



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Product Name** : Ganciclovir for injection, USP 500 mg/vial
- b) **Common/ trade Name** : Ganciclovir for injection
- c) **Chemical Name** : 9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine
- Chemical Family** : Cytomegalovirus Anti-viral
- d) **Product Use** : Pharmaceutical, injectable
- Product type** : Regulated prescription drug
- Container Information** : Vial
- e) **Manufacture Name** : **Gland pharma Limited**
- Address** : Survey No.: 143–148, 150 & 151
Near Gandimaisamma Cross Roads,
D.P.Pally, Quthubullapur Mandal
Ranga Reddy District
Hyderabad- 500043
Telagana, India
- f) **Telephone Number for Info** : +91-40-30510999

SECTION 2: HAZARDS IDENTIFICATION

- a) **Classification:**
- NFPA Rating**
- Health Hazard** : 2
- Flammability Hazard** : 1
- Physical Hazard** : 0

| b) Single word, hazard statement (s), symbol(s), and/or Precautionary statement(s): | c) Description of Hazards |
|---|---------------------------|
| Single word | Danger |
| Hazard statements: May be harmful if swallowed. | |

- d) **Unknown acute toxicity** : N/A



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SECTION 3 – COMPOSITION AND INGREDIENTS

| a) Chemical Name | b) Common Name/ Synonym | % Composition or other measure | c) CAS number | d) Impurities/ stabilizing Additives |
|---|----------------------------|-----------------------------------|---------------|--|
| 9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine | Ganciclovir | 500 mg/vial | 82410-32-0 | N/A |

SECTION 4 - FIRST AID MEASURES

EYE EXPOSURE : In case of contact with eyes rinse thoroughly with plenty of water and get medical advice

Skin Exposure : Remove immediately contaminated clothes, wash affected skin with plenty of water

Ingestion : Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Injection : Under normal use with supervise on of a physician.

Inhalation : In case of inhalation remove to fresh air and seek medical aid.

Notes to Physician : Treat symptoms and eliminate over exposure. See patient package insert in shipping carton for complete information

SECTION 5: FIRE-FIGHTING MEASURES

Flash point: Not applicable

Auto ignition temperature: Not appli

Condition of flammability: Not flammable or combustible.

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

Hazardous combustion products: Hazardous combustion products formed under fire conditions— not data available.



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SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist, gas, or dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods for cleaning up : Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage : Store vials as directed in pack insert. Keep vials closed when not in use. Store away from incompatible materials. Protect from light. Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

a) Exposure limits

| Compound | Issuer | Type | Exposure limit |
|--------------------|--------|------|--|
| Ganciclovir sodium | -- | -- | Contains no substances with occupational exposure limit values |

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3(EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.



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Eye protection

Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

| Property | Ganciclovir |
|----------------------------|---------------------------------------|
| Appearance: | White to off white lyophilized powder |
| pH: | No data available |
| Water Solubility: | ~5 mg/ml |
| Other Solubility: | DMSO (~5 mg/ml) |
| Specific Gravity (g/ml): | No data available |
| Boiling Point (°C): | No data available |
| Melting Point (°C): | No data available |
| Flash Point (°C): | No data available |
| Ignition Temperature (°C): | No data available |
| Density | No data available |
| Evaporation rate | No data available |

SECTION 10: STABILITY AND REACTIVITY

| Property | Ganciclovir |
|------------------------------------|---|
| Chemical stability | Stable under recommended storage conditions |
| Conditions to avoid: | Extreme heat, any conditions that are incompatibility with water, mixing this product with incompatible chemicals |
| Materials to avoid: | Strong oxidizing agents |
| Hazardous decomposition products: | Carbon oxides, nitrogen oxides |
| Possibility of Hazardous Reactions | Hazardous polymerization will not occur |



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SECTION 11: TOXICOLOGICAL INFORMATION

| | | |
|----|---|--|
| a) | Likely route of exposure | Inhalation, eye/skin contact, or ingestion |
| b) | Symptoms related to the physical, chemical and toxicological characteristics | This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. |

c) Acute toxicity

| Component | Type | Route | Species | Dosage |
|--------------------|------|-------|---------|--------|
| Ganciclovir sodium | LD50 | Oral | Rat | 2g/kg |
| Ganciclovir sodium | LD50 | Oral | Dog | 1g/kg |
| Ganciclovir sodium | LD50 | Oral | mouse | 2g/kg |

Reproductive Effects: Teratogenic (several species)

d) Hazardous chemical listing:

IARC : No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No components of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP : No component of this product presents at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA : No components of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

SECTION 12: ECOLOGICAL CONSIDERATIONS

At work practices must be aimed at eliminating environmental contamination.

| | | |
|----|---|---|
| a) | Environmental stability | The components of the product will degrade into organic and inorganic components, especially under sunlight |
| b) | Effect of material on plant and animals | Due to the small product size, no unusual effect on plants or animals is expected if this product is released into environment. |



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| | | |
|----|------------------------------------|---|
| c) | Effect of chemical on aquatic life | No information is currently available on the effect of the components of this product on aquatic animals in the environment |
|----|------------------------------------|---|

SECTION 13: DISPOSAL CONSIDERATIONS

Product: Observe all federal, state, and local environmental regulations.

Waste Disposal: - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use take back programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a take back program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

SECTION 14: TRANSPORT INFORMATION

This product is not hazardous as defined by 49 CFR 172.101 by the U.S department of transportation

| | |
|---|---|
| UN identification number | Not available |
| Hazard class and Description | Not available |
| Pack group | Not applicable |
| Emergency response guide book number (2000) | Not applicable |
| Marine pollutant | Not applicable (49 CFR 172.101, Appendix B) |

Transport Canada, Transportation of dangerous good and regulations: This product is not considered as dangerous goods, per regulations of transport Canada.

DOT (US): Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

SECTION 15: REGULATORY INFORMATION

Ganciclovir:

OSHA Hazards: Reproductive hazard, Target organ effect.

SARA 302 Components: SARA 302: No chemical in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.

SARA 311/312 Hazards: Chronic Health Hazard.



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Massachusetts Right to Know Components: No components are subject to the Massachusetts Right to Know Act. Pennsylvania Right to Know Components: Ganciclovir, CAS-No. 82410-32-0; Revision Date: 2009-07-17

New Jersey Right to Know Components: Ganciclovir, CAS-No. 82410-32-0; Revision Date: 2009-07-17

California Prop. 65 Components: WARNING! This product contains a chemical known to the State of California to cause birth defects or other reproductive harm: Ganciclovir, CAS-No. 82410-32-0; Revision Date: 1997-08-26

EU regulations

| Component | Risk Phrases | Safety Phrases |
|-------------|--------------|------------------|
| Ganciclovir | R62, R63 | S22, S36/37, S53 |

SECTION 16: OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

| | |
|------------|---|
| AIHA | American Industrial Hygiene Association |
| CAS Number | Chemical Abstract Service Registry Number |
| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| EPA | Environmental Protection Agency |
| HEPA | High Efficiency Particulate Air (Filter) |
| IARC | International Agency for Research on Cancer |



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| | |
|-----------|---|
| ICAO/IATA | International Civil Aviation Organization/International Air Transport Association |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NIOSH | National Institute for Occupational Safety and Health |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| IOEL | International Occupational Exposure Limit |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |