



SAFETY DATA SHEET

1. Identification

Product identifier VALTREX FILM-COATED TABLETS

Other means of identification
Synonyms VALACYCLOVIR TABLETS 250 MG * VALACYCLOVIR TABLETS 500 MG * VALACYCLOVIR TABLETS 1000 MG * (ANZ) * VALACYCLOVIR HYDROCHLORIDE, 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	%
VALACYCLOVIR HYDROCHLORIDE	VALACYCLOVIR VALACICLOVIR VALACICLOVIR HYDROCHLORIDE 2-((2-AMINO-1,6-DIHYDRO-6 OXO-9H-PURIN-9-YL)METHOXY)ETHYL -L-VALINATE HYDROCHLORIDE GW282358X 256U87	124832-27-5	81 - 82

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	10 - 11
POLYVINYLPIRROLIDONE	CROSPVIDONE CROSPVIDONE (KOLLIDON CL-SF) PVPP POLY[1-(2-OXO-1-PYRROLIDINYL)-1,2-ETHANEDIYL]	25249-54-1	4.02
POLYVINYLPIRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER POLY(N-VINYLPYRROLIDONE) POVIDONE PVP PLASDONE PLASDONE K29/32 PROVIDONE CROSPVIDONE POLY[1-(2-OXO-1-PYRROLIDINYL)ETHYLENE] POLYVINYLPIRROLIDONE	9003-39-8	3.16
POLYETHYLENE GLYCOL	AZIRIDINE, HOMOPOLYMER, ETHOXYLATED OHS19172 POLYETHYLENEIMINE ETHOXYLATE	68130-99-4	1.61
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	< 1.0
SILICON DIOXIDE COLLOIDAL	SILICA, AMORPHOUS, FUMED SILICA, AMORPHOUS HYDRATED SILICIC ANHYDRIDE AMORPHOUS SILICA SILICA, AMORPHOUS SILICA AMORPHOUS HYDRATED SILICA GEL; SILICA, AMORPHOUS Aerosil 200	7631-86-9	< 0.5
Other components below reportable levels			< 1

*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: Headache. Nausea. dizziness. abdominal discomfort.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed. 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). 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.

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 Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. 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. Use water spray to cool unopened containers.

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 Prevent entry into waterways, sewer, basements or confined areas. Stop the flow of material, if this is without risk. 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 release to the environment. Avoid breaking or crushing tablets. Avoid prolonged exposure. 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). The recommended temperature for storage is less than 30 °C.

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
POLYETHYLENE GLYCOL (CAS 68130-99-4)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	OHC	1	
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
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.

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

Components	Type	Value	Form
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m ³	Total dust.
		15 mg/m ³	Total dust.

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

Components	Type	Value	Form
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	0.8 mg/m ³	
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	20 mppcf	Respirable fraction.
		5 mg/m ³	
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m ³
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m ³
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	10 mg/m ³	Total
		6 mg/m ³	

Biological limit values

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

Exposure guidelines**Appropriate engineering controls**

If material is ground, cut, or used in any operation which may generate dusts, use appropriate local exhaust ventilation to keep exposures below the recommended exposure limits.

Individual protection measures, such as personal protective equipment**Eye/face protection**

Not normally needed. Wear safety glasses with side shields (or goggles).

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.

9. Physical and chemical properties**Appearance****Physical state**

Solid.

Form

Film-coated 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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Prolonged inhalation may be harmful. 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. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. 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: Headache. Nausea. dizziness. abdominal discomfort.
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Information on toxicological effects

Acute toxicity	May be harmful if swallowed. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<u>Acute</u>		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
<u>Chronic</u>		
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
<u>Subacute</u>		
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.
<u>Subchronic</u>		
Inhalation		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
<u>Chronic</u>		
Oral		
NOAEL	Rat	50 mg/kg/day

* 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. Based on available data, the classification criteria are not met.	
Irritation Corrosion - Skin		
TITANIUM DIOXIDE		0, Literature data Result: Non-irritant Species: Guinea pig
VALACYCLOVIR HYDROCHLORIDE		0, Literature data Result: Non-irritant Species: Human Acute dermal irritation; OECD 404 Result: Negative Species: Rabbit
TITANIUM DIOXIDE		Acute dermal irritation; OECD 404, Literature data Result: Non-irritant 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. Direct contact with eyes may cause temporary irritation.	
Eye		
VALACYCLOVIR HYDROCHLORIDE		Acute ocular irritation; OECD 405, Kay and Calandra score = 4; maximum group mean score = 12 Result: Mild irritant Species: Rabbit IRE Assay Result: Negative; not likely to be a 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.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Sensitization		
TITANIUM DIOXIDE		5 % Optimisation Test, Literature data - Vehicle: petrolatum Result: Negative Species: Guinea pig Test Duration: 48 hour exposure
VALACYCLOVIR HYDROCHLORIDE		Method not specified, Acyclovir tested; read across to valacyclovir Result: Negative Species: Guinea pig
TITANIUM DIOXIDE		Patch test, Literature data Result: Negative Species: Human
Germ cell mutagenicity	Due to partial or complete lack of data the classification is not possible.	
Mutagenicity		
VALACYCLOVIR HYDROCHLORIDE		Ames Assay, GLP assay Result: Negative
TITANIUM DIOXIDE		Ames, Literature data Result: Negative
VALACYCLOVIR HYDROCHLORIDE		Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Negative Chromosomal Aberration Assay In Vivo, bone marrow, Maximum dose = 3000 mg/kg Result: Negative Species: Rat GreenScreen Assay Result: Positive (+ S9 only)
TITANIUM DIOXIDE		Micronucleus Assay in vitro, CHO cells, Literature data Result: Negative

