

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 1 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

1. Product Information

Product Name: **Valganciclovir for Oral Solution, 50 mg/mL.**

2. Composition/Information on Ingredients

Ingredient	CAS number	EU EINECS/ELINCS List	EU Classification	GHS Classification
Valganciclovir Hydrochloride	175865-59-5	Not listed	Acute Toxicity	Acute Toxicity, Oral (Category 5)
Mannitol	69-65-8	Not listed	Not listed	Not listed
Povidone K-30	9003-39-8	Not listed	Not listed	Not listed
Fumaric Acid	110-17-8	Not listed	Not listed	Category 2
Flavor	NOT ASSIGNED	Not listed	Not listed	Not listed
Sodium benzoate	532-32-1	208-534-8	Not listed	Not listed

3. Hazards Identification

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Germ cell mutagenicity	:	Category 1B
Carcinogenicity	:	Category 1A
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure	:	Category 1

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 2 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

GHS label elements

Hazard pictograms :



Signal Word :

Danger

Hazard Statements :

H340 May cause genetic defects.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.

Prevention:

Precautionary Statements :

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray. P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 3 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

4. First Aid Measures

General advice	:	Move out of dangerous area. Show this material safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. Rinse mouth with water.
Most important symptoms: and effects, both acute and delayed		May cause genetic defects. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 4 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

5. Fire Fighting Measures

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from firefighting to enter drains or water courses.
- Hazardous products combustion : Carbon oxides
In case of fire hazardous decomposition products may be produced such as:
Carbon monoxide Ammonia
Nitrogen oxides (NO_x)
Gaseous hydrogen chloride (HCl).
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 5 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

7. Handling and Storage

Precautions for Safe Handling

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Refer to Section 12 - Ecological Information, for information on potential effects on the environment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. Exposure Controls/Personal Protection

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Valganciclovir Hydrochloride

IOEL : 0.008 µg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective Equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 6 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Physical State:	Powder
Odor:	No data available
Molecular Formula:	Mixture
Solvent Solubility	No data available
Water Solubility:	No data available
pH:	No data available
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
Mannitol	No data available
Sodium benzoate	No data available
Flavor	No data available
Valganciclovir Hydrochloride	pKa 7.6
Decomposition Temperature (°C):	No data available
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available
Flammability:	
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions	
Oxidizing Properties:	No data available
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 7 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

11. Toxicological Information

Information on Toxicological Effects

General Information:

The information included in this section describes the potential hazards of the individual Ingredients

Short Term:

May be harmful if swallowed. May cause eye irritation (based on components)

Long Term:

Animal studies indicate that this material may cause adverse effects on the cardiovascular system.

Known Clinical Effects:

Elimination half-life-5 hours. After oral administration ester hydrolysis to the active substance Ganciclovir. Causes testicular atrophy as well as renal and hematologic changes.

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium benzoate

Rat Oral LD50 4,070 mg/kg

Mouse Oral LD50 1600mg/kg

Valganciclovir Hydrochloride

Mouse Oral LDmin. > 2000 mg/kg

Dog Oral LDmin. > 2000 mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Valganciclovir Hydrochloride

Eye nonirritant Rabbit

Skin nonirritant Rabbit

Skin non sensitizing Guinea Pig

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Valganciclovir Hydrochloride

No information available

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 8 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Teratogenic & embryotoxic
May lower parental fertility

Carcinogenicity: Carcinogenic

Mutagenicity: Mutagenic

12. Ecological Information

Environmental Overview: In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Barely toxic for bluegreen algae NOEC (12d) 1000 mg/l
Barely toxic for fish
Barely toxic for crustaceans

Mobility in Soil: No data available

13. Disposal Considerations

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 9 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

14. Transport Information

International Regulations

UNRTDG

UN number : UN 3077
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
 SOLID, N.O.S.
 (Valganciclovir mixture)
 Class : 9
 Packing group : III
 Labels : 9

IATA-DGR

UN/ID No. : UN 3077
 Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
 (Valganciclovir mixture)
 Class : 9
 Packing group : III
 Labels :
 Packing instruction (cargo aircraft) : 956
 Packing instruction (passenger aircraft) : 956
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
 SOLID, N.O.S.
 (Valganciclovir mixture)
 Class : 9
 Packing group : III
 Labels : 9
 EmS Code : F-A, S-F
 Marine pollutant : yes

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

Not applicable

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 10 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

Domestic regulation

49 CFR

UN/ID/NA number	: UN 3077
Proper shipping name	: Environmentally hazardous substance, solid, n.o.s. (Valganciclovir mixture)
Class	: 9
Packing group	: III
Labels	: CLASS 9
ERG Code	: 171
Marine pollutant	: no

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. Regulatory Information

EPCRA - Emergency Planning and Community Right-to-Know CERCLA

Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
2-Butenedioic acid (2E)-	110-17-8	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Germ cell mutagenicity Carcinogenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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 III, Section 313.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 11 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489):

2-Butenedioic acid (2E)- 110-17-8 $\geq 1 - < 5 \%$

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

2-Butenedioic acid (2E)- 110-17-8 $\geq 1 - < 5 \%$

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

2-Butenedioic acid (2E)- 110-17-8 $\geq 1 - < 5 \%$

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To know

2-Butenedioic acid (2E)- 110-17-8

1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1) 128-44-9

Pennsylvania Right To Know

D-Mannitol 69-65-8

Valganciclovir 175865-59-5

2-Butenedioic acid (2E)- 110-17-8

1,2-Benzisothiazol-3(2H)-one, 1,1-dioxide, sodium salt (1:1) 128-44-9

Maine Chemicals of High Concern

Product does not contain any listed chemicals

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 12 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California List of Hazardous Substances

2-Butenedioic acid (2E)-	110-17-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer	9003-39-8

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Valganciclovir

non hazardous compounds

AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

 MSN Pharmaceuticals Inc.	MSN PHARMACEUTICAL INC 20 DUKE ROAD, PISCATAWAY, NJ-08854, USA	Page 13 of 13
	SAFETY DATA SHEET (SDS)	
Product Name	Valganciclovir for Oral Solution, 50 mg/mL	

16. Other Information

NFPA:	HMIS® IV:
Flammability Health Instability Special hazard 0 0 0	HEALTH * 3 FLAMMABILITY 0 PHYSICAL HAZARD 0 HMIS® ratings are based on a 0-4 rating scale with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554

MSN Pharmaceutical Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Disclaimer: This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. It is not meant to be an all-inclusive document on worldwide hazard communications regulations. This information is offered in good faith. Each user of this material needs to evaluate the conditions of use and design the appropriate mechanisms to prevent employee exposures, property damage or release to the environment.

End Of Safety Data Sheet