

**SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION**

**1.1 Product identifier**

**Product name:** Acyclovir Oral Suspension, USP 200 mg/5 mL

**Product Code:** 66689-342-16

**Synonym(s):** None

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

**Recommended use:** Acyclovir, USP is a synthetic nucleoside analogue active against herpes viruses. Acyclovir Oral Suspension, USP is a formulation for oral administration

**Restrictions on use:** The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

**1.3 Details of the supplier and of the safety data sheet**

**Distributed by**

VistaPharm, Inc.  
 7265 Ulmerton Road  
 Largo, FL 33771 USA  
 +1-727-530-1633

**Manufactured by**

VistaPharm, Inc.  
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 Largo, FL 33771 USA  
 +1-727-530-1633

**1.4 Emergency telephone number:** In the continental USA: +1-727-530-1633

**SECTION 2 - HAZARDS IDENTIFICATION**

**2.1 Classification of substance or mixture**

**Product definition:** Mixture

**Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation EC No. 1272/2008**

Not a dangerous substance or mixture according to OSHA or to European Union Legislation

**2.2 Label elements**

**Signal Word:** Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Hazard Statement:** Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Precautionary statement**

<b>Prevention</b>	Observe good industrial hygiene practices. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	Wash hands after handling. If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store away from incompatible materials. Store at 20 - 25 °C (68 - 77 °F). Protect from light. Store locked up.
<b>Disposal</b>	Incineration of waste at an approved USEPA incinerator is recommended.

**2.3 Hazards not otherwise classified (HNOC) or not covered by GHS**

None known

**SECTION 3 – COMPOSITION INFORMATION ON INGREDIENTS**

**3.1 Substances**

Not applicable

**3.2 Mixtures**

Concentration	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
3 - < 6%	Acyclovir	59277-89-3	-----	-----	H300, H330
10 - < 20%	Glycerin	56-81-5	-----	-----	H225, H301, H311
0.5 - < 2%	Microcrystalline Cellulose	9004-34-6	-----	-----	-----
0.09	Methylparaben	99-76-3	-----	-----	H315, H319, H335
0.02	Propylparaben	94-13-3	-----	-----	H315, H319, H335

Inactive ingredients: Purified Water. Any concentration shown as a range is to protect confidentiality. There are no additional ingredients present in this product which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

## SECTION 4 - FIRST AID MEASURES

### 4.1 Description of first aid measures

**Inhalation:** IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.

**Skin contact:** Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

**Eye contact:** In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

**Ingestion:** Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.

#### Potential health symptoms and effects

**Inhalation:** This product is not expected to be an inhalation hazard when used as directed.

**Ingestion:** Ingestion above therapeutic dose may cause nausea, vomiting, dizziness, and headache. Muscle pain. Diarrhea. May cause light sensitivity which appears as a skin rash when exposed to sunlight. Steven-Johnson syndrome

**Chronic:** Refer to product insert for full details of chronic effects.

### 4.2 Indication of any immediate medical attention and special treatment needed

#### Advice to doctor and hospital personnel

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

## SECTION 5 - FIRE FIGHTING MEASURES

### 5.1 Extinguishing media

**Suitable methods of extinction:** Use extinguishing media suitable for the surrounding fire.

**Unsuitable methods of extinction:** None known

### 5.2 Special hazards arising from the substance or mixture

During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

**Explosion hazards:** This product is not considered to be an explosion hazard.

### 5.3 Advice to firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water to prevent environmental contamination.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Evacuate non-essential personnel. Wear appropriate protective clothing and equipment designated in Section 8.2. Ventilate the area. Remove all sources of ignition. No smoking. Clean up spills immediately. Spills create slip hazards.

### 6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers or waterways.

### 6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, fleece). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Clean contaminated area with soap and water.

### 6.4 Reference to other sections

See Section 13 for additional waste treatment information.

## SECTION 7 - HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Observe all label precautions. Wear all appropriate personal protective equipment specified in Section 8.2. Do not get in eyes or on skin or clothing. No smoking. If normal use of material presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

#### Advice on protection against fire and explosion

Product does not present a fire or explosion hazard.

### 7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat. Protect from light.

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

### 7.3 Specific end uses

Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

## SECTION 8 - EXPOSURE CONTROLS | PERSONAL PROTECTION

### 8.1 Control parameters

#### Occupational exposure limit values

Ingredient Name	Type	Exposure Limits
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m <sup>3</sup> Respirable fraction 15 mg/m <sup>3</sup> Total dust
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5mg/m <sup>3</sup> Respirable fraction

### 8.2 Exposure controls

**Engineering measures:** No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits us of local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

**Individual protection measures:** Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

**Hygiene measures:** Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

**Eye/face protection:** None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

**Hand protection:** Wear Nitrile rubber gloves or those recommended by glove supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

**Other protective equipment:** Not normally needed. Wear protective clothing and protective boots if the situation requires.

