SAFETY DATA SHEET

1. Identification

Product identifier **ZOVIRAX FOR INJECTION**

Other means of identification Not available.

Synonym(s) ZOVIRAX FOR INJECTION 500 MG * ZOVIRAX FOR INJECTION 1000 MG * ZOVIRAX IV FOR INFUSION 250 MG * ZOVIRAX IV FOR INFUSION 500 MG * ACYCLOVIR SODIUM, 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	5 - < 10
Other components below reportable levels			90.0 - 95.0

*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	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. 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	In the event of fire, cool tanks with water spray.
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. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	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.
Environmental precautions	Prevent further leakage or spillage if safe to do so.

7. Handling and storage

Precautions for safe handling	Use care in handling/storage.
Conditions for safe storage, including any incompatibilities	Store in accordance with local/regional/national/international regulation. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

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

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	Freeze dried powder.
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	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	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.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Based on available data, the classification criteria are not met.
Symptoms related to the physical, chemical and toxicological characteristics	Not available.

Information on toxicological effects

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

Components	Species	Test Results
ACYCLOVIR (CAS 59277-89-3)		
Acute		
Inhalation		
LC50	Rat	> 15.1 mg/l, 4 hours
Oral		
LD50	Rat	> 20 g/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

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Eye

ACYCLOVIR
Acute ocular irritation
Result: Negative
Species: Rabbit

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 This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Based on available data, the classification criteria are not met.

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.

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

ACYCLOVIR	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			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	> 99 mg/l, 96 hours, Static test, OECD 201
Crustacea	EC50	Water flea (Daphnia magna)	> 93 mg/l, 48 hours, Static test, OECD 202
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	> 95 mg/l, 96 hours, Static renewal test, OECD 203
Microtox	MIC	Aspergillus flavus	> 993 mg/l, 5 days
		Azotobacter chroococcum	> 993 mg/l, 5 days
		Chaetomium globosum	> 993 mg/l, 5 days
		Nostoc sp.	> 993 mg/l, 5 days
		Pseudomonas fluorescens	> 993 mg/l, 5 days
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	> 10 mg/l, 7 days, 7 day static renewal, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	10 mg/l, 7 days

* 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-aqueous)

ACYCLOVIR 3.55 Hours Measured, pH 7 Buffer Solution

Hydrolysis

Half-life (Hydrolysis-neutral)

ACYCLOVIR > 1 Years Measured

Bioaccumulative potential No data available for this product.

Partition coefficient n-octanol / water (log Kow)

ACYCLOVIR -1.2

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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

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.

Read safety instructions, SDS and emergency procedures before handling.

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 - No 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: 0 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

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)	Yes
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 11-28-2013

Revision date 11-28-2013

Version # 12

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: 0
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: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Ecological Information: Reports
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection