1. Identification

Product identifier: ZOVIRAX FOR INJECTION

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.

3. Composition/information on ingredients

Mixtures

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACYCLOVIR</td>
<td>ACICLOVIR 248U74 CCI 22890 9-((2-HYDROXYETHOXY)METHYL)GUANIN ACYCLOGUANOSINE 2-AMINO-1,9-DIHYDRO-9-(2-HYDROXYETHYL)-1335 (GW ACN) ACYCLOVIR</td>
<td>59277-89-3</td>
<td>5 - &lt; 10</td>
</tr>
</tbody>
</table>

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. 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

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACYCLOVIR (CAS 59277-89-3)</td>
<td>8 HR TWA</td>
<td>5000 mcg/m3</td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>1</td>
</tr>
</tbody>
</table>

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

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.

Hand protection

Glove approved safety glasses with side shields or cover goggles if eye contact is possible.

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.

Other

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.
<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACYCLOVIR (CAS 59277-89-3)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Inhalation</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>&gt; 15.1 mg/l, 4 hours</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 20 g/kg</td>
</tr>
<tr>
<td>* Estimates for product may be based on additional component data not shown.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><em>Irritation Corrosion - Skin</em></td>
<td>ACYCLOVIR</td>
<td>Acute dermal irritation, Tested at 5% in a cream; Irritation Index 0.02; Result: Negative; Species: Rabbit</td>
</tr>
<tr>
<td><strong>Serious eye damage/eye irritation</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><em>Eye</em></td>
<td>ACYCLOVIR</td>
<td>Acute ocular irritation; Result: Negative; Species: Rabbit</td>
</tr>
<tr>
<td><strong>Respiratory sensitization</strong></td>
<td></td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td><strong>Skin sensitization</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><em>Sensitization</em></td>
<td>ACYCLOVIR</td>
<td>Method not specified; Result: Negative; Species: Guinea pig</td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><em>ACYCLOVIR</em></td>
<td>Ames Assay</td>
<td>Result: Negative</td>
</tr>
<tr>
<td></td>
<td>C3H/T10 1/2 Cell Transformation Assay</td>
<td>Result: Negative</td>
</tr>
<tr>
<td></td>
<td>Chromosomal Aberration Assay In Vitro, Positive response only with levels much above equivalent of human therapeutic dose</td>
<td>Result: Positive; Species: Hamster</td>
</tr>
<tr>
<td></td>
<td>Chromosomal Aberration Assay In Vitro, human lymphocytes</td>
<td>Result: Equivocal</td>
</tr>
<tr>
<td></td>
<td>Cytogenetic Analysis In Vivo, bone marrow</td>
<td>Result: Negative; Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>Mouse lymphoma cell (L5178Y TK) Assay</td>
<td>Result: Positive</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td></td>
<td>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.</td>
</tr>
<tr>
<td><em>ACYCLOVIR</em></td>
<td>2 year bioassay</td>
<td>Result: Negative; Species: Mouse</td>
</tr>
<tr>
<td></td>
<td>2 year bioassay</td>
<td>Result: Negative; Species: Rat</td>
</tr>
<tr>
<td><strong>IARC Monographs. Overall Evaluation of Carcinogenicity</strong></td>
<td>ACYCLOVIR (CAS 59277-89-3)</td>
<td>3 Not classifiable as to carcinogenicity to humans.</td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><em>ACYCLOVIR</em></td>
<td>Subcutaneous injection</td>
<td>Result: NOAEL = 25 mg/kg/day; LOAEL = 50 mg/kg/day (decreased implantation efficiency, no effect on litter size); Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Embryo-foetal development - Oral, sub-cutaneous administration</td>
<td>Result: NOAEL = 50 mg/kg/day; no adverse foetal effects; Species: Rabbit</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACYCLOVIR (CAS 59277-89-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated Sludge Respiration</td>
<td>IC50</td>
<td>Residential sludge</td>
</tr>
<tr>
<td>Algae</td>
<td>EC50</td>
<td>Green algae (Selenastrum capricornutum)</td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Fathead minnow (Juvenile Pimephales promelas)</td>
</tr>
<tr>
<td>Microtox</td>
<td>MIC</td>
<td>Aspergillus flavus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Azotobacter chroococcum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chaetomium globosum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nostoc sp.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pseudomonas fluorescens</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>LOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
</tr>
</tbody>
</table>

* 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

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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) and 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