MATERIAL SAFETY DATA SHEET

Product Name: Acyclovir Sodium Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Acyclovir Sodium Injection

Synonyms
6H-Purin-6-one, 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Acyclovir

Chemical Formula
C₈H₁₁N₅O₃

Preparation
Non-hazardous ingredients include Water for Injection. Sodium hydroxide and/or hydrochloric acid may be added for pH adjustment. Formulation also contain acyclovir sodium.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acyclovir</td>
<td>2.5</td>
<td>59277-89-3</td>
<td>UP0791400</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acyclovir</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Acyclovir Sodium Injection is a sterile injectable drug that contains acyclovir, a synthetic guanine nucleoside. Clinically, it is an anti-viral drug used to treat mucosal or cutaneous herpes simplex (HSV-1 and HSV-2), herpes zoster (shingles), and varicella-zoster (chickenpox) infections. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potential sensitizer. Based on clinical use, possible target organs include the central nervous system and kidneys.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from workplace exposures. In clinical use, adverse effects may include local effects at the site of injection (cutaneous irritation, erythema, or pain) following parenteral administration. Other adverse effects have included headache, dizziness, fatigue, insomnia, confusion, depression, agitation, tremors, seizures, nausea/vomiting, diarrhea, abdominal pain,
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increased BUN, decreased creatinine clearance, impaired renal function, obstructive nephropathy and acute renal failure, elevated liver function tests, rash and urticaria. Rarely anemia, neutropenia, thrombocytopenia, thrombocytosis, leukocytosis, and neutrophilia have been reported.

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to acyclovir, valacyclovir, or related compounds; pre-existing renal or hematological ailments.

4. FIRST AID MEASURES

Eye contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability

None anticipated for this aqueous product.

Fire & Explosion Hazard

No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures

No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

No special handling required under conditions of normal product use.

Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special precautions required for hazard control.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospira EEL</td>
<td>mg/m³</td>
<td>ppm</td>
</tr>
<tr>
<td>Acyclovir</td>
<td></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Clear</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>10.7 to 11.7</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Acyclovir Sodium Injection

10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and oxides of sodium.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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</thead>
<tbody>
<tr>
<td>Acyclovir</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;20,000</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt;10,000</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acyclovir</td>
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<td>LD50</td>
<td>Intravenous</td>
<td>750</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acyclovir</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>860</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>724</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Acyclovir did not impair fertility or reproduction in mice (450 mg/kg/day, PO) or in rats (25 mg/kg/day, SC). In the mouse study, plasma levels were the same as human levels, while in the rat study, they were 1 to 2 times human levels. At higher doses (50 mg/kg/day, SC) in rats and rabbits (1 to 2 and 1 to 3 times human levels, respectively) implantation efficacy, but not litter size, was decreased. In a rat peri and post-natal study at 50 mg/kg/day, SC, there was a statistically significant decrease in group mean numbers of corpora lutea, total implantation sites, and live fetuses. Acyclovir administered during organogenesis was not teratogenic in the mouse (450 mg/kg/day, PO), rabbit (50 mg/kg/day, SC and IV), or rat (50 mg/kg/day, SC). No testicular abnormalities were seen in dogs given 50 mg/kg/day, IV for 1 month (1 to 3 times human levels) or in dogs given 60 mg/kg/day orally for 1 year (the same
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as human levels). Testicular atrophy and aspermatogenesis were observed in rats and dogs at higher dose levels.

Mutagenicity
Acyclovir was tested in 16 in vitro and in vivo genetic toxicity assays. Acyclovir was positive in 5 of the assays.

Carcinogenicity
Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of up to 450 mg/kg administered by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system and kidneys.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product IC50: > 100 mg/l, 3 Hours, Activated sludge for acyclovir. The active ingredient acyclovir is not toxic to activated sludge microorganisms. space MIC (minimum inhibition concentration): > 993 mg/l, 5 Days, 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 Acyclovir is not toxic to these microorganisms. ace IC50: > 99 mg/l, 96 Hours, Selenastrum capricornutum, green algae, Static test. Acyclovir is not toxic to algae. pace EC50: > 93 mg/l, 48 Hours, Daphnia magna, Static test Chronic LOEC: > 10 mg/l, 7 Days, Ceriodaphnia dubia Chronic NOEC: 10 mg/l, 7 Days, Ceriodaphnia dubia Acyclovir is not toxic to daphnids or harmful to daphnids in chronic toxicity studies. EC50: > 95 mg/l, 96 Hours, Static renewal test, Juvenile Pimephales promelas, fathead minnow. Acyclovir is not toxic to fish. * GSK MSDS for Zovirax Suspension

Persistence/Biodegradability
Not determined for product. Hydrolysis: Half-Life, Neutral: > 1 Years, Measured Acyclovir has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism. Photolysis: Half-Life, Aqueous: 3.55 Hours, Measured, pH 7 Buffer Solution Acyclovir has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism. Biodegradation: Aerobic – Ready: Percent Degradation: 0.7 %, 28 days, Sturm test Aerobic – Inherent: Percent Degradation: 50 %, < 1 day, Modified Zahn-Wellens, Activated sludge Acyclovir has been tested and is expected to be biodegradable. It is not expected to persist in the environment. * GSK MSDS for Zovirax Suspension

Bioaccumulation
Not determined for product. The octanol/water partition coefficient data that suggests that acyclovir will not have the tendency to distribute into fats. Acyclovir is not anticipated to bioaccumulate in the food chain. * GSK MSDS for Zovirax Suspension

Mobility in Soil
Not determined for product. Soil Sediment Sorption (log Koc): 2.6 to 2.64, Measured Sludge Biomass Distribution Coefficient (log Kd): 2.33 to 2.37 Estimated Acyclovir is not anticipated to adsorb to sludge or biomass. * GSK MSDS for Zovirax Suspension
13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated
Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acyclovir</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status  Not Listed
U.S. OSHA Classification Target Organ Toxin

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.*

Hazard Class Not Applicable
Hazard Category Not Applicable
Signal Word Not Applicable
Symbol Not Applicable
Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.
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**EU Classification**
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Acyclovir.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: S23 - Do not breathe vapor.
Safety Phrases: S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/27/2011
Obsolete Date: 10/21/2008

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