

Safety Data Sheet

According to Globally Harmonized System Of Classification And Labelling Of Chemicals (GHS)

Version: 06/EN

Product name: Acyclovir ; Aciclovir

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product name: Acyclovir ; Aciclovir
IUPAC name: 9-[(2-Hydroxyethoxy)methyl]guanine;
2-amino-9-[(2-hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6-one
CAS No.: 59277-89-3
EC No.: 261-685-1

Recommended use of the chemical and restrictions on use

Recommended use: Only used for drug product.
Restriction on use: No information available.

Details of the supplier of the product

Company name: Zhejiang Charioteer Pharmaceutical Co., Ltd.
Address: Tongyuanxi, Dazhan, Xianju, Zhejiang Province, 317321, P.R. China

SECTION 2: HAZARDS IDENTIFICATION

GHS classification of the substance/mixture

Physical hazards Not classified.
Health hazards Serious eye damage/eye irritation Category 2B
OSHA hazard(s) Not classified.

GHS label elements

Product identifier:

Chemical name: 9-[(2-Hydroxyethoxy)methyl]guanine;
2-amino-9-[(2-hydroxyethoxy)methyl]-1,9-dihydro-6H-purin-6-one

Hazard pictogram(s): No symbol.

Signal word: Warning.

Hazard statement(s): H320: Causes eye irritation.

Precautionary statements:

Prevention P264: Wash thoroughly after handling.

Response P305+p351+p338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+p313: If eye irritation persists: Get medical advice/attention.

Storage Not available.

Disposal Not available.

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Hazard(s) not otherwise classified (HNOC)

Not classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Hazardous components

Name	Synonym	CAS No.	EC No.	Molecular formula	Concentration
Acyclovir	Aciclovir	59277-89-3	261-685-1	C ₈ H ₁₁ N ₅ O ₃	≥98%

SECTION 4: FIRST AID MEASURES

Description of first aid measures

In case of inhalation:

Move to fresh air. Call a physician if symptoms develop or persist.

In case of skin contact:

Rinse skin with water/shower. Get medical attention if irritation develops and persists.

In case of eye contact:

Rinse with water. Get medical attention if irritation develops and persists.

In case of ingestion:

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed

Irritation of eyes and mucous membranes.

Indication of immediate medical attention and special treatment needed

Treatment of overdose should be symptomatic and supportive and may include the following:

Provide adequate hydration to prevent precipitation of acyclovir in the renal tubules. Administer activated charcoal as a slurry. Monitor for abnormal renal function, elevated hepatic enzymes, and significant CNS symptoms. Hemodialysis may aid in the removal of acyclovir from the blood.

Peritoneal dialysis is not effective in providing acyclovir clearance. [Meditext 2008 and USP DI 2008]

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO₂.

Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical:

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. No unusual fire or explosion hazards noted.

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Special protective equipment and precautions for firefighters:

Wear suitable protective equipment.

Fire-fighting equipment/instructions:

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Environmental precautions

Keeping away from drains, surface and ground water.

Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Protect from light and moisture. Store at room temperature.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure limit values:

Material	Type	Value
Acyclovir (CAS 59277-89-3)	TWA	5mg/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

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Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection: Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection:

Hand protection:

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact.

Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other:

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection: Where respirators are deemed necessary to reduce or control occupational exposures, use an approved/certified respirator.

Thermal hazards Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:	White to off-white crystalline powder.
Physical state:	Solid.
Odour:	Odourless. Not available.
Odor threshold	Not available.
pH:	6.8-7 (10%) Not available.
Melting point/freezing point:	256 - 257 °C (decomposes)
Initial boiling point and boiling range	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability(solid,gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	< 0.0000001 kPa at 25°C

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Vapour density:	Not available.
Relative density:	Not available.
Solubility(ies):	Very slightly soluble in cold water, ethanol.
Partition coefficient (n-octanol/water):	-1.56
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.

