SAFETY DATA SHEETS

This SDS packet was issued with item:

078883267

N/A

Administrative Offices:
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March 10, 2006

3E Company
1905 Aston Ave, Suite 100
Carlsbad CA 92008

70388

Re: Acyclovir 400mg Tablets

Dear Customer:

Thank-you for your inquiry regarding the status of our products under OSHA's Hazard Communication Regulation 29 CFR 1910.1200.

The Hazard Communication Standard exempts most of our products from the scope of its application since they are either in a solid final form for direct administration to a patient; are considered consumer products as defined in the Consumer Product Safety Act (15 U.S.C. 2051 et. seq.); or fall under the guidelines defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et. seq.) and regulations issued under that act by the Food and Drug Administration. **Acyclovir 400mg Tablets** are exempt from the Standard. A Material Safety Data Sheet is not available for this product. All pertinent information regarding the safe handling and use of this product can be found on the package insert.

I hope this information is of value to you. If you have any additional questions regarding the status of our products under the OSHA Standard, please feel free to contact our Security Operations Office.

Sincerely,

Clinton Schaffer

Clinton Schaffer
Security Officer
Security Operations Department

Material Safety Data Sheet

ACYCLOVIR
CAPSULES 200 mg , TABLETS (400 / 800 mg)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
Material	Acyclovir
Empirical Chemical Formula	$C_8H_{11}N_5O_3$
Synonyms	Zovirax, Aciclovir
Manufacturer	Ohm Laboratories, Inc., 1385 Livingston Ave. North Brunswick, NJ, 08907, USA.
Distributor	Ranbaxy Pharmaceuticals Inc., 9431, Florida Mining Blvd. East, Jacksonville, FL, 32257

2. COMPOSITION / INFORMATION ON INGREDIENTS		
Ingredients	CAS Number	Percentage
Acyclovir	59277-89-3	50.00%
Non-Hazardous Ingredients	–	50.00%

3. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible.
Health	Exposure might occur via ingestion, skin and eyes. Possible effects of overexposure in the workplace include: nausea, vomiting, diarrhea, dizziness and headache. Health effects information is based on hazards of components.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES	
Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed person is unconscious or semi-conscious. Wash out the mouth with water. If the exposed person is fully conscious, give plenty of water to drink. Get medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Remove contaminated clothing. Wash affected areas with plenty of water and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

Eye Contact	Flush eyes with large amounts of running water for 15 minutes. Hold eyelids open. Get immediate medical attention.
NOTES TO PHYSICIANS / HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocol. For additional guidance, refer to the current prescribing information or to the local poison control information center.Medical treatment in cases of overexposure should be treated as an overdose of anti-viral agent.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detail description of medical conditions caused by or aggravated by overexposure to this product
Antidotes	No specific antidote exists.

5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	No apparent fire or explosion hazards exist for the product, although the packaging is combustible.
Extinguishing Media	Water spray, dry chemical powder or appropriate foam is recommended. Carbon dioxide may be ineffective.
Special Firefighting Procedures	For single units (packages) – No special requirements needed. For larger amounts (multiple packages/pallets) of product – Since toxic, corrosive or flammable vapours/fumes might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedure	No specific decontamination or detoxification procedures have been identified for this product.
7. HANDLING AND STORAGE	

Safe Handling and Use	Avoid breaking or crushing the capsules.
Storage	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	Wear glasses in case of a possible eye contact.
Respirators	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 Equipment or Procedures	Wear appropriate clothing to avoid skin contact.
Work / Hygienic Practices	Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form (Appearance)	**Color & Shape** **Capsule:** - White to Off-White granular powder filled in Size 1white opaque cap / white opaque body hard gelatin capsules. **Tablet: -** White capsule shaped unscored tablets.

10. STABILITY AND REACTIVITY	
Stability	Stable
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION	
This material contains active pharmaceutical ingredient Acyclovir, the specific information on which is provided below.	
Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	Not expected to be toxic following inhalation.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation might not occur following direct contact with eyes.

Target Organ Effects	No specific target organ effects have been identified.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
Genetic Toxicity	Not expected to be genotoxic, based on effects of individual components.
Carcinogenicity	No components are listed as carcinogens.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure condition.
Gastrointestinal Reactions	n/k
Hypersensitivity Reactions	n/k
Pharmacological Effects	This preparation contains ingredients with the following activity: an anti-viral agent. Adverse effects of over exposure might include: nausea; vomiting; diarrhea; dizziness.
Over Dosage	Overdoses involving ingestion of up to 100 capsules (20 g) have been reported. Adverse events that have been reported in association with overdosage include agitation, coma, seizures, and lethargy. Precipitation of acyclovir in renal tubules may occur when the solubility (2.5 mg/mL) is exceeded in the intratubular fluid. Overdosage has been reported following bolus injections or inappropriately high doses and in patients whose fluid and electrolyte balance were not properly monitored. This has resulted in elevated BUN and serum creatinine and subsequent renal failure. In the event of acute renal failure and anuria, the patient may benefit from hemodialysis until renal function is restored.
Contraindications	Acyclovir is contraindicated for patients who develop hypersensitivity to Acyclovir or Valacyclovir.

12. ECOLOGICAL INFORMATION

This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulation and procedures should be consulted prior to environmental release.
Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge

Respiration

This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
IC50: > 100 mg/l, 3 Hours, Activated sludge

Microbial Growth Inhibition
This material contains an active pharmaceutical ingredient that is not toxic to these micro-organisms.
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

Algal: This material contains an active pharmaceutical ingredient that is not toxic to algae.
IC50: > 99 mg/l, 96 Hours, Selenastrum capricornutum, green algae, Static test

Daphnid: This material contains an active pharmaceutical ingredient that is not toxic to daphnids and not harmful to daphnids in chronic toxicity studies.
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

Fish: This material contains an active pharmaceutical ingredient that is not toxic to fish.
Juvenile Pimephales promelas, fathead minnow
EC50: > 95 mg/l, 96 Hours, Static renewal test

MOBILITY
Solubility: This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Volatility: This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

Adsorption: This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.
This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Soil Sediment Sorption(log Koc): 2.60 to 2.64, Measured
Sludge Biomass Distribution Coefficient (log Kd): 2.33 to 2.37, Estimated

Partitioning: This material contains an active pharmaceutical ingredient with octanol /water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION
Hydrolysis: This material contains an active pharmaceutical ingredient that has been shown to Be chemically stable in water. Hydrolysis is unlikely to be a significant

depletion mechanism.
Half-Life, Neutral: > 1 Years, Measured

Photolysis: This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water when exposed to light. Aqueous photolysis may be a significant depletion mechanism.
Half-Life, Aqueous: 3.55 Hours, Measured, pH 7 Buffer Solution

Biodegradation: This mixture contains an active pharmaceutical ingredient that has been tested and is expected to be biodegradable. It is not expected to persist in the environment.
Aerobic - Ready
Percent Degradation: 0.7 %, 28 days, Sturm test
Aerobic - Inherent
Percent Degradation: 50 %, < 1 day, Modified Zahn-Wellens, Activated sludge

Bioaccumulation: This material contains an active pharmaceutical ingredient that will not have a tendency to bio-accumulate in the food chain.

13. DISPOSAL CONSIDERATIONS	
Disposal Recommendations	Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. The disposal method for rejected product/returned goods must ensure that they cannot be resold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION	
The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.	
Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION	
EU Classification and Labelling	Exempt from requirement of EU Dangerous preparation directive-product regulated as a medicinal product.

US OSHA Standard (29 CFR Part 1910.1200)	This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.
OTHER US REGULATIONS	
TSCA Status	Exempt

16. OTHER INFORMATION

The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. 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.

Ranbaxy shall not be held liable for any damage resulting from handling or from contact with the above product. Ranbaxy reserves the right to revise this MSDS.