**Respiratory protection:** No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

**Environmental exposure controls:** Do not empty into drains.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Liquid: Suspension	<b>Lower Explosive Limit (LEL)</b>	No data available
<b>Odor</b>	No data available	<b>Upper Explosive Limit (UEL)</b>	No data available
<b>Odor Threshold</b>	No data available	<b>Vapor Pressure</b>	No data available
<b>Molecular Weight</b>	225.20 g/mol (Acyclovir)	<b>Vapor Density</b>	No data available
<b>Chemical Formula</b>	C <sub>8</sub> H <sub>11</sub> N <sub>5</sub> O <sub>3</sub> (Acyclovir)	<b>Specific Gravity</b>	No data available
<b>pH (1% aqueous solution)</b>	4.5 – 7.0	<b>Density</b>	No data available
<b>Freezing   Melting Point</b>	No data available	<b>Viscosity</b>	No data available
<b>Boiling Point Range</b>	No data available	<b>Solubility in Water</b>	No data available
<b>Evaporation Rate</b>	No data available	<b>Partition Coefficient (n-)</b>	No data available
<b>Flammability (solid, gas)</b>	No data available	<b>Oxidizing Properties</b>	Not applicable
<b>Flash Point</b>	No data available	<b>Explosive Properties</b>	Not applicable
<b>Autoignition Temperature</b>	No data available	<b>Volatiles by Weight @ 21 °C</b>	No data available
<b>Decomposition Temperature</b>	No data available		

### 9.2 Other Data

No data available

## SECTION 10 - STABILITY AND REACTIVITY

### 10.1 Reactivity

No special reactivity has been reported during normal conditions of handling and use.

### 10.2 Chemical Stability

This material is stable under recommended storage and handling conditions.

### 10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur.

### 10.4 Conditions to avoid

Avoid temperature extremes and contact with incompatible materials. Do not refrigerate.

### 10.5 Incompatible materials

Strong oxidizing agents

## 10.6 Hazardous decomposition products

Thermal decomposition products may include oxides of carbon and nitrogen oxides.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	None known. Direct contact with eyes may cause temporary irritation. Information on toxicological effects
<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

### 11.2 Further information

Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Handle in accordance with good industrial hygiene and safety practice.

## SECTION 12 - ECOLOGICAL INFORMATION

### 12.1 Ecotoxicity

No information available.

### 12.2 Persistence and degradability

No information available.

### 12.3 Bioaccumulation

**There is no data for this product.**

### 12.4 Mobility

No information available.

### 12.5 Other adverse effects

No data is available regarding the environmental toxicity of this product. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

## SECTION 13 - DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

**RCRA F-Series:** No listings above the reportable threshold (de minimis)

**RCRA U-Series:** No listings above the reportable threshold (de minimis)

## SECTION 14 - TRANSPORT INFORMATION

### NOT REGULATED FOR TRANSPORT (NOT DANGEROUS GOODS)

**Note:** Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

## SECTION 15 - REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for substance or mixture

#### International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

## 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.

**SARA 304 Emergency release notification:** Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):** Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

Hazard categories

**SARA 302 Extremely hazardous substance:** Not listed.

**SARA 311/312 Hazardous chemical:** No

**SARA 313 (TRI reporting):** Not regulated.

### 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.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5) Other Flavoring Substances with OSHA PEL's

## US state regulations

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

METHYL PARABEN (CAS 99-76-3)

PROPYL PARABEN (CAS 94-13-3)

## Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

## SECTION 16 - OTHER INFORMATION

### Hazardous Material Information System (HMIS)

HEALTH	*	1
FLAMMABILITY		1
PHYSICAL HAZARD		0
PERSONAL PROTECTION		

### HMIS Hazard Rating Legend

0 = Minimal 1 = Slight 2 = Moderate

3 = Serious 4 = Severe

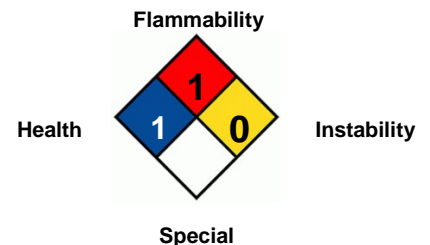
\* = Chronic Health Hazard

### NFPA Hazard Rating Legend

0 = Insignificant 1 = Slight 2 = Moderate

3 = High 4 = Extreme

### National Fire Protection Association (NFPA)



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