SAFETY DATA SHEET

VALCYTE(R) F.C. Tablets (450 mg)

SECTION 1. IDENTIFICATION

Product name : VALCYTE(R) F.C. Tablets (450 mg)
Product code : 00010069575
Common name(s), synonym(s) of the substance : Valganciclovir Film Coated Tablets 450 mg
Common name(s), synonym(s) of the substance : Valganciclovir F.C. Tablets 450 mg

Manufacturer or supplier's details
Company name of supplier : Genentech, Inc.
Address : DNA Way 1
         : 94080 South San Francisco
         : CA
         : USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. 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

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.

Precautionary Statements:

Prevention:
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valganciclovir</td>
<td>175865-59-5</td>
<td>80.6</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>7.8</td>
<td></td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td>2-Pyrrolidinone, 1-ethenyl-, homopolymer</td>
<td>9003-39-8</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td>Octadecanoic acid</td>
<td>57-11-4</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>&lt; 0.9</td>
<td></td>
</tr>
<tr>
<td>non hazardous compounds</td>
<td>Not Assigned</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SECTION 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:
- Flush eyes with water as a precaution.
- 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.

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.

SECTION 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 fire fighting to enter drains or water courses.

Hazardous combustion products:
- In case of fire hazardous decomposition products may be produced such as:
  - Carbon monoxide
  - Ammonia
  - Nitrogen oxides (NOx)
  - Gaseous hydrogen chloride (HCl)
  - Carbon oxides

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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment:
- Use personal protective equipment.
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Date of first issue: 12-10-2015

Emergency equipment and emergency procedures:
Avoid dust formation.
Avoid breathing dust.
Avoid exposure.

Environmental precautions:
Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up:
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling:
Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage:
Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions:
See label, package insert or internal guidelines.

Storage temperature:
Protected from heat and light
Protect from moisture.

Further information on storage stability:
No decomposition if stored and applied as directed.

Packaging material:
Suitable material: Stainless steel, glass, Polyethylene bag in metal drum.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valganciclovir</td>
<td>175865-59-5</td>
<td>IOEL</td>
<td>0.008 mg/m3</td>
<td>Roche Industrial Hy-</td>
</tr>
</tbody>
</table>
### SAFETY DATA SHEET

**VALCYTE(R) F.C. Tablets (450 mg)**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4</td>
<td>01-20-2021</td>
<td>02-28-2020</td>
<td>12-10-2015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material</th>
<th>TWA (Respirable)</th>
<th>TWA (Total)</th>
<th>TWA (Total Dust)</th>
<th>TWA (Respirable Dust Fraction)</th>
<th>TWA (Total Dust)</th>
<th>TWA (Titanium dioxide)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>10 mg/m3</td>
<td>5 mg/m3</td>
<td>15 mg/m3</td>
<td>15 mg/m3</td>
<td>10 mg/m3 (Titanium dioxide)</td>
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<tr>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m3</td>
<td></td>
<td>TWA (Total Dust)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Total)</td>
<td>10 mg/m3</td>
<td></td>
<td>TWA (Respirable Dust Fraction)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Total Dust)</td>
<td>15 mg/m3</td>
<td></td>
<td>TWA (Total Dust)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable Fraction)</td>
<td>5 mg/m3</td>
<td></td>
<td>TWA (Total Dust)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium oxide (TiO2)</td>
<td>13463-67-7</td>
<td>15 mg/m3</td>
<td></td>
<td>TWA (Total Dust)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Total Dust)</td>
<td>10 mg/m3</td>
<td></td>
<td>TWA (Titanium dioxide)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA (Respirable Dust Fraction)</td>
<td>5 mg/m3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Engineering measures**: No data available

**Personal protective equipment**

**Respiratory protection**: In the case of dust or aerosol formation use respirator with an approved filter.
Effective dust mask

**Hand protection**

**Material**: Protective gloves

**Remarks**: Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

**Eye protection**

**Eye wash bottle with pure water**
Tightly fitting safety goggles

**Skin and body protection**

**Dust impervious protective suit**
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

**Protective measures**: Instruction of employees mandatory

**Hygiene measures**: When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: tablet
### SAFETY DATA SHEET

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<td>12-10-2015</td>
</tr>
</tbody>
</table>

- **Color**: light red
- **Odor**: Not applicable
- **Odor Threshold**: Not applicable
- **pH**: Not applicable
- **Melting point/range**: No data available
- **Boiling point/boiling range**: No data available
- **Flash point**: does not flash
- **Evaporation rate**: No data available
- **Self-ignition**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapor pressure**: No data available
- **Relative vapor density**: Not applicable
- **Relative density**: No data available
- **Solubility(ies)**:
  - **Water solubility**: No data available
  - **Solubility in other solvents**: No data available
- **Partition coefficient: n-octanol/water**: No data available
- **Autoignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**:
  - **Viscosity, dynamic**: Not applicable
  - **Viscosity, kinematic**: Not applicable

