

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

Section 1 - Identification

- (a) **Product Identifier:** Ganciclovir Injection
- (b) **NDC:** 25021-185-10
- Common/Trade Name:** Ganciclovir for Injection, USP, Ganciclovir Injection
- Chemical Name:** . 9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine, monosodium salt
- Chemical Family:** Anti-viral DNA polymerase inhibitor
- (c) **Product Use:** CMV retinitis in immunocompromised patients and CMV disease in adult transplant recipients
- Product Type:** Regulated Prescription Drug
- Container Information:** Glass vials
- (d) **Distributor:** Sagent Pharmaceuticals, 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** **GHS Classifications:**
 Germ cell mutagenicity (Category 1A)
 Carcinogenicity (Category 1A)
 Reproductive toxicity (Category 1A)
 Specific target organ toxicity-Repeated exposure (Category 1),

HMIS Rating

Health Hazard	1
Flammability	0
Physical Hazard	0

NFPA Rating

Health Hazard	2
Fire Hazard	1
Reactivity Hazard	0

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u> <u>Symbols:</u>	- DANGER 
H340 H303 H350 H360 H372	<u>GHS Hazard Statements:</u> - May cause genetic defects. - May be harmful if swallowed. - May cause cancer. - May damage fertility or unborn child. - Causes damage to organs through prolonged repeated exposure.
P201 P202 P260 P281 P308 + P313	<u>GHS Precautionary Statements:</u> - Obtain special instructions before use. - Do not handle until all safety precautions have been read and understood. - Do not breathe dust. - Use personal protective equipment as required. - If exposed or concerned: Get medical advice/attention.

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection		
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023	

Ganciclovir for Injection

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine	Ganciclovir	142.86mg/mL	84210-32-0	N/A
Sodium Hydroxide, NF	Sodium Hydroxide, NF	q.s. to pH	1310-73-2	N/A
Water for Injection, USP	Water for Injection, USP	q.s. to 1mL	7732-18-5	N/A
Nitrogen, NF	Nitrogen, NF	q.s.	7727-37-9	N/A

Ganciclovir Injection

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
9-[[2-hydroxy-1-(hydroxymethyl)-ethoxy]methyl]guanine	Ganciclovir	142.86mg/mL	84210-32-0	N/A

Section 4 - First Aid Measures

Eye Exposure:

If airborne dusts generated by opened or damaged capsules and this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes. The contaminated individual must seek immediate medical attention after flushing if any adverse effect occurs.

Skin Exposure:

Use of basic hygiene should prevent any problems. If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek immediate medical attention, especially if an adverse reaction occurs.

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 3 of 12
------------------------------------	--	-----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

- Injection:** Not a route of exposure due to method of administration.
- Inhalation:** If airborne dusts generated by opened or damaged capsules of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.
- Ingestion:** If this product is swallowed, call physician or poison control center for most current information. Do not induce vomiting, unless directed by medical personnel. If conscious, have victim rinse mouth with water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.
- Notes to Physician:** Treat symptomatically, eliminate overexposure. Consult the package insert for additional information that can assist with treatment of overexposure.

Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
- (b) **Hazardous Combustion Products:** Formation of toxic and corrosive combustion gases (ammonia, nitrogen oxides) possible.
- (c) **Special Protective Equipment / Precautions:** Move containers from fire area if it can be done without risk to personnel. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Chemical resistant clothing may be necessary. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if any adverse effect occurs. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive area.

Section 6 - Accidental Release Measures

- Spill:** For small releases of this product take basic hygiene precautions. Lightweight gloves, a lab coat, and eye protection should be worn. Sweep up spilled powder or absorb spilled liquid with paper towels or damp sponge. Wash contaminated area with soap and water, absorb with paper towels, and rinse with water.

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 4 of 12
------------------------------------	--	-----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

Release to Air: Avoid breathing vapors, mist, gas, or dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Release to Water: Prevent further leakage or spillage if safe to do so. Do not let product enter drains or waterways.

