



SAFETY DATA SHEET

1. Identification

Product identifier ZOVIRAX TABLETS

Other means of identification Not available.

Synonym(s) ZOVIRAX TABLETS 400 MG * ZOVIRAX TABLETS 800 MG * ZOVIRAX COMPRESSE * ZOVIRAX COMPRIMES * ZOVIRAX COMPRIMIDOS * ZOVIRAX TABLETAS * ZOVIRAX TABLETES * ZOVIRAX TABLETKI * ZOVIRAX TABLETTA * ZOVIRAX TABLETTER * ZOVIRAX TABLETTI * ZOVIRAX TABLETY * ZOVIRAX WELLSTAT PAC TABLETS * ZOVIRAX ZOSTAB PAC TABLETS * ACYVIR TABLETS * ZOV800 TABLETS * ZOVIR TABLETS * ACYCLOVIR, 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

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ACYCLOVIR	ACICLOVIR 248U74 CCI 22890 9-((2-HYDROXYETHOXY)METHYL)GUANIN ACYCLOGUANOSINE 2-AMINO-1,9-DIHYDRO-9-(2-HYDROXYETH- 1335 (GW ACN) ACYCLOVIR	59277-89-3	70 - < 80

Hazardous components Chemical name	Common name and synonyms	CAS number	%
MAGNESIUM STEARATE	OCTADECANOIC ACID, MAGNESIUM SALT STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE OCTADECANOIC ACID MAGNESIUM SALT MAGNESIUM OCTADECANOATE C36H70MGO4 OHS13505 RTECS W14390000 MAGNESIUMDISTEARAT	557-04-0	1 - < 3
POLYVINYLPIRROLIDONE	2-PYRROLIDINONE, 1-ETHENYL, HOMOPOLYMER 1-ETHENYL-2-PYRROLIDINONE HOMOPOLYMER 2-PYRROLIDINONE, 1-VINYL-, POLYMERS 1-VINYL-2-PYRROLIDINONE POLYMERS POLY(VINYLPYRROLIDINONE) POLY(N-VINYLPYRROLIDINONE) POLY(1-VINYLPYRROLIDINONE) POLY(VINYLPYRROLIDONE) POLY(N-VINYLPYRROLIDONE) POVIDONE PVP VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDINONE POLYMER N-VINYLPYRROLIDONE HOMOPOLYMER VINYLPYRROLIDONE POLYMER N-VINYLPYRROLIDONE POLYMER RTECS TR8370000 PLASDONE PLASDONE K29/32 POLY-1-VINYL-2-PYRROLIDON POLYVINYLPYRROLIDONE PROVIDONE	9003-39-8	1 - < 3

Other components below reportable levels

10 - < 20

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

4. First-aid measures

Inhalation	If not breathing, give artificial respiration. If breathing is difficult, trained personnel should give oxygen. Get medical attention immediately.
Skin contact	Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention if symptoms occur.
Eye contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Get medical attention if irritation develops and persists.
Ingestion	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. If swallowed, rinse mouth with water (only if the person is conscious). Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Not available.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide extinguishers may be ineffective.
Specific hazards arising from the chemical	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.
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 For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear protective clothing and equipment consistent with the degree of hazard. For personal protection, see section 8 of the MSDS.

Methods and materials for containment and cleaning up Collect and place it in a suitable, properly labelled container for recovery or disposal. 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 MSDS. No specific decontamination or detoxification procedures have been identified for this product.

Environmental precautions Prevent further leakage or spillage if safe to do so. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and storage

Precautions for safe handling Avoid breaking or crushing tablets.

Conditions for safe storage, including any incompatibilities Store away from incompatible materials (see Section 10 of the MSDS). No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value
ACYCLOVIR (CAS 59277-89-3)	8 HR TWA	5000 mcg/m3
	OHC	1
MAGNESIUM STEARATE (CAS 557-04-0)	OHC	1

US. ACGIH Threshold Limit Values

Components

Components	Type	Value
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3

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

Appropriate engineering controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. No special engineering controls are required. Local exhaust ventilation (LEV) is recommended. Only authorised personnel may enter the working area.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear approved safety glasses with side shields or cover goggles if eye contact is possible.

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

Other Wear appropriate chemical resistant clothing.

Respiratory protection If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations An eye wash station should be available. Wear appropriate clothing to avoid skin contact. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

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)	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	This product is expected to be stable.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None for normal handling of this product.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	Based on available data, the classification criteria are not met. Inhalation of dusts may cause respiratory irritation.
Skin contact	Based on available data, the classification criteria are not met. Dust or powder may irritate the skin.
Eye contact	Based on available data, the classification criteria are not met. Dust or powder may irritate eye tissue.

