SECTION-1: Identification of the substance / mixture and the company / undertaking

Catalogue Number	CS-O-02567
Product Name	Valganciclovir
CAS No.	175865-60-8
Category	API
Synonyms	(2S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate; (S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Not available

2.2 Label Elements

Signal Word: Not available

Not available

Hazard Statement(s)

Code	Statement
Not available	Not available

Precautionary Statement(s)

Code	Statement
Not available	Not available

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Valganciclovir
CAS Number : 175865-60-8
Molecular Formula : C14H22N6O5
Molecular Weight : 354.36
Parent Chemical : Ganciclovir
Synonyms : (2S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate; (S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate
Concentration : Not available

SECTION 4: First aid measures

SECTION 4: First-aid measures

4.1 Description of first aid measures
- General advice: Seek medical attention if symptoms occur or persist. Show this SDS to medical personnel.
- Inhalation: Move person to fresh air. If breathing is difficult, seek medical attention.
- Skin contact: Wash with soap and water. Remove contaminated clothing and wash before reuse. Seek medical attention if irritation develops.
- Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention.
- Ingestion: Rinse mouth. Do not induce vomiting unless directed by medical personnel. Seek medical attention.

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
- Treat symptomatically. No data available.

SECTION 5: Firefighting measures

SECTION 5: Fire-fighting measures

5.1 Extinguishing media
- Suitable extinguishing media: Water spray, alcohol-resistant foam, dry chemical, carbon dioxide.
- Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture
- Specific hazards: No data available.
- Hazardous combustion products: Not available.

5.3 Advice for firefighters
- Wear self-contained breathing apparatus (SCBA) and full protective gear.
- Use water spray to cool unopened containers.
- Avoid inhalation of combustion products.

SECTION 6: Accidental release measures

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
- Avoid dust formation and inhalation.
- Use appropriate personal protective equipment (see Section 8).
- Ensure adequate ventilation.

6.2 Environmental precautions
- Avoid release to the environment. Prevent entry into drains, surface water, or soil.

6.3 Methods and material for containment and cleaning up
- Small spills: Carefully sweep or scoop up without generating dust; place in a suitable, closed container for disposal.
- Large spills: Contain spill. Collect using methods that minimize dust generation (e.g., HEPA-filtered vacuum). Dispose of collected material appropriately.

6.4 Reference to other sections
- See Section 8 for personal protective equipment and Section 13 for disposal considerations.

SECTION-7: Handling and storage

SECTION 7: Handling and storage

7.1 Precautions for safe handling
- Handle in accordance with good industrial hygiene and safety practice.
- Avoid contact with skin and eyes. Avoid inhalation of dust.
- Use local exhaust ventilation where dust may be generated.
- Wash hands thoroughly after handling.

7.2 Conditions for safe storage, including any incompatibilities
- Store in a tightly closed container.
- Store in a cool, dry, well-ventilated place.
- Protect from moisture. Protect from incompatible materials.
- Incompatible materials: Not available.

7.3 Specific end use(s)
- API / laboratory or industrial use. Specific uses not available.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
- Occupational exposure limits: Not available.
- Biological limit values: Not available.

8.2 Exposure controls
- Appropriate engineering controls: Use adequate general ventilation. Use local exhaust where dust/aerosols may be generated.
- Personal protective equipment (PPE):

- Eye/face protection: Safety glasses with side shields or chemical splash goggles.
- Skin protection: Protective gloves. Protective clothing as appropriate.
- Respiratory protection: If ventilation is inadequate or dust is generated, use a suitable particulate respirator per applicable standards.
- Hygiene measures: Wash hands after handling. Do not eat, drink, or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available

Property	Value
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

SECTION 10: Stability and reactivity

10.1 Reactivity
- No data available.

10.2 Chemical stability
- Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
- No data available.

10.4 Conditions to avoid
- Avoid dust generation. Avoid exposure to moisture and extreme conditions. Specific conditions not available.