Other information

Chemical family:	Synthetic acyclic purine nucleoside analogue.
Molecular formula:	C ₈ H ₁₁ N ₅ O ₃
Molecular weight:	225.2
MIE - Minimum ignition energy of dust cloud:	30 - 100mJ
Pmax - Maximum explosion pressure of dust cloud:	0.86Mpa
Kst - Maximum explosion index of dust cloud:	17.2Mpa·m/s
Minimum explosion concentration of dust cloud:	60g/m ³
MIT - Minimum ignition temperature of dust cloud:	470°C
MIT - Minimum ignition temperature of dust layer:	The sample melted under the test condition.
Conductivity:	No data available.

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	No reactivity hazards known.
Chemical stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	No dangerous reaction known under conditions of normal use.
Conditions to avoid:	None known.
Incompatible materials:	Strong oxidizing agents.
Hazardous decomposition products:	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	Based on available data, the classification criteria are not met.
Skin contact	Due to lack of data the classification is not possible.
Eye contact	Causes eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	Nausea. Vomiting. Diarrhea. Lightheadedness. Mental status changes. Headache. Skin rash. General feeling of discomfort or illness. Abdominal pain. Thirst. Loss of appetite. Decreased urination. Agitation. Trembling. Hallucinations. Seizures.

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Delayed and immediate effects of exposure	Kidney failure. Coma.
Cross sensitivity	Persons sensitive to one ganciclovir or valacyclovir may be sensitive to this material also.
Medical conditions aggravated by exposure	Dehydration. Impaired kidney function.
Acute toxicity	Based on available data, the classification criteria are not met. Acute oral toxicity -LD50: >20000mg/kg (oral, rat) Acute oral toxicity -LD50: >10000mg/kg (oral, mouse) Acute inhalation toxicity -LC50: > 15.1 mg/l(inhalation-rat)
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Causes eye irritation.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Mutagenicity	
Chinese hamster cells Result: Clastogenic.	
Chinese hamster ovary cell assays Result: Negative.	
Dominant lethal study in mice Result: Negative.	
Human lymphocyte cytogenic analysis Result: Positive.	
Microbial assays Result: Negative.	
Carcinogenicity	Based on available data, the classification criteria are not met. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. 50 - 450 mg/kg Carcinogenicity study Result: No evidence of carcinogenicity in lifetime bioassays. Species: Mouse 50 - 450 mg/kg Carcinogenicity study Result: No evidence of carcinogenicity in lifetime bioassays. Species: Rat
Reproductive toxicity	Based on available data, the classification criteria are not met.
Reproductivity	

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450 mg/kg/day Reproductivity study

Result: No increase in birth defects in offspring; did not impair fertility.

Species: Mouse

50 mg/kg/day Reproductivity study

Result: No increase in birth defects in offspring.

Species: Rabbit

50 mg/kg/day Reproductivity study

Result: No increase in birth defects in offspring.

Species: Rat

50 mg/kg/day Reproductivity study

Result: Significant decrease in implantation efficiency, but no decrease in litter size.

Species: Rabbit

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods General : Dispose of this material and its container at hazardous or special waste collection point.

Additional information Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport(ADR/RID/GGVSE)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Sea transport(IMDG-Code/GGVSee)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Air transport (ICAO-IATA/DGR)

This product is not regulated as a hazardous material or dangerous goods for transportation.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.

Additional information

No information available.

SECTION 15: REGULATORY INFORMATION

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US federal and state regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Other chemical inventories

No data available.

SECTION 16: OTHER INFORMATION

Revision information

Issue date Mar 11,2011.
Revision date Aug 26,2014.
Version # 06

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Abbreviations and acronyms

GHS:	Globally Harmonized System of Classification and Labelling of Chemicals.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
ACGIH:	American Conference of Governmental Industrial Hygienists
IARC:	International Agency for Research on Cancer
NTP:	National Toxicology Program
RTECS:	Registry of Toxic Effects of Chemical Substances.
TSCA:	Toxic Substances Control Act, The American chemical inventory.
IECSC:	Inventory of existing chemical substances in China.
DSL:	Domestic Substances List, The Canadian chemical inventory.
AICS:	The Australian Inventory of Chemical Substances.

Declare to reader

The information in this Safety Data Sheet (SDS) was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable.

----- End of the SDS -----