A Division of Fresenius Kabi USA

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Product Name:	**Acyclovir for Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(847) 706-2084
MSDS Creation Date:	January 08, 2009
MSDS Revision Date:	January 08, 2012
(M)SDS Format:	

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Acyclovir Sodium	59277-89-3	500 mg/vial	

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption Injection
Potential Health Effects:	
Eye:	Contact with eyes may cause irritation. Mild local irritation has been reported after ocular use of ointments containing 6 Acyclovir
Signs/Symptoms:	Potential adverse reactions from prescribed doses are described in the package insert and include: renal insufficiency/failure, acyclovir crystaluria, neurologic effects (lethargy or coma), myoclonus, agitation, and tremor. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Individuals with hypersensitivity to acyclovir or valacyclovir.

Acyclovir Sodium

Skin:	Urticaria, erythema, edema and vesicles have been seen after therapeutic administration of 5% acyclovir cream and intravenous acyclovir.

SECTION 4 - FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176 or (847) 706-2084.

SECTION 5 - FIRE FIGHTING MEASURES

Flash Point:	Not established.

Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 - HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 15 to 25°C (59 to 77°F).
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION - EXPOSURE GUIDELINES

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.

Physical State:	Lyophilized powder.
Boiling Point:	Not established.
Melting Point:	220°C
Solubility:	Soluble (1.3 mg/mL)
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	11.0 (Approximately)
Molecular Formula:	Mixture
Molecular Weight:	247.19
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 - STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Parabens will cause precipitation.

SECTION 11 - TOXICOLOGICAL INFORMATION

Acyclovir Sodium :

Acute Toxicity:	IMMEDIATE EFFECTS: Nausea, vomiting, fever and diarrhea. Diffuse urticaria was observed 15 minutes after intravenous acyclovir infusion in an acyclovir-sensitive patient.

Acyclovir Sodium :

OSHA:	Not listed
IARC:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.
NTP:	Not listed

Acyclovir Sodium :

RTECS Number:	UP0791400
Acute Effects:	Nausea, vomiting, fever and diarrhea. Diffuse urticaria was observed 15 minutes after intravenous acyclovir infusion in an acyclovir-sensitive patient.
Skin:	Urticaria, erythema, edema and vesicles have been seen after therapeutic administration of 5% acyclovir cream and intravenous acyclovir.
Ingestion:	Oral - Rat LD50: >20 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Chronic Effects:	DELAYED EFFECTS: Allergic dermatitis, hallucinations, and obstructive nephropathy.
Other Toxicological Information:	Intravenous. - Rat LD50: 750 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: 620 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 1118 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 2400 mg/kg/8W (intermittent) [Reproductive - Tumorigenic effects - uterine tumors Reproductive - Tumorigenic effects - other reproductive system tumors Tumorigenic - active as anti-cancer agent] Subcutaneous - Rat Micronucleus test: 350 mg/kg/20D Subcutaneous - Rat TDLo: 100 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Effects on Newborn - weaning or lactation index (e.g., number alive at weaning per number alive at day 4)] Subcutaneous - Rat TDLo: 200 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)] Subcutaneous - Rat TDLo: 400 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Rat TDLo: 1200 mg/kg [Reproductive - Maternal Effects - other effects Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Intraperitoneal. - Rat LD50: 860 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 724 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo: 250 mg/kg/5D (intermittent) [Kidney/Ureter/Bladder - changes primarily in glomeruli

	Kidney/Ureter/Bladder - urine volume increased Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Mouse TDLo: 700 mg/kg/16D (intermittent) [Lungs, Thorax, or Respiration - tumors Tumorigenic - protects against induction of experimental tumors Tumorigenic - active as anti-cancer agent]
Chronic Effects:	DELAYED EFFECTS: Allergic dermatitis, hallucinations, and obstructive nephropathy.

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 - TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 - REGULATORY INFORMATION

Acyclovir Sodium :

EINECS Number:	261-685-1
Canada DSL:	Listed

SECTION 16 - ADDITIONAL INFORMATION

Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. APP Pharmaceuticals assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.