

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

- 1.1 Product Name:** Acyclovir
Synonyms: 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin-6-one; ACV; BW 248U; NSC 645011;
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:** N/A
- 1.3 Details of the Supplier of the Safety Data Sheet:**
Company Name: Triova Pharmaceuticals LLC
115 W 3rd Street Suite 720
Tulsa, OK 74103
Web site address: www.triovarx.com
- 1.4 Emergency telephone number:**
Emergency Contact: INFOTRAC within USA and Canada: 1-800-535-5035

Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture:**
2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]:
Skin Corrosion/Irritation, Category 2
Serious Eye Damage/Eye Irritation, Category 2A
Target Organ Systemic Toxicity (single exposure), Category 3
Aquatic Toxicity (Chronic), Category 3
- 2.1.2 Classification according to Directive 1999/45/EC:**
Xi: Irritant
N: Dangerous for the environment
Risk Phrases: R36/37/38, R52/53
For full text of R- phrases: see SECTION 15.
- 2.2 Label Elements:**
2.2.1 Labeling according to Regulation (EC) No 1272/2008 [CLP]:

**GHS Signal Word:** Warning**GHS Hazard Phrases:**

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H412: Harmful to aquatic life with long lasting effects.

GHS Precaution Phrases:

P264: Wash {hands} thoroughly after handling.
P280: Wear {protective gloves/protective clothing/eye protection/face protection}.
P362+364: Take off contaminated clothing and wash it before reuse.
P261: Avoid breathing {dust/fume/gas/mist/vapours/spray}.
P273: Avoid release to the environment.

GHS Response Phrases:

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P332+313: If skin irritation occurs, get medical advice/attention.
 P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337+313: If eye irritation persists, get medical advice/attention.
 P309+311: Call a POISON CENTER or doctor/physician if exposed or you feel unwell.
 P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.2.2 Labeling according to Directive 1999/45/EC:



Xi



N

2.3 Adverse Human Health Causes skin irritation.

Effects and Symptoms: Causes serious eye irritation.

Harmful to aquatic life with long lasting effects.

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation, ingestion, or skin absorption.

May cause respiratory irritation.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	Risk Phrases/ GHS Classification
59277-89-3 UP0791400	Acyclovir	100.0 %	261-685-1 NA	Xi;N; R36/37/38-52/53 Skin Corr. 2: H315 Eye Damage 2A: H319 TOST (SE) 3: H335 H336 Aquatic (C) 3: H412

Section 4. First Aid Measures

4.1 Description of First Aid

Measures:

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

- 5.1 Suitable Extinguishing Media:** Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Media: Use water spray to cool fire-exposed containers.
Unsuitable Extinguishing Media: A solid water stream may be inefficient.
- 5.2 Flammable Properties and Hazards:** No data available.
Flash Pt: No data.
Explosive Limits: LEL: No data. UEL: No data.
Autoignition Pt: No data.
- 5.3 Fire Fighting Instructions:** As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

- 6.1 Protective Precautions, Protective Equipment and Emergency Procedures:** Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
- 6.2 Environmental Precautions:** Take steps to avoid release into the environment, if safe to do so.
- 6.3 Methods and Material For Containment and Cleaning Up:** Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

- 7.1 Precautions To Be Taken in Handling:** Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.
- 7.2 Precautions To Be Taken in Storing:** Keep container tightly closed. Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
59277-89-3	Acyclovir	No data.	No data.	No data.
CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
59277-89-3	Acyclovir	No data.	No data.	No data.

8.2 Exposure Controls:

- 8.2.1 Engineering Controls (Ventilation etc.):** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

- Eye Protection:** Safety glasses
- Protective Gloves:** Compatible chemical-resistant gloves
- Other Protective Clothing:** Lab coat
- Respiratory Equipment (Specify Type):** NIOSH approved respirator, as conditions warrant.
- Work/Hygienic/Maintenance Practices:** Do not take internally. Facilities storing or utilizing this material should be equipped with an eyewash and a

safety shower.
Wash thoroughly after handling.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: [] Gas [] Liquid [X] Solid
Appearance and Odor: A crystalline solid
Melting Point: No data.
Boiling Point: No data.
Flash Pt: No data.
Evaporation Rate: No data.
Explosive Limits: LEL: No data. UEL: No data.
Vapor Pressure (vs. Air or mm Hg): No data.
Vapor Density (vs. Air = 1): No data.
Specific Gravity (Water = 1): No data.
Solubility in Water: No data.
Solubility Notes: ~0.2 mg/ml in PBS (pH 7.2); ~16 mg/ml in DMSO; ~1 mg/ml in DMF;
Autoignition Pt: No data.

9.2 Other Information

Percent Volatile: No data.
Molecular Formula & Weight: C₈H₁₁N₅O₃ 225.2

Section 10. Stability and Reactivity

10.1 Reactivity: No data available.
10.2 Stability: Unstable [] Stable [X]
10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.
Polymerization: Will occur [] Will not occur [X]
10.4 Conditions To Avoid: No data available.
10.5 Incompatibility - Materials To Avoid: No data available.
10.6 Hazardous Decomposition Or Byproducts: No data available.

Acyclovir

Section 11. Toxicological Information

11.1 Information on Toxicological Effects:	The toxicological effects of this product have not been thoroughly studied. Acyclovir - Toxicity Data: Oral TDLO (child): 3 gm/kg/22W (intermittent); Oral TDLO (woman): 28 mg/kg/2D (intermittent); Oral TDLO (woman): 12 mg/kg/1D (intermittent); Oral TDLO (man): 486 mg/kg/17D (intermittent); Intravenous TDLO (man): 134 µg/kg/1D (intermittent); Intravenous TDLO (woman): 101 mg/kg/2D (intermittent); Oral LD50 (rat): > 20 mg/kg; Intraperitoneal LD50 (rat): 860 mg/kg; Subcutaneous LD50 (rat): 620 mg/kg; Intravenous LD50 (rat): 750 mg/kg; Oral LD50 (mouse): > 10 mg/kg; Intraperitoneal LD50 (mouse): 724 mg/kg; Subcutaneous LD50 (mouse): 1118 mg/kg; Intravenous LD50 (mouse): 400 mg/kg;
Chronic Toxicological Effects:	Acyclovir - Investigated as a mutagen, reproductive effector, and tumorigen. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Acyclovir RTECS Number: UP0791400
Carcinogenicity:	NTP? No IARC Monographs? No OSHA Regulated? No

Section 12. Ecological Information

12.1 Toxicity:	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
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Section 13. Disposal Considerations

13.1 Waste Disposal Method:	Dispose in accordance with local, state, and federal regulations.
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Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
59277-89-3	Acyclovir	No	No	No
CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists		
59277-89-3	Acyclovir	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No		

European Community Hazard Symbol codes:



Xi



N

European Community Risk and Safety Phrases:

- R36/37/38 Irritating to eyes, respiratory system and skin.
R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S22 Do not breathe dust.
S24/25 Avoid contact with skin and eyes.
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

Regulatory Information Statement: This SDS was prepared in accordance with Regulation (EC) No.1272/2008 and European Directive 67/548/EEC as amended.

Section 16. Other Information

Revision Date: 01/01/2017
Version #: 00

Company Disclaimer: This SDS is intended to provide a summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of Trioiva Pharmaceuticals knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. Trioiva Pharmaceuticals cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.