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Safety Data Sheet acc. to OSHA HCS

Date of issue: 10/10/2024 Revision date 10/10/2024

1 Identification

· Product identifier

· Trade name: Valganciclovir (hydrochloride)

· Synonym

2-[(2-amino-1,6-dihydro-6-oxo-9H-purin-9-yl)methoxy]-3-hydroxypropyl ester L-valine,

monohydrochloride Ro 107-9070/194 CAS Number:

175865-59-5

· Other means of identification

· Article number: 13875

• **EC number:** 641-360-4

· Application of the substance / the mixture

This product is for research use - Not for human or veterinary diagnostic or therapeutic use.

- · Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

Cayman Chemical Co. 1180 E. Ellsworth Rd. Ann Arbor, MI 48108

USA

· Information department: Product safety department

· Emergency telephone number:

During normal opening times: +1 (734) 971-3335

US/CANADA: 800-424-9300

Outside US/CANADA: 703-741-5970

2 Hazard(s) identification

· Classification of the substance or mixture



GHS08 Health hazard

Germ cell mutagenicity 1A H340 May cause genetic defects.

Carcinogenicity 1A H350 May cause cancer.

Reproductive toxicity 1A H360 May damage fertility or the unborn child.

Specific target organ toxicity (repeated exposure) 1 H372 Causes damage to organs through prolonged or repeated exposure.

· Label elements

· GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

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· Hazard pictograms



· Signal word Danger

Hazard statements

H340 May cause genetic defects.

H350 May cause cancer.

H360 May damage fertility or the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

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 thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

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

P314 Get medical advice/attention if you feel unwell.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Information pertaining to particular dangers for man and environment:
- · Classification system:
- NFPA ratings (scale 0 4)



Health = 0 Fire = 0 Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = *0 Fire = 0

Reactivity = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- vPvB: Not applicable.
- Classification according to (d)(1)(ii) of § 1910.12000

The SDS issuer does not object to the classifications provided by importers or manufacturers of precursor products.

Hazards not otherwise classified

There are no adverse physical or health effects known that are not covered by the hazard classes of the Hazard Communications Standard.

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3 Composition/information on ingredients

· Chemical characterization: Substances

· CAS No. Description

175865-59-5 Valganciclovir (hydrochloride)

· Identification number(s)

EC number: 641-360-4

4 First-aid measures

- · Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
- · Suitable extinguishing agents:

Use fire fighting measures that suit the environment.

A solid water stream may be inefficient.

- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

- Protective Action Criteria for Chemicals
- · PAC-1: Substance is not listed.
- · PAC-2: Substance is not listed.
- · PAC-3: Substance is not listed.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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7 Handling and storage

- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage: Store in accordance with information listed on the product insert.
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- Appropriate engineering controls No further data; see section 7.
- · Personal protective equipment:
- General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:



Tightly sealed goggles

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9 Physical and chemical properties

· Information on basic physical and chemical properties

General Information

· Physical state Solid

Color: Not determined.
 Odor: Characteristic
 Structural Formula C14H22N6O5 • HCI

· Molecular Weight 390.8 g/mol

· Storage Buffer

· Odor threshold: Not determined.

· Formulation

Melting point/Melting range:
 Boiling point/Boiling range:
 Undetermined.
 Undetermined.

• **Flammability:** Product is not flammable.

Explosion limits:

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH-value: Not applicable.

Viscosity:

· Kinematic: Not applicable.

SOLUBILITY DMF: 1 mg/ml; DMSO: 20 mg/ml; PBS (pH 7.2): 10

mg/ml

· **Dynamic:** Not applicable.

Solubility in / Miscibility with

Water: Not determined.
 Partition coefficient (n-octanol/water): Not determined.
 Vapor pressure: Not applicable.

Vapor pressure:

Density: Not determined.
 Relative density Not determined.
 Vapor density Not applicable.
 Particle characteristics Not determined.

· Other information

· Appearance:

Form: Solid Important information on protection of health

and environment, and on safety.

Ignition temperature: Not determined.

• Danger of explosion: Product does not present an explosion hazard.

Change in condition

· Evaporation rate Not applicable.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

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- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: strong bases, strong oxidizing agents
- · Hazardous decomposition products:

carbon dioxide, carbon monoxide, hydrogen chloride, nitrogen oxides

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- Primary irritant effect:
- · on the skin: No irritant effect.
- on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- Additional toxicological information:
- · Interactive effects No interactive effects between components are known.
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.
- · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.
- · Alternative sources for toxicological information

No non-standard sources for toxicological information where used.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- vPvB: Not applicable.
- · Other adverse effects
- · Additional ecological information:
- General notes:

Water hazard class 3 (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · Waste treatment methods
- Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

14 Transport information	
· UN-Number · DOT, IMDG, IATA	not regulated
· UN proper shipping name · DOT, IMDG, IATA	not regulated
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA · Class	not regulated
· Packing group · DOT, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.	
· Special precautions for user	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances): Substance is not listed.
- · Section 313 (Specific toxic chemical listings): Substance is not listed.
- · TSCA (Toxic Substances Control Act): Substance is not listed.
- · Hazardous Air Pollutants Substance is not listed.
- · Chemicals known to cause cancer: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- · Chemicals known to cause developmental toxicity: Substance is not listed.
- · Carcinogenic categories
- · EPA (Environmental Protection Agency) Substance is not listed.
- · TLV (Threshold Limit Value) Substance is not listed.
- · NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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16 Other information

All chemicals may pose unknown hazards and should be used with caution. This SDS applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. Cayman Chemical Company assumes no responsibility for incidental or consequential damages, including lost profits, arising from the use of these data. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Cayman Chemical Company assumes no responsibility for the completeness or accuracy of the information contained herein.

- · **Department issuing SDS:** Environment protection department.
- · Contact: -
- · Date of previous version 04/21/2022
- Date of preparation 10/10/2024
- Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxić vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

Germ cell mutagenicity 1A: Germ cell mutagenicity - Category 1A

Carcinogenicity 1A: Carcinogenicity – Category 1A

Reproductive toxicity 1A: Reproductive toxicity – Category 1A

Specific target organ toxicity (repeated exposure) 1: Specific target organ toxicity (repeated exposure) - Category 1

* Data compared to the previous version altered.

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