute</i>			
Earthworm	EC50	Earthworm (Eisenia foetida)	> 1052 mg/kg, 14 days OECD 207
	NOEC	Earthworm (Eisenia foetida)	1052 mg/kg, 14 days
<i>Chronic</i>			
Other	EC50	Collembola (Folsomia candida)	> 1052 mg/kg, 28 days OECD 232
		Soil microorganisms	> 1052 mg/kg, 28 days OECD 216
	LOEC	Collembola (Folsomia candida)	54.7 mg/kg, 28 days
	NOEC	Collembola (Folsomia candida)	30.51 mg/day, 28 days
		Soil microorganisms	1035 mg/kg, 28 days
Plant	EC50	Plant	136.23 mg/kg, 23 days OECD 208
	NOEC	Plant	12.62 mg/kg, 23 days

Components		Species	Test Results
LAMIVUDINE (CAS 134678-17-4)			
Aquatic			
Acute			
Activated Sludge Respiration	EC50	Residential sludge	> 1000 mg/l, 3 hours OECD 209
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 Oncorhyncus 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
Chronic			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	> 100 mg/l, 7 days static renewal, EPA Method 1002
	LOEC	Water flea (Ceriodaphnia dubia)	> 100 mg/l, 7 days
		Water flea (Daphnia magna)	> 100 mg/l, 21 days OECD 211
	NOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 7 days
		Water flea (Daphnia magna)	100 mg/l, 21 days
Fish	LOEC	Fathead minnow (Juvenile Pimephales promelas)	> 10 mg/l, 32 days semi-static, OECD 210
	NOEC	Fathead minnow (Juvenile Pimephales promelas)	10 mg/l, 32 days
Other	EC50	Chironomid (Chironomus riparius)	> 1000 mg/kg, 28 days OECD 218
	LOEC	Chironomid (Chironomus riparius)	180 mg/kg, 28 days
	NOEC	Chironomid (Chironomus riparius)	100 mg/kg, 28 days

MAGNESIUM STEARATE (CAS 557-04-0)

**Aquatic**

*Acute*

Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
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POVIDONE 30 (CAS 9003-39-8)

*Acute*

	IC50	Activated sludge	> 1000 mg/l, 3 hours Static test
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**Aquatic**

*Acute*

Crustacea	EC50	Water flea (Daphnia magna)	84 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	32 mg/l, 48 hours Static test

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

**Persistence and degradability** No data is available on the degradability of this product.

**Photolysis**

**Half-life (Photolysis-atmospheric)**

MAGNESIUM STEARATE 17 Hours Estimated

**UV/visible spectrum wavelength**

ABACAVIR HEMISULPHATE 285 nm, pH 7

**Photolysis****UV/visible spectrum wavelength**

LAMIVUDINE	271 nm, pH 7
MAGNESIUM STEARATE	210 nm

**Hydrolysis****Half-life (Hydrolysis-acidic)**

ABACAVIR HEMISULPHATE	> 1 Years Measured, pH 4 buffer solution
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**Half-life (Hydrolysis-basic)**

ABACAVIR HEMISULPHATE	> 1 Years Measured, pH 9 buffer solution
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**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	37.5 - 48.2 % , Aquatic sediment, 100 days, OECD 308, primary biodegradation
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	8.3 - 11.8 % , Aquatic sediment, 100 days, OECD 308, ultimate biodegradation
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	96 % , 2 days , Modified Zahn-Wellens, Activated sludge
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DOLUTEGRAVIR	50 % , Aquatic-sediment
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	Result: > 1,000 days, OECD 308
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LAMIVUDINE	0 % , 28 days , Modified Zahn-Wellens, DOC removal, Activated sludge
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	4 % , 28 days , Modified Zahn-Wellens, Primary biodegradation, Activated sludge
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	70.6 - 71.3 % , Aquatic sediment, 100 days, OECD 308, primary biodegradation
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	8.5 - 12.6 % , Aquatic sediment, 100 days, OECD 308, ultimate biodegradation
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MAGNESIUM STEARATE	77 % , 28 days BOD
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POVIDONE 30	0 % , 28 days Modified MITI test, Activated sludge
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**Percent degradation (Aerobic biodegradation-ready)**

DOLUTEGRAVIR	0 % , 28 days OECD 301B, CO2 Evolution, ultimate biodegradation, Activated sludge
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	18 % , 28 days OECD 301B, CO2 Evolution, primary degradation, Activated sludge
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LAMIVUDINE	< 1 % , 28 days Modified Sturm test.
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MAGNESIUM STEARATE	95 % , 22 days Sturm test
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**Percent degradation (Aerobic biodegradation-soil)**

DOLUTEGRAVIR	50 % , Soil metabolism
	Result: > 1,000 days, OECD 307

LAMIVUDINE	15 - 24 % , 64 days
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MAGNESIUM STEARATE	50 % , 13 days
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<b>Bioaccumulative potential</b>	Not available.
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**Partition coefficient n-octanol / water (log Kow)**

ABACAVIR HEMISULPHATE	1.08
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DOLUTEGRAVIR	-2.45, Measured at pH 7
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LAMIVUDINE	-0.7
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MANNITOL	-3.1
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**Bioconcentration factor (BCF)**

MAGNESIUM STEARATE	> 9999 Estimated
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MANNITOL	1 Estimated
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**Mobility in soil****Adsorption****Sludge/biomass distribution coefficient - log Kd**

ABACAVIR HEMISULPHATE	1.89 - 2.7 Estimated
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DOLUTEGRAVIR	3.76, pH 6.3-6.38
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**Soil/sediment sorption - log Koc**

ABACAVIR HEMISULPHATE	2.17 - 2.97 Measured
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LAMIVUDINE	1.5 - 2.03 Measured
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MAGNESIUM STEARATE	5.86 Estimated
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MANNITOL	0.7 Estimated
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## Mobility in general

### Volatility

#### Henry's law

ABACAVIR HEMISULPHATE

0 atm m<sup>3</sup>/mol Measured, 25 C

LAMIVUDINE

0 atm m<sup>3</sup>/mol Estimated

MANNITOL

0 atm m<sup>3</sup>/mol

### Distribution

#### Octanol/water distribution coefficient log DOW

ABACAVIR HEMISULPHATE

0.9, pH 5

1.2, pH 7

1.2, pH 9

DOLUTEGRAVIR

-2.28 Measured., pH 5

-2.45, pH 7

-3.21, 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 allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international 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).

### 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

#### UN number

UN3077

#### UN proper shipping name

Environmentally hazardous substances, solid, n.o.s. (DOLUTEGRAVIR SODIUM 50 MG TABLETS)

#### Transport hazard class(es)

##### Class

9

##### Subsidiary risk

-

##### Label(s)

9

#### Packing group

III

#### Special precautions for user

May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.

Consumer Commodity, ORM-D may apply. See 173.155.

#### Special provisions

8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33

#### Packaging exceptions

155

#### Packaging non bulk

213

#### Packaging bulk

240

May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.

ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.

### IATA

#### UN number

UN3077

#### UN proper shipping name

Environmentally hazardous substance, solid, n.o.s. (DOLUTEGRAVIR SODIUM 50 MG TABLETS)

#### Transport hazard class(es)

9

#### Subsidiary class(es)

-

#### Packaging group

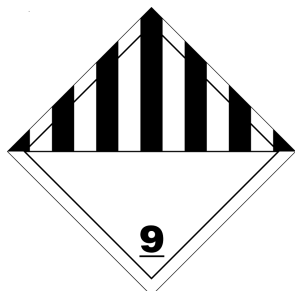
III

#### Labels required

Not available.

<b>Environmental hazards</b>	No.
<b>ERG Code</b>	9L
<b>Special precautions for user</b>	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.
<b>Other information</b>	
<b>Cargo aircraft only</b>	Allowed with restrictions.
<b>Passenger &amp; cargo</b>	Allowed with restrictions.
<b>IMDG</b>	
<b>UN number</b>	UN3077
<b>UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (DOLUTEGRAVIR SODIUM 50 MG TABLETS)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	F-A, S-F
<b>Special precautions for user</b>	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options. May be exempt from IMDG regulations. See SP 335.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	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.

DOT; IATA; IMDG



<b>General information</b>	Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.
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## 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 regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	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.**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** 04-27-2018**Revision date** 04-27-2018**Version #** 04**Further information** HMIS® is a registered trade and service mark of the NPCA.**HMIS® ratings** Health: 3\*  
Flammability: 0  
Physical hazard: 0**NFPA ratings** Health: 3  
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: Synonyms  
Hazard(s) identification: Hazard(s) not otherwise classified (HNOC)  
Fire-fighting measures: Fire fighting equipment/instructions  
Fire-fighting measures: Specific methods  
Handling and storage: Conditions for safe storage, including any incompatibilities  
Exposure controls/personal protection: Respiratory protection  
Stability and reactivity: Conditions to avoid  
Stability and reactivity: Reactivity  
Disposal considerations: Disposal instructions  
Disposal considerations: Local disposal regulations  
Transport information: General information  
Other information, including date of preparation or last revision: References