10.5 Incompatible materials
- Not available.

10.6 Hazardous decomposition products
- Not available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: /CASE REPORTS/ A 13-year-old boy with acute lymphoblastic leukemia was treated for cytomegalovirus retinitis with valganciclovir 450 mg every 2 days in the course of hematopoietic stem cell transplantation. Concomitant medication included omeprazole, furosemide, and acetaminophen. During treatment, when creatinine clearance decreased to 20 mL/min, the child presented with acute neurotoxicity, consisting of mental confusion and hallucinations, which resolved when all medications were stopped. Valganciclovir therapeutic monitoring showed high ganciclovir concentrations in the plasma (3.85 microg/mL) and cerebrospinal fluid (2.6 ug/mL) 48 hours after the last valganciclovir dose. After recovery of neurologic function, valganciclovir was resumed at a lower dosage (225 mg twice a week) with therapeutic drug monitoring and was well tolerated. However, the cytomegalovirus infection was not resolved. The leukemia relapsed, and the patient had terminal renal failure and died. The Naranjo probability scale indicated a probable relationship between valganciclovir and neurotoxicity. Drugs taken by this child (acyclovir, valganciclovir, omeprazole) have been reported to induce neurotoxicity, with the pharmacokinetics of the first 2 being altered by renal failure. At the time when acyclovir was first administered, symptoms of neurotoxicity were already apparent. Moreover, plasma concentrations of ganciclovir were very high during the course of the neurotoxicity. Thus, the adverse effects seemed related to an overdosage of valganciclovir and were worsened by the addition of acyclovir. This case is informative because few clinical and pharmacokinetic data are available concerning the use of valganciclovir in children. A study should be performed to determine the proper pediatric dose of valganciclovir with and without renal impairment to prevent the occurrence of adverse effects. /CASE REPORTS/ ... Valganciclovir has been reported to cause usually mild to moderate hematologic adverse effects such as leukopenia, neutropenia, anemia, thrombocytopenia, and pancytopenia. Severe and fatal bone marrow depression has been described in 1 adult patient. Herein, we describe the cases of 4 patients with

end-stage renal disease who underwent cadaveric renal transplantation and received valganciclovir prophylaxis for CMV at a standard dose of 900 mg/d despite persistant renal failure. This therapy resulted in severe bone marrow failure after 18 to 20 days in all 4 patients, with fatal infections in 2 patients. This report demonstrates the in vivo pharmacodynamics of valganciclovir overdose in terms of hematotoxicity in the setting of renal impairment. ...
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: /GENOTOXICITY/ Valganciclovir increases mutations in mouse lymphoma cells. In the mouse micronucleus assay, valganciclovir was clastogenic. Valganciclovir was not mutagenic in the Ames Salmonella assay. Ganciclovir increased mutations in mouse lymphoma cells ... . In the mouse micronucleus assay, ganciclovir was clastogenic. Ganciclovir was not mutagenic in the Ames Salmonella assay.
- Carcinogenicity: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Ganciclovir was carcinogenic in the mouse at oral doses that produced exposures approximately 0.1x and 1.4x, respectively, the mean drug exposure in humans following the recommended intravenous dose of 5 mg/kg, based on area under the plasma concentration curve (AUC) comparisons. At the higher dose there was a significant increase in the incidence of tumors of the preputial gland in males, forestomach (nonglandular mucosa) in males and females, and reproductive tissues (ovaries, uterus, mammary gland, clitoral gland and vagina) and liver in females. At the lower dose, a slightly increased incidence of tumors was noted in the preputial and harderian glands in males, forestomach in males and females, and liver in females. Ganciclovir should be considered a potential carcinogen in humans. /Ganciclovir/
- Reproductive toxicity: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Ganciclovir was carcinogenic in the mouse at oral doses that produced exposures approximately 0.1x and 1.4x, respectively, the mean drug exposure in humans following the recommended intravenous dose of 5 mg/kg, based on area under the plasma concentration curve (AUC) comparisons. At the higher dose there was a significant increase in the incidence of tumors of the preputial gland in males, forestomach (nonglandular mucosa) in males and females, and reproductive tissues (ovaries, uterus, mammary gland, clitoral gland and vagina) and liver in females. At the lower dose, a slightly increased incidence of tumors was noted in the preputial and harderian glands in males, forestomach in males and females, and liver in females. Ganciclovir should be considered a potential carcinogen in humans. /Ganciclovir/ /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ Valganciclovir is converted to ganciclovir and therefore is expected to have reproductive toxicity effects similar to ganciclovir. Ganciclovir has been shown to be embryotoxic in rabbits and mice following intravenous administration, and teratogenic in rabbits. Fetal resorptions were present in at least 85% of rabbits and mice administered doses that produced 2x the human exposure based on AUC comparisons (all dose comparisons presented are based on the human AUC following administration of a single 5 mg/kg infusion of intravenous ganciclovir). Effects observed in rabbits included: fetal growth retardation, embryolethality, teratogenicity and/or maternal toxicity. Teratogenic changes included cleft palate, anophthalmia/microphthalmia, aplastic organs (kidney and pancreas), hydrocephaly and brachygnathia. In mice, effects observed were maternal/fetal toxicity and embryolethality. Daily intravenous doses administered to female mice prior to mating, during gestation, and during lactation caused hypoplasia of the testes and seminal vesicles in the month-old male offspring, as well as pathologic changes in the nonglandular region of the stomach. The drug exposure in mice as estimated by the AUC was approximately 1.7x the human AUC.
- STOT-single exposure: No data available.
- STOT-repeated exposure: /LABORATORY ANIMALS: Chronic Exposure or Carcinogenicity/ Ganciclovir was carcinogenic in the mouse at oral doses that produced exposures approximately 0.1x and 1.4x, respectively, the mean drug exposure in humans following the recommended intravenous dose of 5 mg/kg, based on area under the plasma concentration curve (AUC) comparisons. At the higher dose there was a significant increase in the incidence of tumors of the preputial gland in males, forestomach (nonglandular mucosa) in males and females, and