Symptoms related to the physical, chemical and toxicological characteristics	Not available.
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Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met.
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Components	Species	Test Results
ACYCLOVIR (CAS 59277-89-3)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 15.1 mg/l, 4 hours

Components	Species	Test Results
Oral LD50	Rat	> 20 g/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
Acute		
Oral LD50	Rat	> 2000 mg/kg
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		
Acute		
Oral 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		
ACYCLOVIR		Acute dermal irritation, Tested at 5% in a cream; Irritation Index 0.02 Result: Negative Species: Rabbit
Irritation Corrosion - Skin: P.I.I. value		
MAGNESIUM STEARATE		0
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met. Dust or powder may irritate eye tissue.	
Eye		
ACYCLOVIR		Acute ocular irritation Result: Negative Species: Rabbit
Eye / Kay and Calandra class - Intact		
MAGNESIUM STEARATE		4 Recovery Period: 2 days
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Sensitization		
ACYCLOVIR		Method not specified Result: Negative Species: Guinea pig
Germ cell mutagenicity	Based on available data, the classification criteria are not met. No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
ACYCLOVIR		Ames Assay Result: Negative C3H/T10 1/2 Cell Transformation Assay Result: Negative Chromosomal Aberration Assay In Vitro, Positive response only with levels much above equivalent of human therapeutic dose Result: Positive Species: Hamster Chromosomal Aberration Assay In Vitro, human lymphocytes Result: Equivocal Cytogenetic Analysis In Vivo, bone marrow Result: Negative Species: Mouse Mouse lymphoma cell (L5178Y TK) Assay Result: Positive
Carcinogenicity	Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.	
ACYCLOVIR		2 year bioassay Result: Negative Species: Mouse 2 year bioassay Result: Negative Species: Rat
IARC Monographs. Overall Evaluation of Carcinogenicity		
ACYCLOVIR (CAS 59277-89-3)		3 Not classifiable as to carcinogenicity to humans.
POLYVINYLPIRROLIDONE (CAS 9003-39-8)		3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity	Based on available data, the classification criteria are not met.
ACYCLOVIR	Subcutaneous injection Result: NOAEL = 25 mg/kg/day; LOAEL = 50 mg/kg/day (decreased implantation efficiency, no effect on litter size) Species: Rat
ACYCLOVIR	Embryo-foetal development - Oral, sub-cutaneous administration Result: NOAEL = 50 mg/kg/day; no adverse foetal effects Species: Rabbit Embryo-foetal development - Oral, sub-cutaneous administration Result: NOAEL = 50 mg/kg/day; no adverse foetal effects Species: Rat
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Not available.

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
ACYCLOVIR (CAS 59277-89-3)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (<i>Selenastrum capricornutum</i>)	> 99 mg/l, 96 hours, Static test, OECD 201
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 93 mg/l, 48 hours, Static test, OECD 202
Fish	EC50	Fathead minnow (Juvenile <i>Pimephales promelas</i>)	> 95 mg/l, 96 hours, Static renewal test, OECD 203
Microtox	MIC	<i>Aspergillus flavus</i>	> 993 mg/l, 5 days
		<i>Azotobacter chroococcum</i>	> 993 mg/l, 5 days
		<i>Chaetomium globosum</i>	> 993 mg/l, 5 days
		<i>Nostoc</i> sp.	> 993 mg/l, 5 days
		<i>Pseudomonas fluorescens</i>	> 993 mg/l, 5 days
<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>)	10 mg/l, 7 days
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult <i>Oryzias latipes</i>)	130 mg/l, 96 hours
Microtox	EC50	Microtox	12.5 mg/l, 15 minutes
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 (<i>Daphnia magna</i>)	84 mg/l, 48 hours, Static test
	NOEC	Water flea (<i>Daphnia magna</i>)	32 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-aqueous)

ACYCLOVIR 3.55 Hours Measured, pH 7 Buffer Solution

Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

UV/visible spectrum wavelength

MAGNESIUM STEARATE 210 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

ACYCLOVIR > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

ACYCLOVIR -1.2

Bioconcentration factor (BCF)

MAGNESIUM STEARATE > 9999 Estimated

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

ACYCLOVIR 2.33 - 2.37 Estimated

Soil/sediment sorption - log Koc

ACYCLOVIR 2.6 - 2.64 Measured

MAGNESIUM STEARATE 5.86 Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

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.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

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.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

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 No

SARA 311/312 Hazardous chemical No

NFPA ratings Health: 1
Flammability: 1
Instability: 0

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

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.

Food and Drug Administration (FDA) Not regulated.

US state regulations

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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)	Yes
New Zealand	New Zealand Inventory	Yes
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 12-17-2013

Revision date 12-17-2013

Version #	10
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 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: Product and Company Identification Composition / Information on Ingredients: Ingredients Exposure Controls / Personal Protection: OELs Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States GHS: Classification