Mutagenicity

TITANIUM DIOXIDE

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

Result: Positive

VALACYCLOVIR HYDROCHLORIDE

Micronucleus Assay, GLP assay; positive result at maximum dose (500 mg/kg), negative study result at 250 mg/kg

Result: Positive

Species: Mouse

TITANIUM DIOXIDE

Mouse Lymphoma Cell (L5178Y) Mutation Assay, GLP assay

Result: Positive (+ S9 only)

Syrian Hamster Embryo (SHE) cell transformation assay

Result: Negative

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. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. 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

VALACYCLOVIR HYDROCHLORIDE

2 year bioassay, Maximum dose = 100 mg/kg/day

Result: Negative

Species: Rat

2 year bioassay, Maximum dose = 120 mg/kg/day

Result: Negative

Species: Mouse

TITANIUM DIOXIDE

25000 - 50000 ppm, Dietary study - Literature data.

Result: Negative

Species: Rat

25000 - 50000 ppm, Dietary study

Result: Negative

Species: Mouse

7.2 - 14.8 mg/m3, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

IARC Monographs. Overall Evaluation of Carcinogenicity

POLYVINYLPIRROLIDONE (CAS 9003-39-8)

3 Not classifiable as to carcinogenicity to humans.

SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

3 Not classifiable as to carcinogenicity to humans.

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic 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

Contains no ingredient listed as toxic to reproduction Due to partial or complete lack of data the classification is not possible.

Reproductivity

VALACYCLOVIR HYDROCHLORIDE

Embryo-foetal development - Oral

Result: Foetal NOAEL = 400 mg/kg/day (maximum dose);

Maternal LOAEL = 200 mg/kg/day (decreased weight gain)

Species: Rabbit

Embryo-foetal development - Oral

Result: Maternal and foetal toxicity (no evidence of

malformations) with doses of 400 mg/kg/day (maximum dose

) Species: Rat

Reproductivity
VALACYCLOVIR HYDROCHLORIDE

Fertility
Result: NOAEL = 200 mg/kg/day (male and female),
maximum dose
Species: Rat
Pre- and Post-natal development
Result: NOAEL = 200 mg/kg/day (maximum dose); no
adverse foetal effects
Species: Rat

Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	Not assigned.
Aspiration hazard	Not likely, due to the form of the product.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
MAGNESIUM STEARATE (CAS 557-04-0)		
Aquatic		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) 130 mg/l, 96 hours
POLYVINYLPIRROLIDONE (CAS 25249-54-1)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours Static test
Aquatic		
<i>Acute</i>		
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
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
<i>Acute</i>		
	IC50	Activated sludge > 1000 mg/l, 3 hours Static test
Aquatic		
<i>Acute</i>		
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
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)		
Aquatic		
<i>Acute</i>		
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
TITANIUM DIOXIDE (CAS 13463-67-7)		
Aquatic		
Fish	LC50	Mummichog (Fundulus heteroclitus) > 1000 mg/l, 96 hours

Components	Species	Test Results
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna)
> 1000 mg/l, 48 hours Static test		
VALACYCLOVIR HYDROCHLORIDE (CAS 124832-27-5)		
Aquatic		
<i>Acute</i>		
Activated Sludge Respiration	IC50	Residential sludge
> 100 mg/l, 3 hours OECD 209		
Crustacea	EC50	Water flea (Daphnia magna)
340 mg/l, 48 hours Static test		
	NOEC	Water flea (Daphnia magna)
56 mg/l, 48 hours Static test		
Microtox	MIC	Aspergillus flavus
> 1000 mg/l		
		Azotobacter chroococcum
> 1000 mg/l		
		Chaetomium globosum
> 1000 mg/l		
		Nostoc sp.
> 1000 mg/l		
		Pseudomonas fluorescens
> 1000 mg/l		

* 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

MAGNESIUM STEARATE 210 nm

VALACYCLOVIR HYDROCHLORIDE 264

Hydrolysis

Half-life (Hydrolysis-acidic)

VALACYCLOVIR HYDROCHLORIDE 68.38 Days Measured

Half-life (Hydrolysis-basic)

VALACYCLOVIR HYDROCHLORIDE 15.13 Hours Measured

Half-life (Hydrolysis-neutral)

VALACYCLOVIR HYDROCHLORIDE 55.92 Hours Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

MAGNESIUM STEARATE 77 %, 28 days BOD

POLYVINYLPIRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

POLYVINYLPIRROLIDONE 0 %, 28 days Modified MITI test, Activated sludge

VALACYCLOVIR HYDROCHLORIDE 100 %, 14 days Modified Zahn-Wellens, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

MAGNESIUM STEARATE 95 %, 22 days Sturm test

VALACYCLOVIR HYDROCHLORIDE 0.08 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

VALACYCLOVIR HYDROCHLORIDE < 1

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

MAGNESIUM STEARATE 5.86 Estimated

Mobility in general Not available.

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 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). 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	Not applicable.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
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)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - No 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 Proposition 65 - CRT: Listed date/Carcinogenic substance

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

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

TITANIUM DIOXIDE (CAS 13463-67-7)

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

Issue date 04-18-2018

Version # 01

Further information HMIS® is a registered trade and service mark of the ACA.

HMIS® ratings
Health: 1
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 1
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.