reproductive tissues (ovaries, uterus, mammary gland, clitoral gland and vagina) and liver in females. At the lower dose, a slightly increased incidence of tumors was noted in the preputial and harderian glands in males, forestomach in males and females, and liver in females. Ganciclovir should be considered a potential carcinogen in humans. /Ganciclovir/
- Aspiration hazard: No data available.

Likely routes of exposure
- No data available.

Symptoms related to the physical, chemical and toxicological characteristics
- /CASE REPORTS/ A 13-year-old boy with acute lymphoblastic leukemia was treated for cytomegalovirus retinitis with valganciclovir 450 mg every 2 days in the course of hematopoietic stem cell transplantation. Concomitant medication included omeprazole, furosemide, and acetaminophen. During treatment, when creatinine clearance decreased to 20 mL/min, the child presented with acute neurotoxicity, consisting of mental confusion and hallucinations, which resolved when all medications were stopped. Valganciclovir therapeutic monitoring showed high ganciclovir concentrations in the plasma (3.85 microg/mL) and cerebrospinal fluid (2.6 ug/mL) 48 hours after the last valganciclovir dose. After recovery of neurologic function, valganciclovir was resumed at a lower dosage (225 mg twice a week) with therapeutic drug monitoring and was well tolerated. However, the cytomegalovirus infection was not resolved. The leukemia relapsed, and the patient had terminal renal failure and died. The Naranjo probability scale indicated a probable relationship between valganciclovir and neurotoxicity. Drugs taken by this child (acyclovir, valganciclovir, omeprazole) have been reported to induce neurotoxicity, with the pharmacokinetics of the first 2 being altered by renal failure. At the time when acyclovir was first administered, symptoms of neurotoxicity were already apparent. Moreover, plasma concentrations of ganciclovir were very high during the course of the neurotoxicity. Thus, the adverse effects seemed related to an overdosage of valganciclovir and were worsened by the addition of acyclovir. This case is informative because few clinical and pharmacokinetic data are available concerning the use of valganciclovir in children. A study should be performed to determine the proper pediatric dose of valganciclovir with and without renal impairment to prevent the occurrence of adverse effects.

SECTION 12: Ecological information

SECTION 12: Ecological information

12.1 Toxicity
- No data available.

12.2 Persistence and degradability
- No data available.

12.3 Bioaccumulative potential
- No data available.

12.4 Mobility in soil
- No data available.

12.5 Results of PBT and vPvB assessment
- Not available.

12.6 Endocrine disrupting properties
- Not available.

12.7 Other adverse effects

- No data available.

SECTION 13: Disposal considerations

SECTION 13: Disposal considerations

13.1 Waste treatment methods
- Dispose of contents/container in accordance with local/regional/national/international regulations.
- Do not discharge to drains or the environment.
- Recommended disposal method: Incineration or disposal via a licensed waste contractor, as permitted by regulations.
- Contaminated packaging: Dispose of as unused product unless cleaned per applicable regulations.

SECTION 14: Transport information

SECTION 14: Transport information

- UN number: Not available.
- UN proper shipping name: Not available.
- Transport hazard class(es): Not available.
- Packing group: Not available.
- Environmental hazards: Not available.
- Special precautions for user: Not available.
- Transport in bulk according to IMO instruments: Not available.

Note: Transport classification may vary by mode (ADR/RID, IMDG, IATA). No data available.

SECTION 15: Regulatory information

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Regulatory listings (e.g., TSCA, REACH, DSL, EINECS/ELINCS, IECSC, AICS, PICCS): Not available.
- GHS classification: Not available.
- Hazard statements / precautionary statements: Not available.

15.2 Chemical safety assessment
- No data available.

SECTION 16: Other information

SECTION 16: Other information

- Product name: Valganciclovir
- Catalog no.: CS-O-02567
- CAS no.: 175865-60-8
- Category: API
- Molecular weight: 354.36

- Synonyms: (2S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate; (S)-2-((2-amino-6-oxo-3H-purin-9(6H)-yl)methoxy)-3-hydroxypropyl 2-amino-3-methylbutanoate
- Parent chemical: Ganciclovir
- Supplier: Clearsynth Labs Ltd., Mumbai, India
- Emergency phone: +91-22-245045900

Disclaimer: The information provided is based on available product identification details and is intended for SDS authoring support. Many hazard and regulatory data elements are not available and must be confirmed from authoritative sources before final SDS issuance.

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