SAFETY DATA SHEET

Product Name: Acyclovir Sodium Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Acyclovir Sodium Injection
Synonyms	9-[(2-Hydroxyethoxy)methyl]guanine;2-Amino-1,9-dihydro-9-(2-hydroxyethoxy methyl)-6H-purin-6-one

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Acyclovir Sodium Injection is a solution containing 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. Based on clinical use, possible target organs include the central nervous system and kidneys.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified
Health Hazards	**Hazard Class**	**Hazard Category**
	STOT – RE	2

Label Element(s)

Pictogram(s)

Signal Word

Warning

Hazard Statement(s)

May cause damage to organs through prolonged or repeated exposures

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response

Get medical attention if you feel unwell.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Acyclovir
Chemical Formula $C_8H_{11}N_5O_3$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Acyclovir	2.5%	59277-89-3	UP0791400

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

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 None anticipated for this aqueous product.

Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting 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 control 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

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Acyclovir	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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

Appearance/Physical State	NA
Odor	NA
Odor Threshold	NA
pH	10.7 to 11.7
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Relative Density	NA
Solubility	NA
Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

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:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Acyclovir	100	LD50	Oral	>20,000 >10,000	mg/kg mg/kg	Rat Mouse
Acyclovir	100	LD50	Intravenous	750 400	mg/kg mg/kg	Rat Mouse
Acyclovir	100	LD50	Intraperitoneal	860 724	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

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 anticipated from normal handling of this product. 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, 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.
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.

11. TOXICOLOGICAL INFORMATION:continued

Reproductive Effects

None anticipated from normal handling of this product. 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 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.

Carcinogen Lists

IARC: Not listed **NTP:** Not listed **OSHA:** Not listed

Specific Target Organ Toxicity – Single Exposure

NA

Specific Target Organ Toxicity – Repeat Exposure

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

IC50: > 99 mg/l, 96 Hours, Selenastrum capricornutum, green algae, Static test.
Acyclvir is not toxic to algae.

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.

12. ECOLOGICAL INFORMATION: continued

***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 is expected to be biodegradable and not expected to persist in the environment.
***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.
***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

Notes:

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

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
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapor or spray.
Wash hands thoroughly after handling.

Response

Get medical attention if you feel unwell.

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.

15. REGULATORY INFORMATION: continued

EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with 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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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