



Safety Data Sheet

Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

1. Product and Company Identification

Product identifier: Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

Recommended use: -Medicinal Product

This Safety Data Sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician.

Manufacturer information and Address: GRANULES PHARMACEUTICALS, INC.

3701 & 3725 Concorde Pkwy

Chantilly, VA 20151- USA

Ph. No.: 571-325-5950

2. Hazard(s) identification

Label elements:



Signal word: Toxic



Signal Word: Danger



Safety Data Sheet

Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

Hazard statement: The Active Ingredient Valganciclovir Hydrochloride has been identified having a possible risk of genetic defects, suspected of causing cancer and may damage fertility or the unborn child

Other Hazards: The Product can support combustion. The ignition of dust in certain conditions can cause and explosion. Dust may be sensitive to electrostatic ignition sources. In case of fire, may emit toxic fumes (oxides of nitrogen, carbon)

PBT Substances: -PBT Substances: Not Classified

Precautionary Statements: Obtain special instructions before use, do not handle until all safety precautions have been read and understood, use personal protective equipment as required, if exposed or concerned: get medical advice/attention

3. Composition/information on ingredients

Name	CAS Number	%w/w	
Valganciclovir Hydrochloride, USP (Amorphous)	175865-59-5	45.96	
Sodium Benzoate, NF	532-32-1	*	
Mannitol, USP	69-65-8	*	
Sucralose Powder, NF	56038-13-2	*	
Tartaric Acid, NF	87-69-4	*	
Tutti Frutti Flavor, ART [¥]	D-Limonene	5989-27-5	*
	Cinnamaldehyde	104-55-2	

¥ Tutti Frutti Flavor, ART is a combination of D-Limonene and Cinnamaldehyde.

Additional information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety

Ingredients in composition: Sodium Benzoate, NF, Mannitol, USP, Sucralose Powder, NF, Tartaric Acid, NF, Tutti Frutti Flavor, ART.



Safety Data Sheet

Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

4. First-aid measures

Eyes: Rinse with water. Get medical attention if irritation develops and persists

Skin: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Ingestion: Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

5. Fire-fighting measures

Suitable extinguishing media: Use fire-extinguishing media appropriate for surrounding materials water, foam, dry chemical or CO₂

Special hazards arising from the substance or mixture: Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential explosion hazard.

Advice for firefighters: Wear self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance

Further information: No data available

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Avoid breathing dust. Provide adequate ventilation.

Environmental precautions: Do not let product enter drains.

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

7. Handling and storage

Handling: Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid prolonged or repeated exposure.

Storage: Store in accordance with information listed in label to ensure product integrity.

8. Exposure controls/personal protection

Engineering controls: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits (0.005mg/m³)

Personal protective equipment

Eye/face protection: Safety glasses

Skin protection: Chemically compatible gloves.

Body Protection: Lab coat

Respiratory protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NOISH-approved under appropriate government standards (US).



Safety Data Sheet

Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

Control of environmental exposure: Do not let product enter drains.

Exposure Limits: -Not available.

Body Protection: Lab coat

Respiratory protection: None required under normal conditions of use.

9. Physical and chemical properties

Physical state: Powder

Odor: Tutti Frutti

Molecular Formula: Mixture

Molecular Weight: Mixture

10. Stability and Reactivity

Chemical Stability: Stable under recommended storage condition.

Conditions to Avoid: Stable under normal conditions

Incompatibilities with Other Materials: N/A

11. Toxicological information

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Potassium Chloride, USP

Rat Oral LD50: >2000 mg/kg

Sodium Benzoate, NF

Rat Oral LD50: > 3140 mg/kg

Mannitol, USP

Rat Oral LD50: 13,500 mg/kg

Sucralose Powder, NF

Rat Oral LD50: >10 g/kg



Safety Data Sheet

Valganciclovir Hydrochloride for Oral Solution, 50 mg/mL

Tartaric Acid

Rabbit Oral DLLO:5000mg/Kg

Dog Oral DLLO:500mg/Kg

LD50 endovenous on rat :485mg/Kg

Tutti Frutti Flavor, ART (D-Limonene+Cinnamaldehyde)

D-Limonene: LD50 Oral Rat:4400mg/Kg

Cinnamaldehyde: LD50 Oral Rat:1850mg/Kg

12. Ecological information

Environmental Overview: No known significant effects or critical hazards.

Other adverse effects: No data available

13. Disposal considerations

Local disposal regulations: Dispose in accordance with all applicable regulations.

14. Transport information

Additional Transport Information: Transport in accordance with local, state regulations.

15. Regulatory information

OSHA: Non-hazardous in accordance with international standards for workplace safety.

16. Other information, including date of preparation or last revision

Issue date: 11/29/2021

Revision date: NA

References: Not available.

Granules Pharmaceuticals, Inc. believe that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet