

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

ACICLOVIRUM

EN

FORM-06-14-01 (V00)

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Aciclovir
Aciclovirum
Aciclovir
Aciclovir
Aciclovir
N° CAS: 59277-89-3
N° EC: 261-685-1

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV
Oostmalsebaan 1c (unit 5)
2960 Sint-Lenaarts
Belgium
Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute toxicity (category 4)	H302
Acute toxicity (category 4)	H312
Acute toxicity (category 4)	H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H302	Harmful if swallowed
H312	Harmful in contact with skin
H332	Harmful if inhaled

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Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P312	Call a POISON CENTER/ doctor/.../if you feel unwell.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P501	Dispose of contents/container according to local / national / regional / international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Aciclovir
IUPAC name:	2-amino-9-(2-hydroxyethoxymethyl)-1H-purin-6-one
Synonyms:	Acyclovir Acycloguanosine Zovirax
N° CAS:	59277-89-3
N° EC:	261-685-1
Molecular Formula:	C ₈ H ₁₁ N ₅ O ₃
Content:	98.5% - 101.0% (anhydrous substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Bring outdoors. If breathing is irregular, call a doctor immediately. Only apply artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry powder, carbon dioxide, carbon, sand, water mist.

Unsuitable extinguishing media: Direct stream of water.

5.2 Special hazards arising from the substance/mixture

Not available.

5.3 Advice for firefighters

Surrounding fires: Use atomized or nebulized water. Cool containers with water to avoid decomposition of the product and the development of potential health hazards. Always wear full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second current regulations.

Protection against fire: Helmet with a visor, fire retardant clothing (jacket and pants with suspenders around the arms, legs and waist), gloves (fireproof and dielectric), a mask with a face mask that covers the entire face of the operator or the car (self-protective) in the case of large amounts of smoke.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Equip cleaning staff with suitable means of protection. Avoid both the formation and aspiration of dust. Avoid breathing vapors, gases or air condensation. Ventilate the area and evacuate unnecessary personnel. For more information on exposure control and individual protection measures, see section 8.

For emergency responders

Equip cleaning staff with suitable means of protection. Avoid both the formation and aspiration of dust. Avoid breathing vapors, gases or air condensation. Ventilate the area and evacuate unnecessary personnel. For more information on exposure control and individual protection measures, see section 8.

6.2 Environmental precautions

Prevent the product from entering the sewers, surface waters, groundwater and / or neighboring areas.

6.3 Methods and material for containment and cleaning up

Sweep limiting the formation of dust and deposit the spilled substance in containers. Ensure that waste is collected and stored safely in appropriate and closed containers for disposal.

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6.4 Reference to other sections

For exposure control and individual protection measures, see section 8. For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid contact with skin and eyes.
Personal protection:	The usual measures will be taken in clothing for protection against fires.
Technical protective measures:	Avoid the formation of dust and aerosols. Provide adequate ventilation in places where dust can be generated.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store at room temperature and in the original container, in a cool, well-ventilated place.
Conditions for safe storage, including any incompatibilities:	Store at room temperature and in the original container, in a cool, well-ventilated place.
Storage – away from:	Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Since the use of appropriate technical measures must always take precedence over personal protective equipment, ensure good ventilation in the workplace through effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Provide an emergency shower with a visco-elastic tray.

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection:	Protective face shields and safety glasses according to EN166.
Skin protection:	Choose protection for the body according to the amount and concentration of the dangerous substance in the workplace.
Hand protection:	Handle with gloves.
Respiratory protection:	Where risk assessment shows that air purifying respirators are appropriate, wear type N95 (USA) or type P1 (EN 143) dust mask.
Thermal hazards:	Not determined.

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Environmental exposure control

Handle with adequate industrial hygiene precautions, and respect safety practices. Wash your hands before breaks and after finishing the workday.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White crystalline powder.
Odour:	Characteristic
Odour threshold:	Not available.
pH:	5.8 (saturated solution).
Melting/freezing point:	254 °C – 258 °C
Initial boiling point:	Not available.
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:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Very slightly soluble in ethanol, slightly soluble in chloroform.
Solubility in water:	Soluble.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions. Stable under recommended storage and handling conditions (see section 7).

10.2 Chemical stability

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

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10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Direct sunlight, humidity and extremely high temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), hydrogen chloride (HCl), and sulfur oxides (SOx).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral: > 20 mg/kg (LD50: Rats) Intraperitoneal: 860 mg/kg (LD50: Rats)
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product, which has levels greater than or equal to 0.1%, is identified as a probable, possible or confirmed human carcinogen by the International Agency for Research on Carcinogens (IARC).
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	Harmful if absorbed through the skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. It might produce an irritation in the respiratory tract.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

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12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state, and local environmental regulations. Contact an authorized professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Discard as unused product.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transportation.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transportation.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transportation.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transportation.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transportation.

14.6 Special precautions for user

It is not dangerous in transportation.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

It is not dangerous in transportation.

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14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available.

Risk phrases: Not available.

Safety phrases: Not available.

15.2 Chemical safety assessment

Not available.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

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16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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