### SECTION 10. STABILITY AND REACTIVITY

- **Reactivity**: No dangerous reaction known under conditions of normal use.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reac-**: No decomposition if stored and applied as directed.
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Incompatible materials: No data available
Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
- Acute oral toxicity: Acute toxicity estimate: 2,960 mg/kg
  Method: Calculation method
- Acute inhalation toxicity: Acute toxicity estimate: 66.92 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method
- Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
  Method: Calculation method

Components:
- Valganciclovir:
  Acute oral toxicity: LD50 Oral (Mouse): > 2,000 mg/kg
- Cellulose:
  Acute oral toxicity: LD50 Oral (Rat): > 5,000 mg/kg
  Acute dermal toxicity: LD50 Dermal (Rabbit): > 2,000 mg/kg
- Titanium oxide (TiO2):
  Acute oral toxicity: LD50 (Rat): > 7,500 mg/kg
  Acute inhalation toxicity: LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Acute dermal toxicity: LD50 (Rabbit): > 10,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
- Valganciclovir:
  Species: Rabbit
  Result: No skin irritation
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Serious eye damage/eye irritation
Not classified based on available information.

Components:
Valganciclovir:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
Valganciclovir:
Species: Guinea pig
Result: Did not cause sensitization on laboratory animals.

Germ cell mutagenicity
May cause genetic defects.

Components:
Valganciclovir:
Genotoxicity in vitro: Result: positive
Genotoxicity in vivo: Species: laboratory animal
Result: positive

Germ cell mutagenicity - Assessment: In vivo tests showed mutagenic effects

Carcinogenicity
May cause cancer.

Components:
Valganciclovir:
Species: laboratory animal
Result: positive
Symptoms: carcinogenic effects
The value is given in analogy to the following substances: Ganciclovir
Carcinogenicity - Assessment: Human carcinogen.

Cellulose:
Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
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IARC  Group 2B: Possibly carcinogenic to humans
Titanium oxide (TiO2)  13463-67-7

OSHA  No component of this product present at levels greater than or equal to 0.1% is
on OSHA’s list of regulated carcinogens.

NTP  No ingredient of this product present at levels greater than or equal to 0.1% is
identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

Valganciclovir:
Effects on fertility  :  Species: laboratory animal
                     Symptoms: Effects on fertility.
                     The value is given in analogy to the following substances:
                     Ganciclovir

Effects on fetal development  :  Species: laboratory animal
                      Result: Teratogenic effects., Embryotoxic effects.
                      The value is given in analogy to the following substances:
                      Ganciclovir

Reproductive toxicity - Assessment  :  Presumed human reproductive toxicant, May damage fertility.
                                   May damage the unborn child.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Components:

Valganciclovir:
Assessment  :  Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Valganciclovir:
Species  :  Rat
NOAEL  :  mg/kg bw/day, 2
Application Route  :  Oral
Exposure time  :  90 d
Remarks  :  Subchronic toxicity

Aspiration toxicity
Not classified based on available information.
Ecotoxicity

Components:

Valganciclovir:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 1,020 mg/l
Exposure time: 96 h
The value is given in analogy to the following substances: Ganciclovir

NOEC (Oncorhynchus mykiss (rainbow trout)): 1,020 mg/l
Exposure time: 96 h
The value is given in analogy to the following substances: Ganciclovir

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1,020 mg/l
Exposure time: 96 h
The value is given in analogy to the following substances: Ganciclovir

NOEC (Lepomis macrochirus (Bluegill sunfish)): 1,020 mg/l
Exposure time: 96 h
The value is given in analogy to the following substances: Ganciclovir

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1,010 mg/l
Exposure time: 48 h
The value is given in analogy to the following substances: Ganciclovir

NOEC (Daphnia magna (Water flea)): 1,010 mg/l
Exposure time: 48 h
The value is given in analogy to the following substances: Ganciclovir

Toxicity to algae/aquatic plants: NOEC (blue-green algae): 1,000 mg/l
End point: see user defined free text
Exposure time: 12 d
The value is given in analogy to the following substances: Ganciclovir

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.012 mg/l
Exposure time: 35 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes
Remarks: average measured concentration
The value is given in analogy to the following substances: Ganciclovir

Toxicity to microorganisms: NOEC (Natural microorganism): 1,000 mg/l
Exposure time: 12 d
Test substance: see user defined free text
The value is given in analogy to the following substances:
Ganciclovir

Cellulose:

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Titanium oxide (TiO2):
Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates : EC0 (Daphnia magna (Water flea)): 3 mg/l
Exposure time: 720 h

Ecotoxicology Assessment
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability

Components:
Valganciclovir:
Biodegradability : Result: Not rapidly biodegradable
Biodegradation: 2 %
Exposure time: 28 d
Remarks: Not inherently biodegradable.
The value is given in analogy to the following substances:
Ganciclovir

Result: Not rapidly biodegradable
Biodegradation: 34 %
Exposure time: 28 d
Method: OECD Test Guideline 308
Remarks: Ultimate aerobic biodegradation
The value is given in analogy to the following substances:
Ganciclovir

Bioaccumulative potential

Components:
Valganciclovir:
Partition coefficient: n-octanol/water : log Pow: 0.009
pH: 6.9

Cellulose:
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Partition coefficient: n-octanol/water : Remarks: No data available

Titanium oxide (TiO2):
Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: 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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company.
Contaminated packaging : Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 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

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.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

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)
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1.4 | 01-20-2021 | 02-28-2020 | 12-10-2015

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.

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).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
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
Cellulose 9004-34-6

Pennsylvania Right To Know
Valganciclovir 175865-59-5
Cellulose 9004-34-6
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

Maine Chemicals of High Concern
Product does not contain any listed chemicals

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 Prop. 65
WARNING: This product can expose you to chemicals including Titanium oxide (TiO2), which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8
2-Pyrrolidinone, 1-ethenyl-, homopolymer 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Cellulose 9004-34-6

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

DSL : This product contains the following components that are not
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.

SECTION 16. OTHER INFORMATION

NFPA:

<table>
<thead>
<tr>
<th>Health</th>
<th>Flammability</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
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<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Special hazard

HMIS® IV:

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
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</thead>
<tbody>
<tr>
<td>*</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants -
## SAFETY DATA SHEET

### VALCYTE(R) F.C. Tablets (450 mg)

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**OSHA Z-1**: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

**ACGIH / TWA**: 8-hour, time-weighted average

**NIOSH REL / TWA**: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

**OSHA P0 / TWA**: 8-hour time weighted average

**OSHA Z-1 / TWA**: 8-hour time weighted average

**AICS** - Australian Inventory of Chemical Substances; **AIIC** - Australian Inventory of Industrial Chemicals; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DOT** - Department of Transportation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with x% response; **EHS** - Extremely Hazardous Substance; **ELx** - Loading rate associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ErCx** - Concentration associated with x% growth rate response; **ERG** - Emergency Response Guide; **GHS** - Globally Harmonized System; **GLP** - Good Laboratory Practice; **HMIS** - Hazardous Materials Identification System; **IARC** - International Agency for Research on Cancer; **IATA** - International Air Transport Association; **IBC** - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; **IC50** - Half maximal inhibitory concentration; **ICAO** - International Civil Aviation Organization; **IECSC** - Inventory of Existing Chemical Substances in China; **IMDG** - International Maritime Dangerous Goods; **IMO** - International Maritime Organization; **ISHL** - Industrial Safety and Health Law (Japan); **ISO** - International Organisation for Standardization; **KECI** - Korea Existing Chemicals Inventory; **LC50** - Lethal Concentration to 50 % of a test population; **LD50** - Lethal Dose to 50% of a test population (Median Lethal Dose); **MARPOL** - International Convention for the Prevention of Pollution from Ships; **MSHA** - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; **NFPA** - National Fire Protection Association; **NO(A)EC** - No Observed (Adverse) Effect Concentration; **NO(A)EL** - No Observed (Adverse) Effect Level; **NOELR** - No Observable Effect Loading Rate; **NTP** - National Toxicology Program; **NZIoC** - New Zealand Inventory of Chemicals; **OECD** - Organization for Economic Co-operation and Development; **OPPTS** - Office of Chemical Safety and Pollution Prevention; **PBT** - Persistent, Bioaccumulative and Toxic substance; **PICCS** - Philippines Inventory of Chemicals and Chemical Substances; **(Q)SAR** - (Quantitative) Structure Activity Relationship; **RCRA** - Resource Conservation and Recovery Act; **REACH** - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; **RQ** - Reportable Quantity; **SADT** - Self-Accelerating Decomposition Temperature; **SARA** - Superfund Amendments and Reauthorization Act; **SDS** - Safety Data Sheet; **TCSI** - Taiwan Chemical Substance Inventory; **TSCA** - Toxic Substances Control Act (United States); **UN** - United Nations; **UNRTDG** - United Nations Recommendations on the Transport of Dangerous Goods; **vPvB** - Very Persistent and Very Bioaccumulative

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**Revision Date**: 01-20-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**US / Z8 / 1810**