Section 7 - Handling and Storage

General Handling: Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Storage Conditions: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature].
Store diluted infusion solution under refrigeration at 2° to 8°C (36° to 46°F) for no longer than 24 hours. Do not freeze.
Discard unused portion.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

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

(b) Engineering Controls

Ventilation: Use with adequate ventilation. Follow standard medical product handling procedures. Technicians should be aware of the risks associated with this drug. Eyewash/safety shower stations are available near areas where this product is used.

(c) Individual Protection Measures

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 5 of 12
------------------------------------	--	-----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

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.
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 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.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	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

(a)	Appearance	Clear solution
(b)	Odor	Practically Odorless
(c)	Odor Threshold	None
(d)	pH	10.8 – 11.4
(e)	Melting Point:	242°C - 255°C
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 6 of 12
------------------------------------	--	-----------------------------

	Sagent Pharmaceuticals			
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection		
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023	

(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Slightly soluble in water (2.67 mg/ml), practically insoluble in organic solvents, soluble in diluted sol. of hydroxides and acids, DMSO (~5 mg/ml)
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable under recommended storage conditions.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Extreme heat, any conditions that are incompatibility with water, mixing this product with incompatible chemicals
(e)	Incompatible Materials	Strong oxidizing agents
(f)	Hazardous Decomposition Products	Carbon oxides, nitrogen oxides

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Skin. Inhalation. Ingestion. Eye contact.
(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	LD ₅₀	Oral	Rat	2g/kg
Ganciclovir sodium	LD ₅₀	Oral	Dog	1g/kg
Ganciclovir sodium	LD ₅₀	Oral	Mouse	2g/kg

(d) Hazardous Chemical Listings

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 7 of 12
-----------------------------	--	-----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

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: Listed

NIOSH: Listed Group 2:Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Reproductive toxicity: May cause temporary or permanent female and male infertility
Pregnancy Category C.

Mutagenesis and Carcinogenesis: Animal data indicate that ganciclovir is mutagenic and carcinogenic. Ganciclovir Injection should therefore considered a potential carcinogen in humans.

Teratogenicity: Has teratogenic potential Can cause fetal toxicity when administered to pregnant females.

Specific target organ toxicity – single exposure (GHS): no data available

Specific target organ toxicity – repeated exposure (GHS): no data available

Aspiration hazard: no data available

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: May be harmful if swallowed.

Signs and Symptoms of Exposure: Exposure may cause nausea, vomiting, weakness, dizziness, headache, and/or sweating.

Synergistic effects: no data available

Additional information: RTECS: MF8407000

Section 12 - Ecological Information

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

(a)	Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution. • Barely toxic for planktonic crustaceans (Daphnia magna) EC50 (48 h) > 1010 mg/l (average measured concentration) NOEC (48 h) 1010 mg/l (average measured concentration) • Barely toxic for fish (rainbow trout) LC50 (96 h) > 1020 mg/l (average measured concentration) NOEC (96 h) 1020 mg/l (average measured concentration) • Barely toxic for microorganisms (bacteria, fungi, cyanobacteria in pure culture) NOEC 1000 mg/l
(b)	Persistence and degradability	Not available
(c)	Bioaccumulative potential	Not available
(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	Not available

Section 13 - Disposal Considerations

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

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 9 of 12
------------------------------------	--	-----------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not dangerous goods.

IATA: Not dangerous goods.

IMDG: Not dangerous goods.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

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

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: Chronic Health Hazard

OSHA Hazards: Reproductive hazard, Target organ effect.

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 Proposition 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

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

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 10 of 12
------------------------------------	--	------------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
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, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found

Previous Document No N/A	Confidential - For Use Only By Affiliates of Sagent Pharmaceuticals	Page Page 11 of 12
------------------------------------	--	------------------------------

	Sagent Pharmaceuticals		
	Document Type Safety Data Sheet (SDS)	Document Title Ganciclovir Injection	
	Document No. MSDS-0089	Version 7.0	Effective Date 27 Sep 2023

NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
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
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System