

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Acyclovir Injection, USP

1.2. Intended Use of the Product

Synthetic purine nucleoside analogue with inhibitory activity against herpes simplex virus types 1 (HSV-1), 2 (HSV-2) and varicella-zoster virus.

1.3. Name, Address, and Telephone of the Responsible Party

Manufacturer

Immaculé Lifesciences (P) Ltd
 Village Thanthawal, Ropar Road,
 Nalagarh, Dist, Solan, (H.P.) – 174101, India
 Tel: +91 01795-228601, 02, 03
 Fax: +91 01795-228600

Distributor

Fresenius Kabi USA, LLC
 Three Corporate Drive
 Lake Zurich, IL 60047
 General Phone Number: (847) 550-2300
 Customer Service Phone Number: (888) 386-1300
 Health Issues Information: (800) 551-7176
<http://www.fresenius-kabi.com/us/>

1.4. Emergency Telephone Number

Emergency Number : VelocityEHS
 (800)255-3924 (North America)
 +1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Reproductive toxicity Category 2	H361
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Specific target organ toxicity (repeated exposure) Category 2	H373

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :



GHS08

Signal Word (GHS-US/CA) :

Warning

Hazard Statements (GHS-US/CA) :

H361 - Suspected of damaging fertility or the unborn child (oral).
 H362 - May cause harm to breast-fed children.
 H373 - May cause damage to organs (kidneys) through prolonged or repeated exposure (oral).

Precautionary Statements (GHS-US/CA) :

P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P260 - Do not breathe vapors, mist, or spray.
 P263 - Avoid contact during pregnancy/while nursing.
 P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
 P270 - Do not eat, drink or smoke when using this product.

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P280 - Wear protective gloves, protective clothing, and eye protection.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA	(CAS-No.) 7732-18-5	80 – 100	Not classified.
Acyclovir sodium	6H-Purin-6-one, 2-amino-1,9-dihydro-9-[[2-hydroxyethoxy)methyl]-, sodium salt (1:1) Aciclovir sodium	(CAS-No.) 69657-51-8	5 – 10	Repr. 2, H361 Lact, H362 STOT RE 2, H373

* The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the Hazardous Products Regulations (HPR) 30 CFR 1910.1200. Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). Full text of H-statements: see section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. If exposed or concerned: Get medical advice/attention.

Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child (if swallowed). May cause damage to organs (kidney) through prolonged or repeated exposure (if swallowed). May cause harm to breast-fed children.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child (if swallowed). May cause damage to organs (kidney) through prolonged or repeated exposure (if swallowed).

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Oxides of carbon, nitrogen, and sodium.

Other Information: No additional information available.

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling: Do not handle until all safety precautions have been read and understood. Obtain special instructions before use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols. Do not breathe mist, spray, or vapors. Avoid contact with skin, eyes and clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 – 77 °F). *Do not freeze!*

7.3. Specific End Use(s)

Synthetic purine nucleoside analogue with inhibitory activity against herpes simplex virus types 1 (HSV-1), 2 (HSV-2) and varicella-zoster virus.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

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8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical goggles or safety glasses.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Thermal Hazard Protection: Not applicable.

Environmental Exposure Controls: Avoid unnecessary release into the environment.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear colorless liquid
Odor	: Odorless
Odor Threshold	: No data available
pH	: ≈ 11
Evaporation Rate	: No data available
Melting Point	: ≈ 0 °C (32 °F)
Freezing Point	: ≈ 0 °C (32 °F)
Boiling Point	: ≈ 100 °C (212 °F)
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: 17 mm Hg [approximately equal to water]
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: Water: Soluble/Miscible
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

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Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Thermal decomposition may produce: Oxides of carbon, nitrogen, and sodium.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Likely routes of exposure: Dermal, Ingestion, Inhalation, Eye contact.

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified.

pH: ≈ 11

Eye Damage/Irritation: Not classified.

pH: ≈ 11

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Specific Target Organ Toxicity (Repeated Exposure): May cause damage to organs (kidneys) through prolonged or repeated exposure (oral).

Reproductive Toxicity: Suspected of damaging fertility or the unborn child (oral). May cause harm to breast-fed children.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child (if swallowed). May cause damage to organs (kidney) through prolonged or repeated exposure (if swallowed).

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)
Acyclovir sodium (69657-51-8)	
LD50 Oral Rat	> 20 g/kg (Source: NLM_CIP)
Acyclovir sodium (69657-51-8)	
IARC Group	3

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

12.2. Persistence and Degradability

Acyclovir, USP	
Persistence and Degradability	Expected to be biodegradable.

12.3. Bioaccumulative Potential

Acyclovir, USP	
Bioaccumulative Potential	Not expected to bioaccumulate.

12.4. Mobility in Soil

Acyclovir, USP	
Ecology - Soil	Adsorbs into the soil. Leaches if exposed to water.

12.5. Other Adverse Effects

Other Adverse Effects: None known.

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Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.

Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Additional Information: Biologically contaminated materials should be incinerated.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Acyclovir, USP	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity Health hazard - Specific target organ toxicity (single or repeated exposure)
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Acyclovir sodium (69657-51-8)	
Not listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed.

15.3. Canadian Regulations

Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

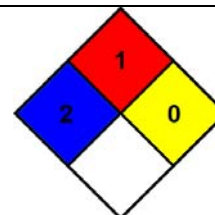
SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: 02/06/2025
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H373	May cause damage to organs through prolonged or repeated exposure

NFPA Health Hazard	: 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.
NFPA Fire Hazard	: 1 - Materials that must be preheated before ignition can occur.
NFPA Reactivity Hazard	: 0 - Material that in themselves are normally stable, even under fire conditions.



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HMIS III Rating

Health	: 2 Moderate Hazard - Temporary or minor injury may occur
Flammability	: 1 Slight Hazard
Physical	: 0 Minimal Hazard
Personal protection	: C

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)

AU_WES: Australia WES

CHEMVIEW: ChemView (U.S. Environmental Protection Agency)

EC_RAR: European Commission Renewal Assessment Report

EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits

ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports

ECHA_API: European Chemicals Agency API

ECHA_RAC: ECHA Committee for Risk Assessment

EFSA: European Food Safety Authority

EPA: U.S. Environmental Protection Agency

EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)

EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)

EPA_HPVC: High Production Volume Chemicals (U.S. Environmental Protection Agency)

EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)

EU_CLH: European Union Harmonised Classification and Labelling Proposal

EU_RAR: European Union Risk Assessment Report

FOOD_JOURN: Food Research Journal (1956)

IARC: The International Agency for Research on Cancer

IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles

IUCLID: International Uniform Chemical Information Database

JAPAN_GHS: Japan GHS Basis for Classification Data

JP_J-CHECK: Japan J-Check

KR_NIER: South Korea National Institute of Environmental Research Evaluations

NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme

NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)

NLM_CIP: National Library of Medicine ChemID plus database

NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank

NLM_PUBMED: National Library of Medicine PubMed database

NTP: National Toxicology Program

NZ_CCID: New Zealand Chemical Classification and Information Database

OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)

OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)

WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)